



National Grain and Feed Association

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August 13, 2004

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

Re: Docket No. 2004N-0264

The National Grain and Feed Association (NGFA) submits this statement in response to the advance notice of proposed rulemaking published jointly on July 14, 2004 by the Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) seeking comments on federal measures to mitigate further the risk of bovine spongiform encephalopathy (BSE) in the United States.

Established in 1896, the NGFA consists of 1,000 grain, feed, processing, exporting and other grain-related companies that operate about 5,000 facilities and handle more than two-thirds of all U.S. grains and oilseeds. With more than 350-member companies that operate commercial feed mills, as well as 30 integrated livestock and poultry operations that manufacture animal food and feed, the NGFA is the nation's largest trade association representing feed manufacturer interests. Therefore, the issues surfaced by FDA in its advance notice of proposed rulemaking (ANPRM) directly and substantially affect NGFA-member companies. The NGFA also consists of 35 affiliated state and regional grain and feed associations, as well as two international affiliated associations.

The NGFA commends FDA for having previously taken a 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 of 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 and only case of BSE to be diagnosed thus far in the United States.

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Thus, the United States is in the enviable position of being able to consider future policy responses from a proactive position of already having implemented prudent and effective BSE-prevention safeguards. The NGFA believes that FDA should view its future regulatory actions from the context of this U.S. and North American experience, which is dramatically different from 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 this advance notice of proposed rulemaking on potential changes to its BSE-prevention feed rule. We believe it is important that FDA take the time to generate the input necessary to evaluate the scientific underpinnings 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. In that regard, the NGFA urges the agency to provide at least a 90-day comment period on any proposed rule it may issue as a result of this ANPRM.

As FDA proceeds to develop a proposed rule concerning the removal of so-called specified risk materials from all animal feed, it is of paramount importance that the agency continue to base its decision-making on the best available science and prudent risk-assessment based on the facts that are known today. To deviate from that sound course could jeopardize the animal agriculture industry and in the long-term undermine consumer confidence.

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 the separate single cases of BSE in Canada and the United States – both in cattle of Canadian origin – the NGFA recognizes that it may be appropriate at some point in the future 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. The NGFA has adopted a BSE-Prevention Policy Statement, which is attached to this statement, pledging its firm commitment to science-based measures to prevent the BSE agent from becoming established or being amplified in the United States.

The NGFA reiterates its policy supporting uniform adoption and enforcement by states of FDA's BSE-prevention regulations, and has strongly encouraged states to amend

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.

their feed laws if needed to clarify that they have such authority. 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.

We recognize that science is not static, and that the agency and the industry have a responsibility to base future decisions on the best available facts that exist. But it is of paramount importance to stress that in contemplating future actions to revise its existing BSE-prevention feed rule, FDA is evaluating ways to strengthen several effective, formidable existing firewalls to further protect **animal, not human, health**. The NGFA's commitment to feed safety is well documented, and we do not minimize the importance of taking prudent and responsible regulatory action when it comes to preventing the establishment or spread of BSE in the United States. But those who argue that there is a sense of urgency for FDA to take action to amend its BSE-prevention feed rule because doing so is a life-or-death matter for human health are at best misguided, misled – and wrong. 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 wishes to present a summary of its thoughts and reasoning concerning FDA's announced intention to propose a ban on the use of all SRMs² in all animal feed, which are expounded upon later in specific responses to the individual questions posed in the advance notice of proposed rulemaking.

The NGFA's core recommendation is that it would be prudent and preferable for FDA to await the results of USDA's current expanded surveillance and subsequent estimation of the prevalence, if any, of BSE in the U.S. cattle herd before promulgating substantive changes to the agency's existing BSE-prevention feed rule. However, if FDA finds it necessary to revise its current feed rule before the results of the surveillance are known and evaluated fully, the NGFA strongly urges the agency to propose for public comment a ban on the use of brain and spinal cord from cattle 30 months or older in all animal feed as a centerpiece of its future BSE-prevention regulations – instead of its announced intention to propose a ban on all SRMs in all animal food and feed.

If FDA decides to proceed with changes to its BSE-prevention feed rules at this stage, we believe a ban on brain and spinal cord of older cattle as part of a systems-based approach would be a prudent science- and risk-based way to provide **protection that is equivalent to a full SRM ban**, and is an economically and environmentally sound policy response for the following reasons:

² Defined as implemented by FDA and USDA's Food Safety and Inspection Service as products banned for use in human food, consisting of the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse 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.

1. First, it would address what science shows is the vast majority of **potential** infectivity **if** BSE exists in an animal. The Scientific Steering Committee of the European Union³ 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 potentially 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. We believe there is merit to removing the vast majority of **potential** infectivity at the “top of the pyramid” of the animal food and feed system, and making meat-and-bone meal inherently safe at its source.

2. If FDA decides to proceed with changes to its BSE-prevention feed rules before USDA’s surveillance is completed, the NGFA believes that proposing a ban on brain and spinal cord from cattle 30 months or older would represent a measured policy response that could be justified based upon the North American experience, in which BSE-prevention firewalls were implemented long before the first BSE case was diagnosed and in recognition of the extraordinarily high rate of compliance with the existing 1997 FDA BSE-prevention feed rule. We also believe this would be a prudent approach, given the fact that the extent to which BSE exists in the United States still is unknown. Filling in that key informational void is the objective of USDA’s current expanded BSE surveillance program, which is to test upwards of 260,000 “high-risk”⁴ animals and has another 16 months to go. The NGFA agrees with FDA and USDA’s assertions in this rulemaking that this surveillance program is “aggressive and comprehensive” and will “assist in estimating the prevalence of BSE in the United States and provide a basis for further assessments of whether and how U.S. actions related to BSE should be adjusted.” Thus, the NGFA respectfully submits that it would be prudent for FDA to await the results and analysis of such data before implementing policy measures as significant as a full SRM removal.

In this regard, the NGFA believes it also is important that FDA formulate future policy with full knowledge of two other unknowns: 1) whether the existence of BSE in North America is attributable to a point-source incident that can be traced to a single geographic area, or whether BSE is indigenous in North America; and 2) whether or not North American BSE case(s) are limited to cattle born – and likely exposed to BSE infectivity – prior to implementation of the BSE-prevention feed rules in the United States and Canada in 1997.

³ “Opinion of the Scientific Steering Committee on the Human Exposure Risk (HER) Via Food with Respect to BSE. Scientific Steering Committee, European Union.

⁴ Defined by USDA’s Animal and Plant Health Inspection Service as non-ambulatory cattle; cattle exhibiting signs of central nervous system disorder; cattle exhibiting other signs that may be associated with BSE (such as emaciation or injury); and dead cattle.

Thus, as noted previously, the NGFA's strong preference would be for FDA to delay its policy response until the results of USDA's current expanded surveillance and subsequent estimation of the prevalence, if any, of BSE in the U.S. cattle herd are known. But the NGFA recognizes this may not be practical, particularly given the expressed desire of the U.S. and Canadian governments to develop and implement a North American approach to BSE prevention. However, in the absence of such surveillance data, we do believe it is advisable for FDA to take a more measured approach, and defer implementing a more Draconian full SRM ban that could force a dramatic restructuring of an entire industry sector and impose adverse economic impacts on the cattle industry – measures that ultimately could prove unwarranted given the extremely low levels of potential infectivity in those additional tissues and particularly if continual surveillance finds that the United States is a minimal-risk country based upon standards established by the Organization of International Epizootics (OIE).

In this regard, as noted previously, it also is important to stress again that with USDA's action in January 2004 to remove all SRMs from all human food products, and FDA's subsequent action effective July 14, 2004 to do likewise in food, dietary supplement and cosmetic products that it regulates, the remaining policy actions related to SRMs represent an animal health, disease control, feed safety, trade and economic issue – not a human food safety or human health issue. The NGFA does not minimize the importance of any of these feed safety-related issues. But it is important to correct the misstatements by some who falsely assert that FDA's prudent decision to take the additional time to obtain public comment on changes to its feed rule somehow poses a threat to human health. It most assuredly does not!

3. We believe this policy response, if FDA decides to act now, would be consistent with the approach recommended by the International Review Team that investigated both the U.S. and Canadian BSE cases, which 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 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

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.

should be taken to prevent the amplification of BSE in the United States.⁷ As such, it would minimize the potential for cross-contamination of facilities and transport vehicles, as well as address the anecdotal reports of misfeeding.

4. Removal of brain and spinal cord from cattle 30 months or older from the animal food and feed chain could well obviate or greatly reduce the need for FDA to implement additional down-stream regulatory controls that ultimately may be less protective of animal health, much more difficult or problematic to enforce, and much more costly and disruptive to implement. In this regard, and very importantly, the NGFA believes that FDA should contract with the Harvard Center for Risk Analysis to conduct an analysis using the mathematical model that Harvard developed for USDA to quantify the additional BSE risk-mitigation that would result from a policy menu whose centerpiece is a ban on brain and spinal cord from cattle 30 months or older, plus a combination of: 1) the existing FDA BSE-prevention feed rule restrictions; and 2) the extraordinary compliance rate with those regulations that has been achieved. It is our understanding that the statement being submitted by Cargill Incorporated in response to this rulemaking demonstrates that this systems-based approach, combined with additional action related to non-ambulatory and dead stock, would provide equivalent protection to a full SRM ban without a need for further BSE-prevention policy measures.

It is the NGFA's view that after analyzing the risk-mitigation impacts that could be expected to be achieved by implementing the aforementioned protections, FDA would be in a much stronger position to evaluate for itself what, if any, additional risk-mitigation measures – some of which are identified by FDA in this rulemaking – may be warranted as part of a systems-based approach. Equally important, FDA would be in a position to quantify the comparative risk-mitigation effectiveness of each additional alternative, and be better prepared to propose additional BSE-prevention measures if necessary once the results of USDA's surveillance are known.

5. While our views represent the perspective of feed manufacturers, 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. In discussions with a packer/renderer, 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 about 2 pounds of wet waste per head. That compares to a total wet waste per head of 90 to 120 pounds that would result from a ban on all SRMs, depending upon the extent of intestinal tract removal. Thus, according to a packer/renderer, 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. It has been estimated by the American Meat Institute (AMI) that just the direct disposal costs for a total

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.

SRM removal will exceed \$55 million annually because of the additional labor and capital investment needed to separate and handle SRMs.

To extrapolate that disparity into an economic impact, a packer/renderer has estimated that removal and disposal costs – including the lost value of the product – would amount to about 20 cents per head if FDA were 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, 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 for a full SRM removal in which the entire small intestine is removed, calculated based upon an estimated average of up to \$10 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.

6. Finally, and very importantly, the NGFA reiterates its belief that FDA should contract with the Harvard Center for Risk Analysis to conduct an analysis using the model that Harvard developed for USDA to assess the additional risk-reduction that could be expected to occur if the agency implemented a brain and spinal cord ban under a system-based approach, instead of a total SRM ban. Such an analysis would enable FDA to consider such SRM policy alternatives in the context of other risk-mitigation measures already in place, such as existing U.S. BSE-prevention firewalls that include FDA's BSE-prevention feed rule and strong compliance rate, and import controls that have been in place since 1989. It also would allow the agency to quantify the additional risk mitigation, if any, that would result from other potential policy steps that are outlined in its ANPRM.

With this groundwork laid, the NGFA wishes to provide specific comments on several of the questions raised in the ANPRM. For ease of reference, our comments correspond to the numerical questions posed in the rulemaking. While the NGFA's responses address SRM-related issues, each is predicated upon the NGFA's belief that FDA should await the results of USDA's BSE surveillance and a determination of the prevalence of BSE in the United States before adopting such policy responses.

3. What information, especially scientific data, is available to support or refute the assertion that removing SRMs 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?

If FDA decides to proceed with changes to its BSE-prevention feed rules before USDA's surveillance data are available and the prevalence of BSE in the United States is established, the NGFA believes that some form of SRM removal – in particular a ban on brain and spinal cord of cattle 30 months or older – warrants consideration by FDA as the centerpiece of a systems-based proposed rule that would further reduce what already is an extremely low risk of BSE in the United States. As noted previously, 90 percent of total potential infectivity exists in the brain and spinal cord if an animal is infected with BSE, and

virtually all of the potential infectivity remaining in other central nervous system tissues is eliminated through normal rendering (such as atmospheric rendering processes).

In addition, as noted previously, scientific studies in which cattle ingested BSE-infected meat-and-bone meal under field conditions found that the brain, spinal cord and retina were the only tissues where BSE infectivity was detected. We believe that removing the vast majority of potential infectivity at the "top of the pyramid" for animal-based feed ingredients as part of a systems-based approach would reduce drastically any potential for accidental cross-contamination of ruminant feed and feed ingredients, particularly at rendering, as well as in on-farm feed manufacturing and accidental misfeeding.

However, it also is important to reiterate that FDA's own inspection results continue to show remarkable compliance with its existing BSE-prevention feed rule. FDA's most recent inspection report, issued July 29, 2004, showed that 99.4 percent of the 2,901 active firms handling materials prohibited from being fed to cattle or other ruminants were found to be in substantial compliance with the BSE-prevention feed rule. That includes 100 percent of renderers, 99.5 percent of commercial feed mills, and 99.3 percent of other types of firms, which include ruminant feeders, on-farm mixers, pet food manufacturers, animal feed salvagers and transporters, and others.

4. If SRMs are prohibited from animal feed, should the list of SRMs be the same as the list as for human food? What information is available to support having two different lists?

As noted previously, the NGFA believes that strong scientific, risk-assessment, economic and environmental reasons exist for FDA to propose 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 normal rendering, in which the use of rendering under vacuum conditions no longer would be permitted. 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.

Further, as noted previously, the NGFA believes strongly that a graduated policy response is warranted when it comes to SRM removal, particularly given the ongoing nature of USDA's enhanced surveillance program to estimate the prevalence of BSE in the United States. We also believe strongly that it is unwise for FDA to propose a ban on all SRMs until the United States has a better comprehension of whether the extent to which BSE exists is attributable to a point-source infection traceable to a single geographic area, or is more widespread. Likewise, it is important for FDA to know the results of epidemiological investigations of any future case(s) of BSE to be able to determine whether the infected animal(s) were born before or after the implementation of the BSE-prevention feed rules by the United States and Canada in 1997.

The NGFA also believes that economic costs and structural dislocation, as well as environmental repercussions, outlined in our response to question 7 make a prohibition on brain and spinal cord of cattle 30 months or older a preferred policy option to propose at this time. If FDA decides to proceed at this stage, a related factor to consider is that removing all SRMs from all animal feed could delay timely and effective implementation of this risk-mitigation measure. The failure of European countries to design an effective SRM disposal system complicated and undermined the effectiveness of their BSE-prevention feed controls on that continent and created huge environmental and warehousing problems. The NGFA submits that the goal should be the effective implementation of targeted actions that achieve the greatest degree of quantifiable risk mitigation in the most efficient period of time at a reasonable cost and with the greatest compliance.

While ancillary issues, such as trade and domestic market competitive issues, are important, we believe FDA should be wary of implementing a full SRM ban for the aforementioned reasons.

5. What methods are available for verifying that a feed or feed ingredient does not contain SRMs?

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 USDA's Food Safety and Inspection Service for human food should be sufficient to prevent the inadvertent inclusion of these materials in animal feed. **Further, the NGFA believes that FDA should implement recordkeeping requirements, as well as more concentrated and frequent inspections, at rendering plants if a partial or full SRM removal policy were to be implemented.** This is where potentially infective material, if it exists in a rendered product, would be at its greatest concentration. And rendering is where the risks of cross-contamination are most acute if prohibited and non-prohibited material is not properly segregated. The NGFA believes FDA and state inspection and compliance efforts should be more focused toward establishments at the "top of the pyramid" – a much smaller number of establishments than currently being inspected.

6. If SRMs are prohibited from animal feed, what requirements (labeling, marking, denaturing) should be implemented to prevent cross-contamination between SRM-free rendered material and materials rendered from SRMs?

The NGFA recommends that FDA consider requiring that rendered brain and spinal cord-derived material from cattle 30 months or older be denatured to ensure it is not, intentionally or accidentally, included in any animal feed. In addition, records indicating the disposition of these materials should be maintained. The ultimate disposition of such materials may be through co-generation as energy sources, disposal rendering, or some other effective processing or industrial use. The NGFA believes that packers and renderers should be required to mark and label such products with the BSE caution statement to prevent inadvertent use in feed or food for animals.

7. What would be the economic and environmental impacts of prohibiting SRMs from use in all animal feed?

The NGFA believes that prohibiting all SRMs from all animal feed could have a major economic and environmental impact. Rendering industry estimates are that the total wet waste would amount to 90 to 120 pounds per head for removal of all SRMs from cattle 30 months or older, with the lower figure representing removal of the entire small intestine and the higher figure attributable to removal of the entire intestinal tract. Waste disposal for full SRM removal in cattle 30 months or younger would amount to 30 to 60 pounds per head, again depending upon the extent of intestinal tract removal. Industry estimates are that a full SRM ban would generate 1.5 billion pounds of material per year.

In this regard, it has been estimated by the meat processing industry that removing all rendered SRMs from all animal feed would result in 112,500 tons of lost meat and bone meal product, while removing all deads and non-ambulatory cattle from the feed chain would remove another 86,500 tons of meat-and-bone meal from the animal feed supply chain. This loss of animal-based protein will have economic consequences for the cost of feed, not only for ruminant feeders but for feeders of other species with protein-dependent diets. For instance, the NGFA estimates it would take almost 9.5 million bushels of additional soybean production -- representing approximately 257,000 additional acres dedicated solely to animal feed -- to yield the soymeal equivalent protein to replace this "lost" product in ruminant feed. The U.S. Department of Agriculture's most recent supply-demand estimates project that U.S. oilseed ending stocks for the 2004/05 marketing year will decline, and soybean meal residual stocks will be sharply lower. In fact, ending stocks of U.S. oilseeds are projected to be the lowest since 1976/77.

A packer/renderer has estimated that removal and disposal⁸ of all SRMs would result in a recurring annual cost of \$157 million -- or \$1.57 billion over 10 years. The per-head weighted average cost is estimated at \$10.70 per head for cows and \$2.55 per head for fed cattle. By comparison, the NGFA has been informed by a significant packer-renderer company that removal of brain and spinal cord of cattle 30 months or older would entail an estimated removal and disposal cost of approximately 20 cents per head, or an estimated annual cost of \$1.6 million -- \$16 million over 10 years -- given the 8 million cattle in this age group marketed each year.

Currently, animal feed and land-fill disposal are the only approved options for disposing of SRMs. 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 economic incentives or remuneration to packers and renderers to compensate for the costs associated with converting their operations into such uses if such a policy change is made.

The NGFA urges FDA to release the results of any economic impact study it already may have conducted concerning its intent to propose a ban on all SRMs from all animal feed, or to undertake such an analysis immediately if one has not been done.

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.

8. What data are available on the extent of direct human exposure (contact, ingestion) to animal feed, including pet food? To the degree that such exposure may occur, is it a relevant concern for supporting SRM removal from all animal feed?

The NGFA is not aware of any data on the extent of direct human ingestion of animal feed, although anecdotal information indicates it is virtually non-existent or very low. Neither is the NGFA aware of any data on direct human ingestion exposure to pet food.

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 SRMs 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 NGFA has long recommended, as a key element of its BSE-Prevention Policy 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 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 in the past has recommended 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.

However, the NGFA does believe FDA should consider requiring that equipment used at rendering establishments that process animals from multiple species, including ruminants, and/or process ruminant-derived SRMs be dedicated solely to handling mammalian material prohibited from being fed to cattle or other ruminants. It is this sector of the industry – the “top of the pyramid” – where the potential for cross-contamination and the potential adverse impacts on down-stream users is greatest. FDA's most recent BSE-compliance inspection data, as of July 31, 2004, show that 557 renderers, protein blenders and feed mills that manufacture, process or blend animal feed or feed ingredients are utilizing mammalian materials prohibited from being fed to cattle or other ruminants. Of those 557 manufacturing firms, 267 of the firms also manufacture, process or blend feeds for ruminant consumption. In addition, based upon the NGFA's analysis of FDA's BSE inspection database, of those 557 manufacturing firms, at least 148 are renderers. And 53 of those 148 renderers also manufacture feed ingredients for ruminant consumption, which 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. FDA's database does not allow for a calculation of the percentage of total meat-and-bone meal produced from these 53 firms.

The NGFA is not opposed to FDA utilizing the Harvard mathematical model to determine what, if any, additional risk mitigation might accrue by requiring dedicated facilities and transport as part of a systems-based approach. But such a policy response should be considered only after evaluating the risk-reduction that would be achieved by a ban on brain-and-spinal cord as the centerpiece of its proposed regulation given the existing FDA BSE-prevention feed rule, the extraordinary level of compliance with that rule and the prevalence of BSE in the United States determined through USDA's cattle surveillance program.

In a related matter, the NGFA was one of the first advocates of FDA adopting 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 recommends 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 if 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.

10. What would be the economic and environmental impacts of requiring dedicated facilities, equipment, storage and transportation?

The NGFA believes that 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 during a period of escalating plant-based protein costs and reduced availability; 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 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 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.⁹ That is another reason the NGFA believes strongly that the additional risk-mitigation, if any, that would result from requiring dedicated facilities or transport conveyances should be evaluated using the Harvard mathematical model after considering the equivalency of removing brain and spinal cord of cattle 30 months or older as the centerpiece of a systems-based approach.

The NGFA also is aware that some renderers in comments previously submitted to FDA have stated that a dedicated transportation requirement would be impractical because of their need to use the same vehicle to haul prohibited and non-prohibited material at different times. Renderers have argued that dedication of separate vehicles for each type of raw material is neither economically feasible nor scientifically justified. The NGFA believes that a dedicated transportation requirement would have limited effectiveness if an exemption is granted at the “top of the pyramid” – where prohibited mammalian material is most concentrated and the risk of cross-contamination is greatest.

If FDA determines that additional controls on truck transport are necessary, the NGFA would suggest that the agency consider requiring placarding of trucks that have been used to haul mammalian material prohibited from being fed to cattle or other ruminants as a way of enhancing its own enforcement and enabling receivers of feed ingredients to be more aware of the transport history of the conveyances being used.

11. What information, especially scientific data, is available to demonstrate that clean-out would provide adequate protection against cross contamination if SRMs are excluded from all animal feed?

The NGFA believes that clean-out procedures (e.g., flushing, sequencing and/or physical clean-out) authorized under the 1997 BSE-prevention feed rule would be more than 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.

FDA’s current BSE-prevention feed rule requires that written procedures be maintained that specify the clean-out procedures or other means used to separate prohibited

⁹ Based upon each affected facility being required to obtain two additional trailers at an estimated cost of \$50,000 per trailer.

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 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.

Again, however, the NGFA believes that FDA could more precisely determine the effectiveness of the existing FDA feed rule clean-out requirements when coupled with a brain-and-spinal-cord removal of cattle 30 months and older by including this among the risk-mitigation measures that are evaluated by the Harvard Center for Risk Analysis.

12. What information, especially scientific data, supports banning all mammalian and avian MBM in ruminant feed?

The NGFA believes there is no scientific justification for banning avian or non-ruminant-derived mammalian (e.g., porcine or equine) meat and bone meal from ruminant feed since these materials 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 and retention of the current BSE-prevention feed rule’s ban on feeding certain mammalian materials to ruminants and the rule’s clean-out requirements conceivably would 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 – would make a ban on mammalian and avian material in ruminant feed unnecessary. Further, we believe it would be a drastic and unwarranted step based upon science, and would greatly limit and increase the costs of protein sources remaining available to ruminant feeders.

13. If SRMs are required to be removed from all animal feed, what information, especially scientific data, is available to support the necessity to also prohibit all mammalian and avian MBM from ruminant feed, or to otherwise amend the existing ruminant feed rule?

As noted in its response to question 12, the NGFA believes there is no justification for amending the current BSE-prevention feed rule in this manner since these materials have never been shown to harbor BSE infectivity.

14. What would be the economic and environmental impacts of prohibiting all mammalian and avian MBM from ruminant feed?

The NGFA believes 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 using 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.¹⁰

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. The NGFA's response to question 7 provides additional information relevant to this question.

15. Is there scientific evidence to show that the use of bovine blood or blood products in feed poses a risk of BSE transmission to cattle and other ruminants?

The NGFA is not aware of any scientific evidence implicating bovine blood or blood products in either the natural or mechanical transmission of BSE. The three known cases of transmission of a transmissible 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 recently reported 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.

Nonetheless, the Harvard study went on to analyze the theoretical risk of BSE transmission through bovine blood and blood products. It's analysis was based upon three

¹⁰ "The Rendering Industry: The Economic Impact of Future Feeding Regulations." Sparks Companies Inc. Prepared for the National Renderers Association, June 2001.

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.

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.

Further, 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 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.

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.

16. What information is available to show that plate waste poses a risk of BSE transmission in cattle and other ruminants?

Plate waste has never been shown to pose a risk of BSE infectivity to cattle or other ruminants. Rather, removing the current exemption for these products has been considered primarily as a method to assist FDA in perfecting an analytical test to determine whether traces of prohibited mammalian material is or is not present in finished feed. 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.

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.**

17. If FDA were to prohibit SRMs from being used in animal feed, would there be a need to prohibit the use of poultry litter in ruminant feed? If so, what would be the scientific basis for such a prohibition?

The NGFA believes that implementing a systems-based approach – with brain and spinal cord removal as its centerpiece – would minimize 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; the attached Appendix 2 provides estimates by state. Particularly in the near term, banning the feeding of poultry litter to cattle could pose a significant disposal issue in some regions of the country, as well as alter the cost structure of feeding cattle.

Again, however, the NGFA believes that FDA could more precisely determine the BSE-risk reduction associated with prohibiting the use of poultry litter in ruminant feed by including this among the risk-mitigation measures that are evaluated using the Harvard mathematical model. When doing so, we recommend that FDA analyze such an option after determining the additional BSE risk-mitigation that would result by removing brain-and-spinal-cord of cattle 30 months or older, plus the risk mitigation already achieved through the current BSE-prevention feed rule.

18. What would be the economic and environmental impact of prohibiting bovine blood or blood products, plate waste, or poultry litter from ruminant feed?

As detailed in our response to question 15, the NGFA believes that available scientific evidence demonstrates that these products do not present a risk of bovine-to-bovine transmission of BSE.

But 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.

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

19. Is there any information, especially scientific data, showing that tallow derived from the rendering of SRMs, dead stock or non-ambulatory disabled cattle poses a significant risk of BSE transmission if the insoluble impurities level in the tallow is less than 0.15 percent?

The NGFA is not aware of any scientific evidence that tallow containing insoluble impurities of less than 0.15 percent pose a risk of transmitting BSE. This standard has been endorsed by the Office of International Epizootics (OIE) – the World Animal Health Organization¹³. This standard enables independent and quantifiable testing of tallow for impurities, and is accepted by the United States' most discriminating trading partners. 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.

20. Can SRMs be effectively removed from dead stock and non-ambulatory disabled cattle so that the remaining materials can be used in animal feed, or is necessary to prohibit the entire carcass from dead stock and non-ambulatory disabled cattle from use in all animal feed?

The NGFA believes that brain and spinal cord from cattle 30 months or older can be removed from non-ambulatory, disabled cattle condemned at slaughter, which USDA's Animal and Plant Health Inspection Service currently estimates comprise 30,000 to 40,000 cattle annually.

21. What methods are available for verifying that a feed or feed ingredient does not contain materials from dead stock and non-ambulatory disabled cattle?

The NGFA is not aware of any currently available methods for distinguishing dead stock and non-ambulatory disabled cattle from other mammalian materials in feed or feed ingredients.

22. What would be the economic and environmental impacts of prohibiting materials from dead stock and non-ambulatory disabled cattle from use in all animal feed?

Most recent estimates are that a prohibition of dead stock and non-ambulatory disabled cattle would generate 692 million pounds per year in total waste, and 182 million pounds annually in solid waste. It has been estimated by AMI that disposal of these materials would result in a recurring annual cost of approximately \$210 million.

30. Do FDA's existing authorities under the Federal Food, Drug and Cosmetic Act (that address food adulteration and misbranding) and under the Public Health Service Act (that address the prevention and spread of communicable diseases) provide a legal basis to ban the use of SRMs and other cattle material in nonruminant animal feed (e.g., feed for horses, pigs, poultry, etc.) notwithstanding that such materials have not been shown to pose a direct risk to nonruminant animals? More specifically, under FDA's existing legal authorities, would the potential occurrence of on-farm feeding errors, of cross contamination of ruminant feed with SRMs and other cattle material, or of human exposure to nonruminant

¹³ Chapter 2.3.13 article 2.3.13.8, Office of International Epizootics.

feed (including pet food) provide a basis to ban SRMs and other cattle material from all animal feed?

FDA is broadly charged with wide-ranging authority to administer many provisions in the Public Health Service Act (PHSA) regarding FDA-regulated products. For example, Section 301 addresses the FDA's extensive role in research and investigation activities "*relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man;*" and Section 1701 authorizes the agency to formulate national strategies and coordinate activities related to health promotion and preventive health measures. In its request for comments, FDA specifically refers to the PHSA's provisions that address the prevention and spread of communicable diseases. FDA has broad authority in this regard, including that it has been specifically delegated the authority under Section 361 (Control of Communicable Diseases), "*to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases....*"

The authority delegated to FDA under the Federal Food, Drug and Cosmetic Act (FDCA) is broader still. Under Section 701(a) of this statute, FDA has express general "*authority to promulgate regulations for the efficient enforcement of this Act.*" This provision sometimes is interpreted to mean that, except where specifically prohibited by Congress, FDA is permitted, if not obligated, to issue regulations as deemed appropriate to implement the fundamental objectives of the FDCA.

In its request for comments, the FDA specifically refers to the FDCA's provisions that address food adulteration and misbranding. Section 402 identifies when a food shall be deemed "adulterated," including if it contains: a "*deleterious substance which may render it injurious to health*" under 402(a)(1); an added deleterious substance that is unsafe within the meaning of the provision for tolerance exceptions for required or unavoidable substances under 402(a)(2)(A); or a food additive not approved as safe under 402(a)(2)(C). Section 201(u) defines the term "safe" in relation to food additives, animal drugs and color additives, as having "*reference to the health of man or animal.*"

To a certain extent, as suggested in the agency's request for comments, the proposed ban on SRMs in non-ruminant feed presents a novel issue given that that such materials have not been shown to pose a direct risk to non-ruminant animals. However, authority provided under Section 402 is not limited to the regulation of products that already are adulterated or contaminated. Section 402(a)(4) provides that food is deemed adulterated if it has been prepared, packed or held under conditions "*whereby it may have been rendered injurious to health.*" The focus is whether the conditions may have rendered the food injurious to health or resulted in contamination, not whether the food itself is unsafe. Rulemaking designed to prevent contamination or adulteration of products is an accepted regulatory technique. FDA successfully has promulgated current good manufacturing practices (CGMPs) under the general authority in 402(a) that provide standards food processing and handling to avoid contamination of food with deleterious substances or potentially harmful organisms. CGMPs also have been implemented for medicated feed.

Foodborne pathogens have presented comparable regulatory problems. The FDCA provides no direct authority for the FDA's implementation of hazard analysis and critical

control point (HACCP) standards, but Section 402(a)(4) has been interpreted broadly to give the agency control over preventive contamination measures. Historically, FDA has responded by broadly construing its authority under various provisions of the FDCA to establish measures to avoid potential contamination in the first place. The justification for imposition of these requirements is that serious risks could result if they are not followed. The courts have upheld the application of Section 402 as authorizing standards for the handling of food, and the courts have upheld determinations that a food be considered contaminated or adulterated if it is held in conditions where it *may* have been contaminated. To reach the determination that a food is "safe" requires a reasonable certainty that no harm will result from the proposed use.

FDA's broad authority in this regard includes the resolution of issues that were not foreseen when the FDCA was passed. To ensure that foods are safe, to address critical public health problems and to protect the public health through the prevention of injury due to unsafe products, FDA traditionally has very broad discretion to take inventive measures, and to adopt and revise regulatory approaches under the FDCA. "Many of its most important provisions are couched in general language, which FDA has had the responsibility and opportunity to adapt to contemporary problems." (Hutt & Merrill, *Food and Drug Law*, (1991) (p. 20)).

Therefore, to the extent that the ban of SRMs in non-ruminant feed to protect ruminants and humans is an innovative approach, FDA has ample legal authority given its broad mandate in the implementation of the statutes to which it is charged and in the service of the public health.

Conclusion

The U.S. government rightfully merits the 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, and merits 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. In this regard, the NGFA reiterates its belief that it would be prudent and preferable for FDA to await the results USDA's expanded surveillance and subsequent estimates of the prevalence of BSE in the United States before determining which, if any, SRM-related policy options to pursue. If and when developing its proposed rule related to SRMs, the NGFA urges FDA to strongly consider a systems-based approach that utilizes cost-effective options that are shown to provide protection equivalent to a full SRM ban.

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. At some point in the future, it may be necessary to consider additional risk-mitigation steps either because of emerging science or the results of surveillance data on the prevalence of BSE in the United States and other countries of North America. 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 advance notice of 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



Randall C. Gordon
Vice President, Communications and Government Relations



David A. Fairfield
Director of Feed Services

Appendix 1 – NGFA BSE-Prevention Policy Statement



National Grain and Feed Association

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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.

Appendix 2 – Estimated Broiler Litter by State

State	<u>Millions of Broilers</u>	<u>Houses</u>	<u>Estimated litter tons/yr.</u>
Georgia	1,260.5	8,426	947,903
Arkansas	1,192.4	7,971	896,691
Alabama	1,039.4	6,948	781,634
North Carolina	708.2	4,734	532,570
Mississippi	790.3	5,283	594,310
Texas	601.5	4,021	452,331
Delaware	251.2	1,679	188,904
Kentucky	275.9	1,844	207,478
California*	240.0	1,604	180,481
Maryland	292.4	1,955	219,886
Virginia	265.1	1,772	199,357
South Carolina	197.4	1,320	148,446
Oklahoma	223.0	1,491	167,697
Tennessee	182.3	1,219	137,091
Pennsylvania	129.6	866	97,460
Florida	91.3	610	68,658
West Virginia	87.2	583	65,575
Minnesota	44.8	299	33,690
Ohio	41.0	274	30,832
Washington*	40.8	273	30,682
Wisconsin	34.4	230	25,869
Oregon*	21.5	144	16,168
Nebraska	4.0	27	3,008
New York	2.6	17	1,955
Hawaii	0.7	5	526
Others 2/	475.3	3,177	357,428
U.S. Total	8,492.8		6,386,631

<u>Assumptions</u>	
27,200	birds/house
<u>5.5</u>	<u>flocks/year</u>
149,600	birds/year/house
225	litter tons/house
Cleanout every other year	

1/ December 1, 2001 through November 30, 2002.

2/ IA, IN, OR, and WA combined.

*Estimated by the National Chicken Council