National Grain and Feed Association

February 4, 2003

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

Re: Docket No. 02N-0273

Dear Sirs:

The National Grain and Feed Association appreciates the opportunity to submit this statement in response to the Food and Drug Administration's advance notice of proposed rulemaking requesting information concerning potential changes to its current animal feeding regulations designed to prevent the establishment or spread of bovine spongiform encephalopathy (BSE) in the United States.

Established in 1896, the NGFA is the U.S.-based non-profit trade association that consists of more than 1,000 grain, feed, processing and grain-related firms that operate more than 5,000 facilities and handle more than two-thirds of U.S. grains and oilseeds. More than 300 of the NGFA's member companies operate feed manufacturing and integrated feeding operations, ranging from the largest commercial feed manufacturer in North America to small grind-and-mix operations.

At the outset, it is important to emphasize that there has not been a single case of BSE in the United States. This is the case though the U.S. government has maintained a vigilant surveillance program since 1990 – surveillance that was expanded in 1993 to include non-ambulatory cattle (fallen stock) and is viewed as the most extensive of any country in the world with the exception of Europe, where the BSE agent does exist[1]. During fiscal 2002, USDA more than tripled – to 19,990 head – the number of "high-risk" cattle tested for the presence of BSE, without detecting a single case. This exceeds by more than 40 times the standard set by the Office International des Epizooties (OIE), the standard-setting organization for animal health for member nations.

[1] Testimony of Dr. William D. Hueston, DVM, PhD, Professor and Associate Dean of the Virginia-Maryland Regional College of Veterinary Medicine, before the Senate Commerce, Science and Transportation Committee's Subcommittee on Consumer Affairs, Foreign Commerce and Tourism, April 4, 2001.

02N-0273 C24

1250 Eye St , N.W , Suite 1003, Washington, D.C 20005-3922
Phone (202) 289-0873, FAX: (202) 289-5388, E-Mail ngfa@ngfa.org, Web Site http://www.ngfa.org

Thus, the U.S. government is in the enviable position of implementing safeguards that are prudent in preventing the occurrence of BSE, rather than attempting to control or eradicate it. The NGFA believes that FDA should review potential changes to its existing regulations from this perspective.

The success in keeping the United States BSE-free has been attributable in no small part to the effective "three-firewall" strategy implemented by government and strongly supported by the NGFA and other industry and animal agriculture organizations:

- The first, and arguably most important, of those firewalls is an intensive program of import controls implemented by USDA, FDA and the U.S. Customs Service that is designed to prevent the importation of animals and animal products from Europe, Japan and other countries where BSE is known or suspected to exist, or where domestic controls are insufficient to protect against the risk of BSE.

- The second firewall consists of the FDA's rule, which took effect on Aug. 4, 1997, that prohibits the feeding of specified mammalian material to ruminant animals and is widely considered to be a model for the world. The NGFA was an active participant in the process that resulted in FDA's rule, as well as in education and information efforts initiated by the agency and the private sector to acquaint affected industry sectors about the rule's requirements.

- The third firewall consists of an active, government-based inspection and surveillance program implemented by FDA and state feed control authorities to verify compliance with the FDA rule. This third firewall also includes USDA's active surveillance of livestock to detect BSE referenced earlier.

The NGFA commends FDA for initiating this rulemaking to review its current BSE-prevention regulations. As it does so, we believe it is of paramount importance for FDA to continue to base its decision-making on the best available science and prudent risk-assessment based on the facts that are known today. It can be argued that the entire world is looking to FDA as a model agency for prudent, science-based risk assessment for preventing the establishment or amplification of BSE. To deviate from that sound course could undermine the agency's moral authority to regulate protection of food and feed safety. Were that to occur, we likely would see a hodge-podge of different state laws and regulations emerge to address BSE and other food safety issues, as well as an undermining of consumer confidence.

The NGFA has adopted a proactive BSE-Prevention Policy Statement[2] *[copy attached]*, pledging its firm commitment to science-based measures to prevent the BSE agent from entering the United States. 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 based upon our understanding of current science related to BSE, the NGFA fully supports FDA's existing regulations, and does not believe that the current ban on feeding certain mammalian material to ruminant animals should be expanded beyond the restrictions currently in place. We support the continued use of ruminant-derived protein as a safe, nutritious and wholesome feed ingredient for species for which it is legally approved.

It is in this context that the NGFA wishes to respond to several of the questions posed by FDA in its November 6, 2002 ***Federal Register*** notice.

Preventing Cross-Contamination

FDA raises several questions as to whether there are "practical ways, other than dedicated (feed and rendering facilities)" to prevent cross-contamination of feed from plants that manufacture ruminant feed and handle both prohibited and non-prohibited mammalian material.

The exhaustive 500-page study released on November 30, 2001 by the Harvard Center for Risk Analysis found that current controls – including the "three-firewall strategy" outlined previously – and the declining number of new cases of BSE worldwide have made the United States "resilient" and "highly resistant" to the emergence of BSE. It is significant to stress that this assessment was made at a time when inspection compliance rates were characterized as "imperfect" and were considerably lower than exist currently. Further, as noted previously, the BSE agent is not known to exist in the United States.

Given these factual premises, the NGFA believes that the existing clean-out procedures – which in the case of feed mills include flushing, sequencing and physical clean-out considered to be appropriate for minimizing the potential for illegal drug carryover in manufactured medicated feed – continue to constitute an appropriate level of protection against cross-contamination under FDA's BSE-prevention regulations.

---

[2] 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 also wants to take this opportunity to strongly urge that FDA **not** amend its current regulations to require dedicated facilities for the production of animal feed containing prohibited mammalian material. The NGFA's BSE Prevention Policy Statement recommends, as a best-management practice, that feed mills that manufacture ruminant feeds voluntarily discontinue using prohibited mammalian material unless they have separate and distinct mixing, handling and storage systems to prevent accidental commingling or cross-contamination. But the NGFA believes strongly that this decision should be made by individual companies based upon their individual circumstances, including the price relationships of different protein sources, the product mix of feeds they manufacture in response to customer demand and their capability to comply with FDA's existing requirement to develop, implement and adhere to appropriate written clean-out procedures. For some feed manufacturers, 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. For this reason, we believe it would be inadvisable and costly to these firms for FDA to mandate such a requirement.

However, it is important to note that a significant number of mills that produce feeds for multiple species, including ruminants, already have made the voluntary business decision to avoid handling prohibited mammalian material in their manufacturing operations. They have done so either because they believed it represented the easiest and most effective way for them to comply with the BSE-prevention rule or because of recommendations from their trade association or requests from insurance carriers and feeder-customers. FDA's own inspection data indicate that this trend has accelerated in recent months. FDA's most recent inspection data show that only 24 percent of the 1,117 FDA-licensed feed mills and only 11 percent of the 4,830 feed mills not licensed by FDA are currently handling prohibited mammalian material. Further, some of these facilities do not manufacture ruminant feed.

Ultimately, though, the NGFA believes the decision on whether to utilize prohibited mammalian material is a decision best made by the management of the individual facility. Rather than revising the existing regulations, we believe FDA should continue the demonstrable progress being made to achieve as close to 100 percent compliance with the existing rule as possible, particularly among multi-specie feed mills that manufacture ruminant feed and handle prohibited mammalian protein.

Remarkable progress has been made on the compliance front. FDA's most recent data from more than 17,000 inspections conducted by FDA and the states show that less than only 12 – or **0.8 percent** – detected violations sufficient to warrant an "official action indicated" (OAI) citation among facilities handling prohibited mammalian material. Further, FDA officials have said that most of these violations were "easily correctible."

Because it is such a crucial component to the nation's BSE prevention strategy, it is appropriate to elaborate on FDA's inspectional approach. The NGFA commends FDA for adopting a more targeted inspection and enforcement program related to its BSE-prevention rule. The NGFA in 2001 had recommended that the agency adopt a trace-forward inspectional approach, in which the movement and use of mammalian protein that is prohibited from use in ruminant feed is tracked from its source to subsequent receivers and handlers. The NGFA recommended that this be accomplished through the development of a statistically valid random inspection program, and that it be augmented and backstopped by states conducting BSE-rule compliance inspections as part of their routine feed mill inspections. We commended the Association of American Feed Control Officials (AAFCO) for including this latter component in its BSE Policy Statement. The NGFA also supports trace-back investigations and inspections if violations are detected among subsequent handlers and users of restricted-use material.

It is our understanding that FDA is now narrowing its inspection focus to the estimated 1,431 rendering and feed manufacturing firms that handle prohibited mammalian material. We believe this approach makes sense from both a risk-assessment and resource-allocation standpoint. Surveillance and enforcement also should be directed at the disposition of salvaged products that may contain mammalian protein prohibited from use in ruminant feed.

The NGFA also encourages continued efforts to enhance coordination and uniformly interpret inspection results by states and FDA. The ongoing review and modifications to FDA's BSE Inspection Checklist to improve its clarity are a positive step and should lead to improved uniformity of the inspection interpretations and results. We are aware that some of the alleged "violations" of the BSE-prevention rule in the initial round of inspections resulted from misinterpretation of the questions posed on the previous inspection checklist form. The NGFA believes that FDA, industry and other interested parties should continue to evaluate the BSE inspection checklist based upon actual field experience, and to make future modifications that may be needed to ensure accurate inspection results.

The NGFA believes that enhanced cooperation between FDA and states also will have a benefit in encouraging states to adopt and enforce FDA's BSE-prevention regulations, rather than developing alternative rules or interpretations that may not be science-based and result in unjustified disruptions in interstate commerce and inefficiencies and costs for the U.S. animal feed and feeding industries. We are very concerned that differing state feed laws and regulatory requirements on BSE – such as those enacted in 2001 in South Dakota and under consideration this year in New York and other states – are having unintended and negative consequences, have the potential to create confusion among the regulated industries as to compliance requirements, and result in additional costs that will be borne by feed manufacturers, feeders and consumers, without providing substantive food or feed safety protections.

We also submit that compliance can be improved by continued efforts of industry organizations and companies – in partnership with efforts underway by FDA and states – to provide accurate and timely education and information on the BSE-prevention rule. To this end, the NGFA in 1994 developed a Model Feed Quality Assurance Program for commercial feed mills – a first for the industry – which has been updated frequently to incorporate the latest in best management practices for the industry. As part of that program – as well as in stand-alone pieces – the NGFA has developed and disseminated widely a compliance guide for commercial feed mills concerning the BSE-prevention rule. The NGFA, in partnership with its Affiliated State and Regional Grain and Feed Associations, as well as several state agencies and universities, has conducted 17 Feed Quality Assurance Workshops in all regions of the country to encourage broad implementation of Q/A principles. In December 2001, the NGFA also produced a set of four feed quality assurance videos, which also incorporate compliance information on the FDA BSE-prevention rule and can be used by feed mill managers as a continuing education tool for their employees.

The NGFA also wants to take this opportunity to reiterate its position on what role, if any, public or private certification programs should play as part of an overall compliance strategy. The NGFA's BSE-Prevention Policy Statement is outspoken in its strong support for government-based inspections – by FDA and states – leading to full and fair enforcement of the BSE-prevention rule to ensure compliance throughout the supply chain, including by renderers, feed manufacturers, feeders, transporters and meat processors. It is absolutely essential for the feed manufacturing industry to support existing, government-based inspection and compliance efforts. A strong, credible government-based inspection and enforcement program provides the integrity and impartiality that is essential to maintaining consumer confidence.

For the feed manufacturing sector, the NGFA's policy statement commits our organization to work to facilitate marketplace acceptance of individual company-to-company assurances, including contractual guarantees, company affidavits and other self-certification mechanisms, that may be requested by certain customers and that are responsive to customer needs. The NGFA's Feed Trade Rules and Arbitration System, as well as the courts, provide a time-honored mechanism for enforcing such assurances. We have worked directly with the National Cattlemen's Beef Association on just such an approach. It is our understanding that these feed manufacturer-to-feeder affidavits are meeting the needs of most customers. In this regard, we strongly urge FDA to work with AAFCO to develop a mechanism whereby copies of the BSE Inspection Checklist can be provided to inspected firms after appropriate review to attest to their compliance with the rule to facilitate company efforts provide verification to feeder/customers. We are pleased that this concept is part of AAFCO's BSE Policy Statement.

The NGFA fully recognizes and appreciates the rendering industry's decision to voluntarily undertake a third-party inspection and certification program for its segment of the industry. Its decision to do so is understandable, given the fact that renderers represent the "foundation" for compliance with the BSE-prevention rule; if prohibited mammalian material produced and shipped from rendering plants is properly labeled and has been produced in accordance with the rule, compliance benefits accrue to each subsequent handler that purchases and utilizes the product.

But there is a fundamental difference in the feasibility and cost-impact of such a third-party certification approach that applies to 260 or so rendering plants and the economies of scale that apply when transposing such an approach to the breadth of the commercial feed manufacturing industry, with its 6,000-plus mills, only a small percentage of which are multi-specie mills still utilizing mammalian material banned from use in ruminant feed.

For these reasons, the NGFA believes strongly that the use of public or private certification programs for the feed manufacturing sector should be an individual company decision, based upon the perceived value of such certification vis-à-vis customer preferences and market demand. Our industry has the integrity to truthfully attest in company self-certifications or affidavit statements as to their use – or non-use – of prohibited mammalian material and their awareness of and compliance with the FDA rule. Simply put, a feed manufacturer's decision on whether or not to participate in such certification approaches should imply that its feed products are any safer or less safe than those that do not.

Facilitating compliance among transporters with FDA's regulations, especially regarding procedures for avoiding cross contamination, is another important aspect of BSE prevention. The NGFA has led the industry's efforts to develop voluntary best management practices for the transportation sector to facilitate compliance with the FDA BSE-prevention rules. To address the transportation conveyance issue, the NGFA established an Animal Protein Transportation Task Force consisting of representatives from its Feed Industry/Animal Agriculture Committee and Rail Shipper-Receiver Committee, the Association of American Railroads, the American Trucking Associations, the National Renderers Association and the National Oilseed Processors Association. This task force in 2002 finalized a set of voluntary "best management practices" for transporting animal and plant protein products to foster compliance with the aspects of the FDA rule that apply to distributors, including the prohibition on commingling or cross-contaminating ruminant feed or feed ingredients with mammalian proteins that are banned from use in ruminant animals.

For rail carriers, the voluntary best management practices include such steps as maintaining a dedicated fleet or establishing a customer-assigned pool of cars. The Association of American Railroads has developed a special standard transportation classification code (STCC) and grade code identifying cars dedicated solely to hauling prohibited mammalian material. These codes allow carriers to restrict the issuance of a waybill if the car is placed at the wrong facility.

For truckers, the voluntary best management practices contain suggested compliance methods – including air-blowing, sweeping, vacuuming and pressure washing. The document also recommends that truckers establish and utilize cleaning stations and maintain written records of the clean-out process. It is advised that such records include: 1) the identification code of the truck trailer; 2) the date cleaned; 3) the entity performing the cleaning; 4) the location where the cleaning occurred; 5) the clean-out method used; and 6) the disposition of the residue product resulting from the clean-out process. The voluntary best management practices also recommend that truckers record trailer-specific information that identifies the contents of the preceding load hauled, and provide such information to the shipper or receiver upon request.

The NGFA and other organizations that participated in this effort will be disseminating this set of voluntary best management practices widely – including to FDA and states – and encouraging that they be adopted and utilized. Further, we were pleased to have provided these voluntary best management practices to FDA as the basis for its script for a new educational video, scheduled for release later this year, designed to familiarize trucker-haulers with the requirements of the BSE-prevention rule and appropriate clean-out methods when hauling prohibited mammalian material. This video is designed to be shown by feed mill managers to truckers at the plant while trucks are being unloaded. The NGFA is participating as a sponsor of this project, and we look forward to distributing the video and accompanying educational materials widely once they are completed.

These voluntary best management practices and the concentrated educational effort that will ensue make it unnecessary for FDA to change its current regulations to require dedicated transportation of animal feed containing mammalian protein. Doing so would increase delivery costs and present operational challenges to feed manufacturers, rail carriers and truckers in effectively transporting feed and feed ingredients. A case-in-point is the change in South Dakota's statute and regulations in 2001, which has resulted in feed companies making duplicate deliveries to wholesale dealers and to farms that previously were efficiently and safely done with one. This creates additional costs and inefficiencies.

In short, the NGFA believes the current FDA rule as it pertains to cross-contamination is adequate to meet the stated objective of preventing the amplification through feed of BSE if the agent ever were to enter the United States.

Use of Pet Food in Ruminant Feed

FDA also solicits comments on whether to change its existing regulations to require the BSE caution statement on pet food sold at retail that contains or may contain prohibited mammalian material.

The NGFA strongly endorses the position and commends to FDA's attention the economic analysis of its strategic partner, the Pet Food Institute, concerning this matter. We join PFI in strongly supporting the agency's 1997 decision to exempt pet food sold at retail from the BSE caution statement labeling requirement, and believe reversing course would cause unwarranted consumer alarm and result in significant economic damage to retail sales of pet food, with reverberating consequences for sales of products sold at the meat counter. Another consequence of inserting the caution statement on labels of retail pet foods containing ruminant protein ingredients may be a consumer shift to pet food products that do not contain those ingredients and, therefore, would not be labeled with the BSE caution statement. This unintended shift could further disrupt the marketplace for ruminant protein ingredients and affect not only pet food manufacturers, but also renderers, meat processors and other related industries.

The NGFA believes FDA's reasoning for exempting pet food sold at retail from being labeled with the BSE caution statement – as articulated in its preamble to the 1997 rule[3] – remains sound and valid. FDA's rule prudently established a requirement that distressed and salvage pet food be labeled with the cautionary statement "Do not feed to cattle or other ruminants." The responsibility for such labeling rests with the reseller of such pet food, and compliance with the feeding restriction rests with the buyer. Therefore, **the current regulations need to be enforced.** When salvaged or distressed pet food is found in commerce or distribution and is labeled as a different product; or is mixed improperly with other ingredients; or is being used as feed for cattle or other ruminants, the agency or appropriate state authorities should take immediate enforcement action to stop the misuse, mislabeling or mishandling of the material. It also is important to note that the amount of distressed pet food possibly included in ruminant feed, even taking into consideration anecdotal reports, is very small.

---

[3] "FDA agrees that the cautionary statement **serves no useful purpose** on pet food and feed for nonruminant laboratory animals and has amended the rule by creating a new Sec. 589.2000(d)(4) to exclude pet food products that are sold or intended for sale at retail to non-food producing animals and feed for nonruminant laboratory animals. These products typically cost substantially more per ton than most complete feeds intended for food-producing animals. Therefore, there is little, if any, risk that pet foods or feeds for nonruminant laboratory animals will be purchased at full price for use in ruminant rations. (62 Federal Register 30955, 06/05/97)." [Emphasis added.]

PFI has been extremely proactive in its efforts to alert those that handle and receive salvaged and distressed pet food with the requirements of the FDA rule. In 2001, it developed an eye-catching pamphlet entitled ***"Handling Salvage and Distressed Pet Food."*** At its expense, more than 10,000 copies have been produced and distributed widely nationwide. The NGFA has part of its strategic alliance with PFI has assisted in the distribution of this pamphlet, focusing on its 36 affiliated State and Regional Grain and Feed Associations and NGFA-member commercial feed mills that do business and interact with dairy producers.

The most recent online consumer survey conducted by PFI in August 2002 has documented and quantified the degree to which consumers would draw incorrect conclusions from labeling retail pet food with the BSE caution statement, and the catastrophic economic impact and ripple effects that would result for the pet food, rendering and meat industries. PFI's consumer survey found that 57 percent of respondents would be concerned or very concerned about the safety of feeding pet food whose label bore the BSE caution statement. Twenty-six percent responded that they would stop buying pet food if such a caution statement were present, while another 18 percent said they were unsure how their purchasing behavior would change. Further, 19 percent responded that the presence of the BSE caution statement on retail pet food would create concern over whether beef and lamb sold at the meat counter was safe for human consumption.

Based upon this anticipated consumer reaction, PFI conservatively estimates that the economic impact of such labeling on U.S. pet food sales – which amounted to an estimated $12 billion in 2002 – would be severe, with at least a 17 percent decline. That would equate to an economic loss of approximately $2 billion annually to the pet food industry alone.

For these reasons, the NGFA submits that the prudent course of action is two-fold: 1) strong regulatory enforcement by FDA and state governments of the current requirement to label and appropriately use salvaged or distressed pet food that is being withdrawn from retail sale for subsequent resale; and 2) support for ongoing joint industry and government efforts – under PFI's leadership – to aggressively educate retailers and feeders about the illegality of feeding such pet food products to ruminants.

Excluding Brain and Spinal Cord from Rendered Animal Products

FDA asks whether "high-risk materials, such as brain and spinal cord from ruminants two years of age and older, (should) be excluded from all rendered products."

Consistent with its comments concerning cross-contamination, the NGFA believes that it is important that FDA's risk assessment of the costs and benefits of such a potential course of action be done in the context of the Harvard study's assessment that the United States is "resilient" and "highly resistant" to the emergence of BSE, the absence of the BSE agent in the United States, and high level of compliance that exists with FDA's existing BSE-prevention regulations.

The NGFA is concerned about the disruption, impracticalities and additional costs that would be forced upon the rendering industry if the agency prohibits the use of brain and spinal cord from ruminants two years and older in all rendered products for all species. Considering this, the current FDA feeding restrictions should **not** be broadened to include other mammalian materials unless there is compelling scientific evidence to demonstrate that such materials pose a risk of transmitting the BSE agent in the United States or have the potential to cross species barriers and cause similar diseases in other species.

Elimination of Plate Waste Exemption

FDA asks whether it should reconsider the current exemption that allows "inspected meat products which have been cooked and offered for human food and further heat-processed for feed (such as plate waste and used cellulosic food casings" to be fed to ruminants.

As FDA acknowledges, the Harvard Center for Risk Analysis study concluded that such plate wastes pose a minimal risk. The NGFA does **not** support broadening the current FDA feeding restrictions to include plate waste unless scientific evidence supports or shows that these materials are a causative agent of BSE in ruminant animals or have the potential to cross species barriers and cause similar diseases in other species. The NGFA also believes it would be problematic for FDA to explain why inspected meat products sold for human consumption would be unfit for consumption by ruminants.

Use of Poultry Litter in Cattle Feed

As with other aspects of the BSE-prevention rule, the NGFA believes any change to broaden the mammalian material feeding ban to encompass poultry litter should be based upon sound scientific evidence that it will demonstrably reduce the risk of the spread of BSE if and when the BSE agent ever enters the United States.

However, it is important to clarify that these products are not typically used in commercial feed operations because onerous safety-testing requirements and transportation costs far outweigh the value of the protein derived from such products. It also is our understanding from animal agriculture groups that use of poultry litter waste as a feed ingredient on the farm is very limited.

In evaluating its future regulatory options, the NGFA also believes FDA and states should consider how they propose to conduct inspections and bring enforcement action of any rule banning such usage.

Changes in Labeling Requirements

The NGFA is aware that FDA may receive comments from some organizations requesting that FDA revisit the labeling requirements contained in the current BSE-prevention rules, even though the agency did not solicit comments on this in its ANPR notice of November 6, 2002.

The NGFA strongly opposes any change to the current labeling requirements. In fact, we believe one of the strengths of the current rule is that its labeling requirements and the BSE caution statement are well understood by feed manufacturers and their customers. Rather than providing additional clarity, amending the current labeling requirement to require the identity of the specific mammalian species from which the protein was derived would create unnecessary confusion and require an additional "learning curve." Such a change also would be extremely costly for the feed manufacturing industry because of the resultant labeling changes. And we are unaware of any evidence concerning how specie-specific ingredient labeling would be of value in preventing the occurrence and amplification of BSE in the United States. It is the presence, or absence, of the BSE caution statement that animal feed manufacturers and feeders widely understand to be the determinative indicator of whether the feed contains or may contain restricted-use protein.

In this regard, the NGFA also wants to again go on record in strong support of the continued use of the "animal protein products" collective term as recognized by AAFCO. Collective terms were created by AAFCO after consultation with FDA and the industry in 1969 as a method for describing – in a single term on feed labels – a group of ingredients that perform a similar function, but do not necessarily have equivalent nutritional values. The "animal protein products" collective term – one of seven collective terms currently approved by AAFCO – encompasses 45 different ingredients, including meat and bone meal, poultry byproducts, milk protein, various forms of whey, fish meal and other forms of fish protein, casein and other protein-based ingredients of animal origin.

In 1998, AAFCO, with the strong support of the NGFA, acted to designate individual ingredients found within the "animal protein products" collective term, which, if derived from ruminant animals, are prohibited from being used in ruminant feed under FDA's BSE-prevention regulations. In the ***AAFCO Official Publication***, mammalian materials that are prohibited from use in ruminant feed are designated clearly with an asterisk.

For feed manufacturers, collective terms are extremely useful and cost-effective. They enable feed manufacturers to interchange sources of various ingredients that have a similar function based on least-cost formulations, without having to change the list of individual ingredients preprinted on feed bags, tags and labels. At the same time, feed customers are assured that the feed contains protein sources adequate for the species for which the feed is intended.

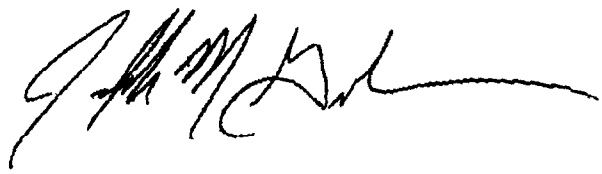
The NGFA is unaware of any misuse of the animal protein products collective term that would justify a change in the label to require identification of the specific mammalian protein source. Further, we do not believe eliminating or changing the collective term would improve either the efficiency of BSE inspections or enhance compliance. The NGFA notes that even if use of the animal protein products collective term were disallowed, inspectors still would be expected to review records as part of their BSE inspections to verify the source of the proteins being used in ruminant feeds, regardless of whether the "animal protein products" collective term was used.

Some have cited the desire of a few customers for information on the source of animal protein as being a justification for a change in the labeling requirement. The NGFA notes that it is common practice in the feed industry to provide such information to customers upon request – either orally or in writing. The NGFA believes it is inappropriate for FDA through this rulemaking process to interject itself into such customer-relations issues that are not food- or feed-safety related.

Conclusion

The NGFA appreciates the opportunity to provide its views on this important matter, and pledges its continued efforts to achieve the mutual objective of keeping the United States free of BSE.

Sincerely,



Joe Garber
Chairman
Feed Industry/Animal Agriculture Committee
National Grain and Feed Association

National Grain and Feed Association

Policy Statement of the National Grain and Feed Association Concerning Efforts to Prevent BSE in the United States[4]

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.

[4] 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.

1250 Eye St , N W., Suite 1003, Washington, D.C. 20005-3922
Phone (202) 289-0873, FAX· (202) 289-5388, E-Mail· ngfa@ngfa.org, Web Site: http·//www.ngfa.org

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.