



National Grain and Feed Association

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

***Re: Docket No. 2002N-0273; Substances Prohibited from Use
in Animal Food or Feed; Proposed Rule***

The National Grain and Feed Association (NGFA) submits this statement in response to the proposed rule published on October 6, 2005 by the Food and Drug Administration (FDA) seeking comments on additional measures to mitigate further the risk of bovine spongiform encephalopathy (BSE) in the United States.

To summarize, the NGFA strongly supports FDA's proposal to require the removal of brain and spinal cord from all cattle 30 months or older from all animal feed as a science- and risk-based approach for further substantially reducing what already is an extremely low risk of BSE in the United States. In addition, as amplified subsequently in this statement, the NGFA generally supports FDA's proposal to allow the use in non-ruminant animal feed of cattle that are not inspected and passed for human consumption (i.e., nonambulatory cattle), provided brain and spinal cord have been removed. However, we strongly urge FDA to amend its proposed rule to require removal of brain and spinal cord only from non-ambulatory cattle that are 30 months or older, provided the ages of such cattle can be accurately and consistently verified. Further, the NGFA urges that FDA amend its proposed regulations to implement several additional safeguards, including a requirement that renderers that handle prohibited mammalian material, including cattle material prohibited from use in all animal feed and food, be required to register with the agency unless, as in the case of packer-renderers, such operations already are under the supervision of government meat inspectors. We also recommend that renderers and other parties be required to obtain a special permit from FDA if they intend to introduce allowable rendered product from dead cattle into the feed chain after removing brain and spinal cord; as a precondition for such permits, the NGFA recommends that FDA require such parties to demonstrate to the agency's satisfaction that they have implemented a system that is consistently and uniformly effective in removing such materials.

Established in 1896, the NGFA consists of 900 grain, feed, processing, exporting and other grain-related companies that operate about 6,000 facilities and handle more than 70 percent of all U.S. grains and oilseeds. With more than 300-member companies that operate commercial feed mills, as well as 30 integrated livestock and poultry operations that

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manufacture animal feed, the NGFA is the nation's largest trade association representing feed manufacturer interests. As such, FDA's proposed rule directly and substantially affects NGFA-member companies. The NGFA also consists of 35 affiliated state and regional grain and feed associations, as well as two international affiliated associations. In addition, the NGFA is co-located and has a joint operating agreement with the North American Export Grain Association, as well as strategic alliances with the Pet Food Institute and Grain Elevator and Processing Society.

The NGFA commends FDA for having taken a proactive, science- and risk-based approach to regulatory policies designed to prevent the establishment or amplification of BSE in the United States. This approach is reflected in the development and implementation in 1997 of the feed restrictions that prohibit the use of certain mammalian material in feed for cattle and other ruminants. It is one of the principal reasons the FDA feed rule has enjoyed such an extraordinary level of compliance – exceeding 99 percent – which FDA has stated publicly is the most successful compliance rate associated with any of its regulations.

The U.S. government, with the active support and involvement of a wide spectrum of the animal agriculture industry, also had the foresight to implement two other pillars of a three-firewall strategy – import controls and an active surveillance program – more than 15 years before the first case of BSE was diagnosed in the United States. Thus, the United States is in the enviable position of being able to consider further policy responses from the standpoint of already having implemented prudent and effective BSE-prevention safeguards. As such, we believe FDA should consider further policy responses based upon the North American – rather than a European – experience, mindful that Canada has implemented comparable BSE-prevention measures. The North American experience stands in stark contrast to the sequence of events and delayed policy responses that unfolded in Europe.

We also believe it was appropriate and prudent for FDA to take the additional time to solicit public comment through the advance notice of proposed rulemaking published in 2004 on potential changes to its BSE-prevention feed rule. We believe it was important that FDA take the time to generate the input necessary to evaluate the scientific underpinnings and industry ramifications for each policy option and the additional risk mitigation that might result, as well as to fully evaluate the costs and benefits of various options.

The NGFA reiterates its support for the continued use of animal proteins – including ruminant-derived material – as safe, nutritious and wholesome feed ingredients for species for which they are legally approved, and as an environmentally and economically sound practice. It is important to recognize that attaining a zero-risk environment is impossible, as it assumes perfect controls, perfect compliance and, most importantly, perfect knowledge about the vagaries of this complex, mysterious and still-relatively new animal disease. Policies can be implemented that approach near-zero or virtually zero risk; but the costs grow exponentially the closer one gets to zero risk, and can result in unintended consequences that create even more health risks or environmental hazards.

Following the diagnoses of five cases of BSE in North America – four involving cattle of Canadian origin and one involving a native-born animal – the NGFA supports

amendments to the 1997 BSE-prevention feed rule to add further protections and redundancies to America's existing firewalls to reduce further what the Harvard Center for Risk Analysis¹ has determined to be an extremely low risk of BSE.

Based upon the preponderance of scientific evidence available to date, it appears that the North America cattle herd sustained at least a limited degree of exposure to BSE, most likely well before the imposition of BSE-prevention feed controls in 1997. But such exposure appears to be extremely limited, as borne out through the enhanced surveillance conducted by the U.S. Department of Agriculture that has detected only one BSE-positive result among 548,786 cattle tested as of December 11, 2005 under its enhanced surveillance that began on June 1, 2004. In addition, USDA detected no BSE-positive results in its testing of 21,216 clinically normal adult cattle. Nonetheless, we believe it is prudent for FDA to implement additional science-based measures to further hasten the eradication of any latent BSE that may exist in the U.S. cattle population.

For these reasons the NGFA:

1. **Strongly supports FDA's proposal to require the removal of brain and spinal cord from live cattle 30 months or older before remaining material can be used in any animal feed.** This mirrors the policy recommendation made by the NGFA to FDA in response to the agency's advance notice of proposed rulemaking.
2. **Supports FDA's proposal to allow the use in non-ruminant animal feed of cattle that are not inspected and passed for human consumption (so-called nonambulatory, or "downer" cattle), provided the brain and spinal cord are removed. However, the NGFA recommends that FDA amend its proposed rule with respect to nonambulatory disabled cattle to require brain and spinal cord removal only from such cattle that are 30 months or older, provided the ages of the cattle can be accurately and consistently verified. This age-verification could be accomplished through several means, including herd records (in the case of dairy operations), the nature of the livestock operation (e.g., feedlot cattle); the on-site presence of a USDA Food Safety Inspection Service inspector (or an inspector designated by the agency); and/or through the existence of a mandatory animal identification system capable of accurately and consistently verifying animal ages.** We believe this recommendation conforms with scientific evidence that shows the clinical onset of BSE does not manifest itself in younger cattle, and is consistent with FDA's science-based proposal to require removal of brain and spinal cord from live cattle only if they are 30 months or older.

¹ "Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States." Cohen, Joshua T.; Duggar, Keith; Gray, George M.; Kreindel, Silvia. Harvard Center for Risk Analysis, Harvard School of Public Health. Abdelrahman; HabteMariam, Tsegaye; Oryang, David; Tameru, Berhanu. Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University. November 26, 2001; Revised October 2003.

3. Urges that FDA amend its proposed regulations to require that renderers that handle prohibited mammalian material, including cattle material prohibited from use in all animal feed and food, be required to register with the agency unless, as in the case of the presence of meat inspectors at packer-renderers, such operations already are under the on-site supervision of government inspectors. Further, we believe such renderers should be required to demonstrate to the agency's satisfaction that they have implemented a system for removing brain and spinal cord that is consistently and uniformly effective in extracting such material within acceptable parameters set by FDA before the remaining rendered cattle material is allowed to be used in animal food or feed.
4. Do not disagree with FDA's proposal to require the removal of brain and spinal cord from the carcasses of all cattle dead stock, regardless of age, before remaining material is allowed to be used in animal food or feed. However, the NGEA strongly recommends that FDA require that renderers and other parties that opt to utilize systems for removing brain and spinal cord from dead stock obtain a special permit from the agency if they intend to introduce the remaining cattle material into the non-ruminant feed chain. Further, as a precondition for such a permit, we believe such renderers (as recommended in #3 above) should be required to demonstrate to the agency's satisfaction that they have implemented a system for removing brain and spinal cord that is consistently and uniformly effective in extracting such material within acceptable parameters set by FDA before the remaining rendered cattle material is allowed to enter the non-ruminant feed chain. Renderers without such permits should be restricted to processing dead stock solely for disposal, industrial or other allowable non-feed uses.
5. Believes FDA in the preface to a final rule should continue to emphasize that requirements contained in its 1997 BSE-prevention feed regulations continue to apply. In particular, while existing scientific evidence shows that removing brain and spinal cord from cattle eliminates the vast majority of potential infectivity if it exists in an animal, it is imperative that establishments that manufacture ruminant feed and handle both prohibited and non-prohibited mammalian material continue to comply with FDA's requirement to implement written clean-out procedures to minimize the potential for cross-contamination of facilities, equipment and conveyances.
6. Encourages FDA to consult with other federal, state and local agencies, as well as affected industry sectors, concerning the impact that a ban on brain and spinal cord will have on animal and tissue disposal, as well as proper and environmentally safe disposal of on-farm animal dead stock. In this regard, we believe FDA should consider an appropriate phase-in period for this requirement, and that other federal agencies should examine potential

incentives to encourage the continued pick up and environmentally safe disposal of dead stock.

7. **Supports FDA's proposal to require that tallow from "cattle materials prohibited from animal feed/food," as defined under this proposal, contain no more than 0.15 percent impurities.**
8. Continues to support the use of dedicated facilities, equipment and conveyances as a **voluntary best-management practice** as an additional risk-mitigation redundancy, when it can be accomplished practically and effectively.
9. Supports the recommendation of the Pet Food Institute that FDA amend its BSE-prevention feed rule to clarify that **pet food products that are sold or intended for sale at retail and for use in non-ruminant laboratory animals are exempt from the rule's labeling and recordkeeping requirements, unless such products are sold or intended for sale as distressed or salvage items.**

The NGFA recognizes that science is not static, and that the agency and the industry have a responsibility to base BSE-prevention policy decisions on the best available facts that exist. But it is important to stress that further amending FDA's BSE-prevention feed rule represents an additional strengthening of multiple effective, formidable existing firewalls to further protect principally **animal, not human, health**. USDA's actions in January 2004 to remove all SRMs from all human food products, and to prohibit certain slaughter-stunning practices – combined with FDA's action effective July 14, 2004 to ban all SRMs in the food, dietary supplement and cosmetic products that it regulates – have protected human health.

At the outset, the NGFA also wishes to reiterate its policy supporting strong, uniform inspection and enforcement by FDA and states of the agency's BSE-prevention feed regulations. In this regard, the NGFA strongly opposes the U.S. government requiring the use of – or relying in lieu of government inspection and oversight upon – non-governmental, third-party certification of regulated facilities or feed products for compliance with FDA's BSE-prevention feed rule.

Having presented the aforementioned summary of its recommendations, the NGFA wishes to expound on the reasons for its position.

Cattle Materials Prohibited in Animal Food or Feed

The NGFA strongly supports FDA's proposal to ban the use of brain and spinal cord from live cattle 30 months or older from all animal feed as a centerpiece of its future BSE-prevention feed regulations, and to define such products as "cattle materials prohibited in animal food and feed."

As noted in the Harvard-Tuskegee report on the relative infectivity of specific cattle tissues based upon pathogenesis studies conducted in the United Kingdom, the fraction of potential total infectivity in each tissue consists of: 1) brain, 64.1 percent; 2) spinal cord,

25.6 percent; 3) dorsal root ganglia, 3.8 percent; 4) trigeminal ganglia, 2.6 percent; 5) distal ileum, 3.3 percent; and 6) tonsils and eyes, less than 1 percent each. Importantly, these data represent a “worst-case” scenario, since the BSE dose administered to calves during the pathogenesis study was at a substantially greater level than would be expected to occur under natural transmission under field conditions. Thus, removing brain and spinal cord removes upwards of 90 percent of potential infectivity that may exist in an animal.

Further, the Harvard Center for Risk Analysis reported at a Conference on BSE Prevention in North America² conducted on January 27, 2005 that a ban on brain and spinal cord of older cattle, as part of a systems-based approach, provides **protection that is equivalent to a ban on a much more extensive list of specified risk materials**³.

The NGFA believes prohibiting the use in all animal feed of brain and spinal cord from cattle 30 months or older represents a sound policy response from a food and feed safety, environmental and economic standpoint for the following reasons:

- First and foremost, from a feed safety standpoint, it addresses what science shows is the vast majority of **potential** infectivity **if** BSE exists in an animal. The Scientific Steering Committee of the European Union⁴ also has estimated that 90 percent of total infectivity present in a BSE-infected animal nearing clinical onset exists in the brain and spinal cord. It is our understanding that nearly all potential infectivity is eliminated by removing these tissues after taking into account the effects of normal rendering. In addition, during scientific studies in which cattle were fed BSE-infected meat-and-bone meal under field conditions, the brain, spinal cord and the retina of the eye of infected cattle were the **only tissues** where infectivity was detected.

The NGFA believes there is substantial merit to removing the vast majority of **potential** infectivity at the “top of the pyramid” of the animal food and feed system, thereby making meat-and-bone meal inherently safe at its source. We believe such an approach also will help address the potential for accidental cross-contamination in on-farm feed manufacturing and accidental misfeeding on-farm. Doing so also reduces or eliminates altogether the need for FDA to implement additional down-stream controls (such as requiring the use of dedicated facilities and transportation conveyances, or banning restaurant plate waste or poultry litter feeding to ruminants) that ultimately would be much less protective of animal

² Conference on BSE Prevention in North America – An Analysis of Science and Risk, Jan. 27, 2005, Washington, D C.

³ Consisting of brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the traverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) and dorsal root ganglia of cattle 30 months or older, and the tonsils and entire small intestine of all cattle.

⁴ “Opinion of the Scientific Steering Committee on the Human Exposure Risk (HER) Via Food with Respect to BSE. Scientific Steering Committee, European Union.

health, much more difficult or problematic to enforce, and much more costly and disruptive to implement.

- A ban on brain and spinal cord from cattle 30 months or older represents a prudent policy response to further reduce the already extremely low risk of BSE amplification in North America. Further, it is justified based upon the North American experience, in which: 1) BSE-prevention firewalls were implemented long before the first BSE case was diagnosed; 2) USDA's enhanced surveillance of the U.S. cattle herd has provided an additional indicator that the prevalence of BSE in the United States is extremely low; and 3) compliance with FDA's existing 1997 BSE-prevention feed rule is extraordinarily high.

In this latter regard, FDA's most recent update on compliance with its existing feed regulations issued on December 5, 2005 continues to show compliance exceeding 99 percent. Those data summarize the results of more than 41,000 inspection reports received by the agency as of November 26, 2005. Of the 4,553 active firms still handling mammalian materials prohibited from being used in ruminant feed, only nine (0.2 percent) had violations significant enough to warrant an "official action indicated" inspection status from FDA.

- Such a policy provides an opportunity for the United States and Canada to continue to have a harmonized approach to BSE-prevention feed regulation. One of the strengths of BSE-prevention efforts in North America has been that Canada and the United States have acted responsibly and proactively since 1989 to implement prudent science- and risk-based measures to address BSE, including largely harmonized BSE-prevention feed regulations to protect animal health. The NGFA believes that it is essential to continue a harmonized approach to BSE-prevention feed regulation in North America, and that a brain-and-spinal cord ban proposed by FDA offers the best opportunity for achieving that goal.
- A ban on brain and spinal cord is consistent with the approach recommended by the International Review Team that investigated both the U.S. and Canadian BSE cases. Specifically, the group recommended that, "...until the level of BSE risk has been established, the (International Review Team) concedes that exclusion of CNS, skull and vertebral column from cattle over 30 months, and intestines from cattle of all ages, for use in human food is a reasonable temporary compromise." [Emphasis added.]⁵ Equally important, the International Review Team stated in its report that it "recognized" the absence of an established infrastructure in the United States to separate and dispose of SRMs, and "accepted" the fact that a "staged approach may be necessary for implementation."⁶ Further, during an address at the NGFA's 108th annual convention, the sole U.S. member of the

⁵ "Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States." International Review Team. February 2004. Pg. 5.

⁶ Ibid. Pg. 9.

International Review Team – Dr. William D. Hueston of the University of Minnesota’s Center for Animal Health and Food Safety – stated unequivocally that removal of brain and spinal cord from cattle 30 months or older was the single most important step that could and should be taken to prevent the amplification of BSE in the United States.⁷

- The NGFA is concerned about the economic and environmental ripple effects of SRM-related policy choices on the businesses of ingredient suppliers and customers that feed beef and dairy cattle, swine, poultry and other species. It is the NGFA’s understanding that since brain and spinal cord consist of about 90 percent water by weight, a ban on these products would be equivalent to removing approximately 1.3 pounds of wet waste per head. That compares to a total wet waste per head of approximately 90 to 120 pounds that would result from a ban on all SRMs, depending upon the extent of intestinal tract removal. Thus, a ban on all SRMS would generate an estimated 1.5 billion pounds a year of product that would need to be land-filled, digested or converted to non-edible rendering, or directed to other industrial uses.

To extrapolate that disparity into an economic impact, A packer/renderer has estimated that removal and disposal⁸ costs – including the lost value of the product – would amount to about 20 cents per head if FDA proceeds to ban from all animal food and feed the use of brain and spinal cord of cattle 30 months or older. That would represent an annual cost of approximately \$1.6 million – or \$16 million over 10 years – given the 8 million estimated cattle that are marketed each year that are 30 months or older. That compares to a recurring annual cost of approximately \$157 million – or \$1.5 billion over 10 years – for a full SRM removal in which the entire small intestine is removed, calculated based upon an estimated average of up to \$10.70 per head for cows and \$2.55 for fed cattle. The estimated cost is even higher – \$250 million a year and \$2.5 billion over 10 years – for full SRM removal if the entire intestinal tract is included.

Currently, animal feed, incineration, alkaline digestion and land-fill disposal are the only available options for disposing of SRMs. Further, the availability of these disposal methods varies by state. However, the NGFA is aware that the packing and rendering industries are exploring alternative industrial uses – such as energy co-generation – as well as disposal rendering as potential future options. In this regard, the NGFA believes that the U.S. government should consider providing an appropriate phase-in period, as well as economic incentives or remuneration to renderers to compensate for the costs associated with converting their operations into such uses or to other alternative, environmentally safe

⁷ “Will Science Drive Future BSE Policy?” Dr. William D. Hueston. Center for Animal Health and Food Safety, University of Minnesota, St. Paul, MN. National Grain and Feed Association 108th annual convention, San Antonio, TX. March 16, 2004.

⁸ Estimated removal and disposal costs include removal and segregation of SRMs at the packing plant, lost value of rendered product, transport to disposal rendering site, disposal rendering processing fee and disposal of resulting banned SRMs.

disposal methods. The failure of European countries to design an effective SRM disposal system complicated and undermined the effectiveness of their BSE-prevention feed controls and created huge environmental and warehousing problems. It is important that the United States minimize the potential for such an environmental impact.

- When evaluating the economic impact of this policy change, it also is incumbent upon FDA to consider the severe economic losses to the U.S. beef industry and the overall U.S. economy that result when beef trade is suspended as a result of the diagnosis of BSE cases. While the World Animal Health Organization (OIE) has made substantial progress in revising its BSE guidelines to encourage a more science- and risk-based assessment of beef products that are safe for trade, these standards are voluntary. And regrettably, the initial reaction of foreign buyers has been to suspend trade in beef products – for prolonged periods – after a country diagnoses a case of BSE. That certainly characterized the U.S. experience – only now, after two years, are significant Far Eastern markets for U.S. beef being restored to a limited degree. Thus, to the degree that removing brain and spinal cord from cattle 30 months or older hastens the eradication of BSE from North America, such a policy change offers significant potential economic benefits to all sectors of the beef value chain.

As noted previously in this statement, the NGFA believes that strong scientific, risk-assessment, economic and environmental reasons exist for FDA to implement an SRM list for animal feed/food that **is different** from what has been implemented for human foods and cosmetics because doing so can be demonstrated to provide equivalent protection to a full SRM ban as part of a systems-based approach. As noted previously, the vast majority of **potential** BSE infectivity, to the degree it exists in an animal, is found in the brain and spinal cord of cattle 30 months or older. Further, nearly all of the potential infectivity is eliminated by removing those tissues after taking into consideration the effects of rendering. In addition, scientific studies of cattle fed BSE-infected meat-and-bone meal under field conditions only detected BSE infectivity in the brain, spinal cord and retina of the eye. **For these reasons, the NGFA opposes a ban on a more expansive list of SRMs.**

NGFA-Recommended Modifications to Definition of Cattle Materials Prohibited in Animal Food or Feed

As noted previously, the NGFA recommends an amendment to FDA's definition of cattle materials prohibited from use in animal food or feed with respect to nonambulatory disabled cattle.

Specifically, the NGFA recommends that FDA amend the requirement that brain and spinal cord be removed from all cattle not inspected and passed for human consumption **regardless of age**. This category of cattle includes nonambulatory disabled cattle, which includes cattle with broken legs, severed tendons or ligaments and other conditions that are totally unrelated to central nervous system disorders. The NGFA strongly recommends that FDA amend this requirement **with respect to nonambulatory disabled cattle** to stipulate

that the brain and spinal cord be removed **only from such cattle that are 30 months or older, provided** that the ages of cattle can be accurately and consistently verified. This age-verification could consist of a variety of methods, including: 1) herd records (in the case of dairy operations); 2) the nature of the livestock feeding operation itself (e.g., feedlot cattle); 3) the on-site presence of a USDA Food Safety Inspection Service meat inspector (or an inspector designated by the agency); and/or 4) through the existence of a mandatory animal identification system capable of accurately and consistently verifying animal ages. We believe the scientific basis for this recommendation – that the clinical onset of BSE infectivity does not manifest itself in cattle less than 30 months of age – is well established. Further, it is consistent with FDA's proposal to remove brain and spinal cord from live cattle presented for slaughter only if such animals are 30 months or older.

We do not disagree with FDA's proposal to require the removal of brain and spinal cord from the carcasses of all cattle dead stock, regardless of age, before remaining material is allowed to be used in animal food or feed. In these cases, the cause of death cannot be determined with sufficient accuracy or reliability to exclude the potential of central nervous system disorders.

Requirements for Renderers

Given that the centerpiece of FDA's proposal for further reducing potential BSE risk is removal of brain and spinal cord, the NGFA believes that additional regulatory controls and safeguards are appropriate to ensure that cattle material prohibited from use in animal feed and food is being removed and either disposed or diverted to approved industrial uses in an effective, uniform and consistent manner. Full compliance will be essential to achieving the maximum level of additional risk reduction envisioned under this proposal.

For this reason, the NGFA offers the following recommendations:

- **Registration by Renderers Handling Prohibited Mammalian Material:** The NGFA recommends that renderers and other parties that handle prohibited mammalian material, including cattle material prohibited from use in animal feed and food, that are subject to FDA's BSE-prevention feed regulations be required to be registered with the agency unless, as in the case of packer-renderers, such operations already are under the on-site supervision of government inspectors (e.g., FSIS). We believe this will facilitate the ongoing surveillance and inspection program implemented by FDA and states to ensure that renderers have implemented systems that are effective in removing brain and spinal cord and other cattle material prohibited in animal feed and food, and that such material is being diverted to approved uses or disposed of in an appropriate manner.
- **Special Permit for Dead-Stock Renderers Removing Brain and Spinal Cord:** As an additional safeguard, the NGFA recommends that renderers that opt to remove brain and spinal cord from dead cattle apply for and obtain a special permit from FDA if they intend to introduce the remaining cattle material into the non-ruminant feed chain. Renderers and other parties without such permits

should be restricted to processing dead stock solely for disposal, industrial or other allowable non-feed uses.

- **Demonstrating Effectiveness of Systems/Processes for Removing Brain and Spinal Cord:** The NGFA strongly urges FDA to require renderers to demonstrate to the agency's satisfaction that they have implemented a system or process for removing brain and spinal cord that is consistently and uniformly effective in extracting such materials within tolerances/parameters acceptable to FDA before the remaining rendered cattle protein is allowed to be used as an ingredient in non-ruminant animal food or feed.
- **Recordkeeping for Cattle Material Prohibited in Animal Feed/Food:** The NGFA concurs with FDA's proposal to require renderers that manufacture, process, blend or distribute cattle materials prohibited in animal feed or food to establish and maintain records that are sufficient to demonstrate that such material was not introduced into the feed chain. However, the NGFA believes FDA should provide additional specificity on the types of records that should be maintained by renderers to document compliance with this requirement. Among other things, we believe FDA should require renderers to establish and maintain written procedures on the system(s) or process(es) being used to remove brain and spinal cord from affected cattle; verification that such systems are effective within tolerances acceptable to FDA; and the method(s) by which such prohibited material is being disposed or utilized.

The NGFA believes the recordkeeping documentation and on-site inspections currently required of meat packers and processors as part of their hazard analysis and critical control point (HACCP) programs with FSIS for human food likely will be sufficient to achieve the aforementioned recommendations.

The NGFA concurs with FDA's view that it is unnecessary for persons – other than renderers – who are involved in the manufacture or processing of feed or feed ingredients to maintain records documenting the exclusion of cattle materials prohibited in animal feed or food beyond those records already required under the agency's 1997 BSE-prevention feed regulations. Additional recordkeeping would not be relevant for entities – other than renderers – that are not be involved in the removal of brain and spinal cord or other cattle materials prohibited in animal feed or food. As FDA states, requiring the maintenance of such records at all manufacturing and processing points downstream would be redundant and provide little additional information of value to inspectors.

- **Marking of Cattle Material Prohibited in Animal Feed/Food:** The NGFA concurs with FDA's proposal that rendered brain and spinal cord-derived material be marked with an agent (e.g., dye) to ensure it is not, intentionally or accidentally, included in any animal feed or food. In addition, as noted previously, renderers should be required to maintain records indicating the disposition of these cattle materials prohibited in animal food and feed. The

ultimate disposition of such materials may be through co-generation as energy sources, disposal rendering, or some other effective processing or industrial use.

Tallow

The NGFA supports FDA's proposal to prohibit the use of tallow in animal food or feed that is derived from "cattle materials prohibited in animal feed or food" if it contains more than 0.15 percent insoluble impurities. The NGFA is not aware of any scientific evidence that tallow containing insoluble impurities of 0.15 percent or less poses a risk of transmitting BSE. This standard has been endorsed by the Office of International Epizootics (OIE) – the World Animal Health Organization⁹. Further, the Harvard Center for Risk Analysis found that tallow does not present a risk of BSE transmission, and the recommendations of the International Review Team did not raise tallow as a material of concern. In addition, this standard enables independent and quantifiable testing of tallow for impurities, and is accepted by the United States' most discriminating trading partners.

The NGFA also supports FDA's proposal to allow the use of the American Oil Chemists' Society's (AOCS) method for measuring insoluble impurities – or another method that is equivalent in accuracy, precision and sensitivity – rather than the method prescribed in the Food Chemicals Codex. As noted by FDA, the AOCS Official Method is the method primarily used by the domestic tallow industry, and is less expensive, requires less solvent and has lower solvent-disposal costs than the Codex method. In addition, this AOCS method does not require specialized equipment or supplies.

In addition, the NGFA supports FDA's proposal to exempt tallow derivatives from the BSE-prevention feed regulations. These derivatives are produced by subjecting tallow to chemical processes (hydrolysis, transesterification and saponification) that involve high temperature and pressure. As noted by the agency, FDA's TSE Advisory Committee has considered this issue and determined that the rigorous conditions of manufacture to which tallow derivatives are subjected are sufficient to reduce BSE risk in tallow derivatives to insignificant levels.

NGFA Responses to Other Questions Posed by FDA

The NGFA also wishes to raise the following issues that it believes are important to preventing the spread of BSE, several of which FDA seeks comment on as part of its proposed rule:

- **Clean-Out Procedures:** The NGFA believes it is imperative that FDA retain and continue to emphasize in the final rule resulting from this proposal the requirement under the 1997 BSE-prevention feed rule that multi-specie facilities that manufacture ruminant feed while also handling mammalian material prohibited from use in ruminants maintain and utilize written clean-out procedures (e.g., flushing, sequencing and/or physical clean-out). FDA's current

⁹ Chapter 2.3.13 article 2.3.13.8. Office of International Epizootics.

BSE-prevention feed rule requires that written procedures be maintained that specify the clean-out procedures or other means used to separate prohibited mammalian material from non-prohibited mammalian material or non-mammalian materials. Further, such procedures are required to “correspond to the facility’s actual operations.” FDA properly recognizes in the preface to its 1997 BSE-prevention feed rule that the clean-out procedures recognized as effective under the agency’s current good manufacturing practice regulations for medicated feed mills are appropriate and adequate for use in compliance with this rule

We believe these procedures are adequate to minimize potential carry-over of what at most would be infinitesimally small quantities of potentially infective material if the vast majority of potentially infective material was removed at the packing and rendering sector through a ban on brain and spinal cord of cattle 30 months or older, particularly given current data concerning the extremely low risk of BSE in the United States and the extraordinary level of compliance with FDA’s existing BSE-prevention feed rule.

- **Dedicated Facilities, Equipment and Transportation Conveyances:** The NGFA has long recommended, as a key element of its BSE-Prevention Policy Statement (attached as appendix to this statement) that, as an industry best-management practice, that feed mills that manufacture ruminant feeds voluntarily discontinue using prohibited mammalian protein unless they have separate and distinct mixing, handling and storage systems to prevent accidental commingling or cross-contamination. As documented by FDA’s own BSE-compliance inspection data, most commercial feed manufacturers have made such a voluntary business decision, either because they believed it represented the least disruptive and most cost-effective way to comply with the BSE-prevention feed rule or because of recommendations from their trade association or requests from insurance carriers and/or feeder-customers.

For some feed manufacturers, though, using dedicated plants or equipment may be impractical given the lines of feed they manufacture (e.g., dairy and pet food) and their use of least-cost formulated rations. That’s why the NGFA continues to recommend that this decision best be left to the management of individual establishments. A government-mandated requirement to utilize dedicated facilities could force additional concentration in the industry.

Further, at the previously referenced Conference on BSE Prevention in North America conducted on Jan. 27, 2005, a representative of the Harvard Center for Risk Analysis said that its modeling had shown that requiring dedicated facilities and manufacturing lines in rendering and feed manufacturing operations would have no appreciable effect – removing only 0.0089 potentially infective cattle oral ID₅₀ doses – from the feed chain, assuming the removal of brain and spinal cord from cattle 30 months or older, as well as dead stock, from all animal feed.

In addition, while not accruing additional measurable BSE risk reduction, the economic impacts of requiring dedicated facilities, equipment, storage and transportation would be significant. It either would result in establishments: 1) discontinuing the use of ruminant-derived feed ingredients and relying exclusively upon plant-based proteins; 2) discontinuing manufacturing various product lines for ruminant feeds; 3) reconfiguring their facilities to add separate storage and dedicated manufacturing lines; and/or 4) purchasing additional transport conveyances (e.g., trucks) to maintain a dedicated fleet.

Rail carriers already have shifted to dedicated transportation for animal-based feed ingredients as an outcome of best management practices for transport developed in 2002 by the National Grain and Feed Association, Association of American Railroads, National Renderers Association and National Oilseed Processors Association. But the impacts on the truck transportation sector would be severe, disruptive and potentially very difficult to enforce. The NGFA conservatively estimates the initial cost of adding dedicated transportation equipment to fleets at firms that distribute prohibited materials and manufacture, process or blend feeds for ruminants to be at least \$26.7 million.¹⁰

However, the NGFA believes FDA should consider requiring the use of dedicated equipment at rendering establishments that manufacture feed ingredients for ruminants and also process animals from multiple species, including ruminants, and/or process material that under this proposed rule would be defined as "cattle materials prohibited in animal food and feed." It is this sector of the industry – the "top of the pyramid" – where the potential for cross-contamination, the potential concentration of infective material and the potential adverse impacts on down-stream users are greatest if prohibited and non-prohibited material is not properly segregated. FDA's database as of December 16, 2005 shows that of 273 active rendering firms, 172 – or 63 percent of the total – handle prohibited mammalian materials. Of those 172 rendering firms, 68 also manufacture feed ingredients for ruminant consumption. While FDA's database does not allow for a calculation of the percentage of total meat-and-bone meal produced by those 68 firms, the NGFA submits that they present the greatest risk of "downstream" cross-contamination if proper clean-out procedures are not used, or mix-ups occur as a result of human error.

The NGFA also believes FDA and state inspection and compliance efforts should be more focused toward establishments at the "top of the pyramid."

- **Blood and Blood Products:** The NGFA also strongly supports FDA's decision not to propose a ban the use of bovine blood or blood products in ruminant animals. We concur with FDA's assessment that current scientific evidence does not implicate bovine blood or blood products in either the natural or mechanical transmission of BSE. The three known cases of transmission of a transmissible

¹⁰ Based upon each affected facility being required to obtain two additional trailers at an estimated cost of \$50,000 per trailer.

spongiform encephalopathy through blood involved: 1) a single case in which scrapie-infected blood was injected into sheep; 2) a single case of v-CJD contracted by a British citizen allegedly through a v-CJD-infected blood transfusion; and 3) a case of another British citizen who received a blood transfusion from a v-CJD-infected patient and whose spleen reportedly tested positive during a post-mortem examination for the infectious agent that causes vCJD, but who died from an unrelated cause. There are considerable data demonstrating that the pathology of TSE diseases differs significantly depending upon the disease and the animal model being studied. Thus, the transmission of TSEs through sheep or between humans via blood transfusion should not be used as a substitute for the absence of data of such transmission from bovines-to-bovines.

Further, the Harvard Center for Risk Analysis' study¹¹ also evaluated the potential for BSE to be transmitted orally to cattle through blood products. The study noted that "no detectable infectivity has been found in blood or blood components of cattle infected with BSE." The study went on to state that, "[e]ven if infectivity does exist in the blood of BSE-infected cattle, the total amount of infectivity is below the level of detection of the mouse bioassay. We assume that recycling this material poses little risk of exposing cattle to BSE." The study further noted that air-injection stunning of cattle at slaughter, which potentially could dislodge and deposit central-nervous system tissue emboli in blood, heart, lung and liver, no longer is used in the United States (and subsequently has been banned by federal regulation).

Nonetheless, the Harvard study went on to analyze the theoretical risk of BSE transmission through bovine blood and blood products. Its analysis was based upon three assumptions: 1) the potential that BSE infectivity could exist at levels below the limit of detection; 2) the potential risk for BSE in blood that might result through the now-banned practice of stunning cattle at slaughter; and 3) that BSE existed in the U.S. cattle herd. Even based upon these theoretical assumptions, Harvard's model determined that blood conceivably could be responsible for introducing an average of only 0.11 new cases of BSE over a 20-year period. Even when applying these precautionary assumptions used in the Harvard mathematical model, the use of blood as a feed ingredient for ruminants does not amplify BSE in the U.S. cattle population.

In addition, the recommendations of the International Review Team did not raise blood and blood products as a material of concern. To the contrary, during a public meeting on Feb. 4, 2004 to present its findings to the Secretary of

¹¹ "Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States." Cohen, Joshua T.; Duggar, Keith; Gray, George M.; Kreindel, Silvia. Harvard Center for Risk Analysis, Harvard School of Public Health. Abdelrahman: HabteMariam, Tsegaye; Oryang, David; Tameru, Berhanu. Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University. November 26, 2001; Revised October 2003. Pg. 35.

Agriculture's Animal and Poultry Disease Advisory Committee, the chair and U.S. member of the International Review Team specifically stated that blood and blood products were not a risk factor for BSE transmission.

Further, the economic and environmental impacts of such a policy action would be severe. The use of bovine blood and blood fractions is critical to the dairy, beef cattle and feed industries as a means for supplementing the immune systems of young calves. More than 40 percent of heifer calves raised in the United States suffer from a failure of passive immunity transfer attributable to inadequate intake of immunoglobulin from colostrums. Half of the early (pre-weaning) mortality in heifer calves results from inadequate intake of quality colostrums; approximately 11 percent of heifer calves died before weaning. Colostrums also are a vector for transmitting a number of disease organisms, including those that cause Johne's disease in dairy cattle. Bovine serum and blood fractions have been shown in several published scientific studies to be the only effective alternatives for colostrums in providing passive immunity, and their use should be preserved.¹² These arguments support the conclusion that oral consumption of bovine, porcine or avian blood do not transmit BSE, and that these feed ingredients should not be banned from ruminant feed.

Thus, the NGFA believes the rationale used by FDA in its 1997 rule remains valid:

"FDA excluded these items from the definition because the agency believes that they represent a minimal risk of transmitting TSE's to ruminants through feed. The excluded proteins and other items are materials that the available data suggests do not transmit the TSE agent, or have been inspected by the FSIS or an equivalent State agency at one time and cooked and offered for human food and further heat processed for feed and thus are of lower risk than those products that the agency has determined to be nonGRAS, or current industry practices can provide assurances that certain mammalian products can be produced without becoming commingled with potentially infective materials." [62 Federal Register 30938, June 5, 1997.]

In short, the scientific basis for the exemptions for blood and blood products has not changed. And banning them would have severe economic impacts, particularly on the dairy industry.

- **Plate Waste:** The NGFA also supports FDA's decision not to ban the use of restaurant plate waste in ruminant feed. Plate waste has never been shown to pose a risk of BSE infectivity to cattle or other ruminants. Further, given the implementation of their respective bans on all SRMs in all human food by USDA and FDA, these potentially infective tissues no longer are present in plate waste. It appears that this policy option was considered primarily as a method to assist

¹² Quigley, et al., 1998, 2000, 2001, 2004; Halloway, et. al., 2002; Poulson, et. al., 2003.

FDA in perfecting an analytical test to determine whether traces of prohibited mammalian material is or is not present in finished feed. We respectfully submit that rationale standing on its own is insufficient for such a policy response. However, we do believe FDA should consider establishing a more precise definition for plate waste as being **limited only to food that has been offered for human consumption.**

- **Poultry Litter:** The NGFA believes that implementing a systems-based approach – with brain and spinal cord removal as its centerpiece – effectively minimizes the potential for poultry litter to be contaminated with potential BSE infectivity. A major NGFA-member integrator company involved in poultry operations has estimated that approximately 6.4 million tons of litter are generated annually by broiler chicken production in the United States. Particularly in the near term, banning the feeding of poultry litter to cattle could pose significant disposal issues in some regions of the country, as well as alter the cost structure of feeding cattle.

Other Issues

The NGFA wishes to support the recommendation of the Pet Food Institute, in its comments filed with the agency on November 21, 2005, urging that FDA amend its BSE-prevention feed rule to clarify that pet food products that are **sold or intended for sale at retail and for use in non-ruminant laboratory animals are exempt from the rule's labeling and recordkeeping requirements,** unless such products are sold or intended for sale as distressed or salvage items. We believe this interpretation is consistent with FDA's intent, and would help immensely in rectifying the misinterpretation that has existed among some states and FDA district offices concerning whether individual retailers selling pet food directly to end-consumers have an obligation to affix the BSE caution statement or maintain records of customers purchasing such products. Clearly, these sales do not involve salvage or distressed product, which is where FDA's labeling and recordkeeping requirements should apply.

The NGFA also wishes to take this opportunity to reiterate its support of FDA's adoption of a trace-forward, trace-back approach as part of a more targeted method for BSE feed rule inspection and enforcement. Under this concept, the movement and use of mammalian material prohibited from being fed to ruminants is tracked from its origin to subsequent receivers, handlers and mixers. This enables FDA and states conducting BSE inspections on the agency's behalf to prioritize inspection and compliance efforts on facilities that actually distribute such materials and also receive, manufacture, handle or use prohibited mammalian materials. The NGFA offers its previous recommendation that FDA consider requiring establishments – including on-farm mixer-feeders – that utilize prohibited mammalian material and which also manufacture ruminant feed or feed ruminant animals to register with the agency **provided FDA believes doing so will assist the agency and states in performing such trace-forward inspections.** If such a determination is made, the NGFA encourages FDA to examine carefully if such registration data for commercial packing, rendering and feed manufacturing facilities already could be obtained as a subset of the

facility registrations required by the agency under the Bioterrorism Preparedness and Emergency Response Act of 2002 **before** initiating a new facility registration process. If such a registration process is initiated, the agency could use the same requirement imposed under its bioterrorism-preparedness regulations to mandate that facilities update their registration information within 60 days if substantive changes occur that affect the status, ownership or products handled at the facility.

In addition, the NGFA continues to support trace-back government-based inspections if violations are detected among subsequent handlers and users of prohibited mammalian materials. **We believe government-based surveillance and enforcement should focus on direct purchasers of mammalian material prohibited from being fed to ruminants to ensure that the product is being directed and sold to approved channels.** Surveillance and enforcement also should be directed at the disposition of salvaged products that may contain prohibited mammalian material. Again, the NGFA believes that facility registration should be considered by FDA **only if** it believes doing so would assist its efforts to obtain customer lists or other records to assist in trace-forward or trace-back inspections.

While not proposed by FDA, the NGFA is concerned that some interested parties responding to this rulemaking again will urge the agency to take the ill-founded and scientifically unjustifiable step of banning the use of avian or non-ruminant-derived mammalian material in ruminant rations, or ban the use of all mammalian material in all animal feed and food. Therefore, the NGFA wishes to utilize this opportunity to reiterate its belief that there is not scientific justification for doing either.

In the case of avian or non-ruminant-derived mammalian (e.g., porcine or equine) material, these products have never been shown to harbor BSE infectivity. Further, removing brain and spinal cord of cattle 30 months or older from the animal food/feed chain **combined with** the current BSE-prevention feed rule's ban on feeding certain mammalian materials to ruminants and the rule's clean-out requirements effectively minimize the potential for cross-contamination. As FDA is aware, the International Review Team recommended consideration of this step as yet another redundancy to protect against cross contamination – **not** because these tissues inherently contain BSE infectivity. In fact, the International Review Team's report states, "...science would support the feed bans limited to the prohibition of ruminant-derived MBM (meat and bone meal) in ruminant feed...."

The NGFA believes that other redundancies in a systems-based approach to preventing BSE transmission – with its centerpiece being a removal of brain and spinal cord of cattle 30 months or older in all animal feed – makes a ban on non-ruminant mammalian and avian material in ruminant feed unnecessary. Further, we believe it would be a drastic and scientifically unwarranted step, and would greatly limit and increase the costs of protein sources remaining available to ruminant feeders.

Similarly, the NGFA wants to reiterate its opposition to prohibiting the use of all mammalian and avian meat and bone meal from ruminant feed. We believe the economic and environmental costs would be very significant, most likely reaching hundreds of millions of dollars across many segments of the feed industry. While the use of non-ruminant

mammalian protein in ruminant diets has declined, it still represents a significant portion of ruminant feed rations based upon least-cost formulations. According to industry estimates, the NGFA believes that beef and dairy feed rations currently contain approximately 8 percent non-prohibited mammalian protein products.¹³ Thus, among the economic repercussions would be: 1) a potential decline in value of mammalian animals being raised by producers, resulting from less usable product from those animals; 2) increased production costs for ruminant feeders; 3) increased pressure on non-animal-based protein sources; and 4) increased demand for non-animal-based feed ingredients.

Conclusion

The U.S. government rightfully merits the strong confidence that has been shown by consumers because of the science- and risk-based approach that has been taken to BSE and other food and feed safety issues. Ultimately, it is a government that does not deviate from policies that are grounded in science that best protects human and animal health, thereby meriting such consumer confidence.

It is vitally important that FDA retain this science- and risk-based approach to BSE as it evaluates future policy options, and to recognize that preventive measures already have been implemented to further protect human health. We believe strongly that FDA's proposal to ban brain and spinal cord from cattle 30 months or older, as well as from all dead stock regardless of age, would represent such a sound policy approach.

The NGFA recognizes that science is not static, and that government, scientists, industry and the public still are learning more about this relatively new animal disease. We pledge to be vigilant and open-minded, and to work with government and others involved in addressing the BSE challenge to continually evaluate scientifically sound, cost-effective policy choices.

The NGFA appreciates this opportunity to provide its views on this proposed rulemaking, and pledges its continued efforts to achieve the objective of preventing the establishment or spread of BSE in the United States.

Sincerely,



Joseph Garber
Chairman
Feed Legislative and Regulatory Affairs Committee
National Grain and Feed Association

¹³ "The Rendering Industry: The Economic Impact of Future Feeding Regulations." Sparks Companies Inc. Prepared for the National Renderers Association, June 2001.



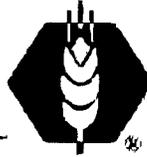
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Appendix 1 – NGFA BSE-Prevention Policy Statement



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Policy Statement of National Grain and Feed Association Concerning Efforts to Prevent BSE in the United States¹⁴

The National Grain and Feed Association reaffirms its commitment to science-based measures to prevent the bovine spongiform encephalopathy (BSE) agent from entering the United States, including strict enforcement of import restrictions. Active surveillance in the United States since 1990 has not detected a single case of BSE.

The NGFA fully supports Food and Drug Administration regulations, predicated upon sound science, that prohibit the feeding of ruminant-derived protein to cattle and other ruminant animals, and reiterates the importance of full compliance. To facilitate compliance and ensure consumer confidence, the NGFA recommends as a best management practice that feed mills that manufacture ruminant feeds voluntarily discontinue the use of prohibited ruminant-derived protein unless they have separate and distinct mixing, handling and storage systems to prevent accidental commingling or cross-contamination.

Consistent with its belief in science-based standards, the NGFA fully supports the continued use of ruminant-derived protein as a safe, nutritious and wholesome feed ingredient for species for which it is legally approved.

¹⁴ Developed and recommended by the Feed Industry Committee of the National Grain and Feed Association and adopted unanimously by the NGFA Board of Directors on March 16, 2001. Subsequently amended by the NGFA Executive Committee on June 13, 2001 and ratified by the NGFA Board of Directors on September 9, 2001.

The NGFA urges uniform adoption by states of FDA's BSE-prevention regulations to facilitate compliance and avoid unnecessary and scientifically unjustified disruption of efficient animal agriculture production, which benefits U.S. and world consumers with safe, wholesome, abundant and affordable supplies of meat, milk and eggs.

Further, the NGFA reiterates its support for FDA and State inspections leading to full and fair enforcement of FDA's BSE-prevention regulations to ensure compliance throughout the supply chain, including renderers, feed manufacturers, farmers and ranchers, transporters and meat processors. In this regard, the NGFA supports efforts by the Association of American Feed Control Officials to make BSE-compliance inspections a continuing part of routine feed mill inspections conducted by the States. Upon completion of the initial round of inspections of all identified renderers and feed manufacturers – and reinspections of facilities where warranted – the NGFA recommends that FDA maintain an ongoing, but targeted inspection and enforcement effort. Specifically, to ensure efficient and effective regulatory control, the NGFA supports the development and implementation by FDA of a statistically valid random inspection program that traces forward the movement and use of prohibited mammalian protein from rendering plants through the supply chain to facilitate continued compliance with the agency's BSE-prevention rule. The NGFA also supports trace-back investigations and inspections if violations are detected among subsequent handlers or users of such products.

To further reassure consumers, the NGFA will continue to work with other involved parties – renderers; farmers and ranchers; meat packers; meat processors; food processors, manufacturers and retailers; and government – to provide mechanisms through which feed manufacturers can affirm their compliance with FDA's BSE-prevention regulations on the basis of existing government-based inspections. In particular, the NGFA will work to facilitate marketplace acceptance of individual company-to-company assurances, including contractual guarantees, company affidavits and other mechanisms, which are responsive to customer needs.

Further, as part of a comprehensive approach, the NGFA supports research on the causes of – and methods for preventing – BSE. In addition, the NGFA supports research to develop accurate and scientifically validated tests capable of detecting the BSE agent and/or the presence of BSE in live animals.

The NGFA will continue its intensive, ongoing BSE-prevention education, training and information efforts, in cooperation with its 37 affiliated State and Regional Grain and Feed Associations, to complement the efforts of government and industry to ensure a continued safe, abundant and wholesome food supply of animal origin.