TAB 36

National Grain and Feed Association

# Oral Statement

of the

# National Grain and Feed Association

before the

# Food and Drug Administration Public Hearing

# on BSE Prevention Strategies

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The National Grain and Feed Association welcomes this opportunity to provide its thoughts on the Food and Drug Administration's current animal feeding regulations designed to keep the United States free of bovine spongiform encephalopathy (BSE).

I am Joe Garber, chairman of the NGFA's Feed Industry Committee. I am nutrition and research coordinator for Wenger's Feed Mill Inc. in Rheems; Pa. Also presenting a portion of this testimony is Brad Gottula, chairman of the NGFA Feed Industry Committee's Legislative and Regulatory Affairs Subcommittee, as well as chairman of our Animal Protein Transportation Task Force. Mr. Gottula is director of quality assurance and regulatory compliance for Land O'Lakes Farmland Feed LLC, Fort Dodge, Iowa. Also on our panel is Randy Gordon, NGFA's vice president for communications and government relations, who is based in Washington, D.C.

Established in 1896, the NGFA is the non-profit trade association of more than 1,000 grain, feed and processing facilities and other grain-related firms. Our members 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 plants and integrated feeding operations.

I request that this statement, as well as our subsequent written statement, be included in the official record for this rulemaking.

We commend 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. The entire world is looking to FDA as a model agency for prudent, science-based risk assessment. To deviate from that sound course could undermine the agency's moral authority for regulating food and feed safety. Were that to occur, we likely would see the emergence of a hodge-podge of different state laws and regulations to address BSE, and an undermining of consumer confidence.

We also believe FDA should review its rule from the perspective that not a single case of BSE has been detected in the United States. This is the case though the U.S. government has maintained a vigilant surveillance program since 1990 that is viewed as the most extensive of any country in the world with the exception of Europe, where the BSE agent does exist[1].

This is attributable in large part to an effective and science-based triple-firewall strategy implemented by government that the NGFA strongly supports. Those firewalls consist of import bans; a prohibition on feeding specified mammalian proteins to cattle and other ruminant animals; and active inspection and surveillance programs.

The NGFA has adopted a BSE-Prevention Policy that pledges our firm commitment to science-based BSE-prevention measures. We recognize that science is not static, and that the agency and industry have a responsibility to base future decisions on the best available facts that exist. But based upon our understanding of the current science related to BSE, the

[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.

NGFA fully supports FDA's existing regulations and does not believe that the current ban on feeding certain mammalian protein to ruminant animals should be expanded beyond the restrictions now 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.

With this groundwork laid, we now would like to respond to several of the major questions posed by FDA in its October 5 ***Federal Register*** notice. We have organized our responses to FDA's questions into three broad areas: the scope of the feeding restrictions; enforcement- and compliance-related issues; and operational issues.

First, concerning the scope of the feeding restrictions, we believe the current FDA rule is adequate to meet the stated objective of preventing the spread through feed of the BSE agent if it ever were to enter the United States. *[Question 2]*

Rather than broadening the rule's objectives, we believe the first order of business is to achieve as close to 100 percent compliance with the existing rule, particularly among multi-specie feed mills that manufacture ruminant feed and handle prohibited mammalian protein. The NGFA does not believe the current FDA feeding restrictions should be broadened to include other mammalian proteins unless there is compelling scientific evidence that the ingredient is a vector of the BSE agent. *[Question 3]*

For the same science-based reasoning, we also do not believe FDA should revoke or change the exclusions for certain products allowed in the current rule. *[Question 7]* Nor should the agency add to the list of mammalian proteins that are restricted from being used in feed for cattle or other ruminants. *[Question 8]*

Second, FDA poses several enforcement- and compliance-related questions. The NGFA believes that the existing authorities at both the federal and state level, including states' authority to issue stop-sale orders, are strong and effective tools to ensure compliance. *[Question 14]* We believe a visible surveillance presence by FDA and states is more important to encouraging compliance than additional enforcement authorities.

Concerning future enforcement activities *[question 1]*, the NGFA recommends strongly that FDA and its state partners adopt a more targeted inspection and enforcement plan for the future. We believe the central component of such a plan should be a trace-forward approach, in which the movement and use of ruminant-prohibited mammalian protein is tracked from its source to subsequent receivers.

We recommend this be accomplished through the development of a statistically valid random inspection program. We believe this should be augmented by states conducting BSE-rule compliance inspections as part of their routine feed mill inspections, and commend the Association of American Feed Control Officials for including this component in its BSE Policy Statement.

In joint meetings with other animal industry, feed and rendering organizations, we believe there is an emerging consensus that a trace-forward approach makes sense from both a risk-assessment and resource-allocation basis. As part of such an approach, the NGFA recommends that FDA develop an overall strategic plan to guide its future BSE-prevention surveillance and inspection efforts. From an inspection standpoint, we believe FDA's first priority should be facilities that manufacture feed for ruminants and other species, and which handle prohibited mammalian protein. Surveillance also should be focused on direct purchasers of prohibited mammalian protein, as well as salvaged feed or pet food, to ensure the product is being directed and sold to appropriate channels. Of secondary importance should be multi-specie facilities that utilize prohibited mammalian protein but do not manufacture ruminant feed. As part of this strategic approach, we also recommend that FDA and states enhance their coordination of inspections and interpretation of inspection results. In this regard, the recent modifications to FDA's BSE Inspection Checklist are a positive step and should lead to improved uniformity of inspection interpretations and results.

FDA also asks what role, if any, that public or private certification programs should play. *[Question 15]* The NGFA strongly supports government-based inspections by FDA and states as providing the integrity and impartiality that is essential to maintaining consumer confidence. For the feed manufacturing sector, the NGFA believes that the decision on whether to participate in a public or private certification program should be an individual company decision, based upon the perceived value of such certification vis-à-vis customer preferences and market demand.

The NGFA believes in the integrity of our industry to truthfully attest to their use – or non-use – of prohibited mammalian protein, and has worked 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 which 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.

Given the breadth and scope of the feed manufacturing industry, the NGFA believes that government actions to mandate or endorse a private-sector, fee-based certification program are neither feasible nor appropriate. While we do not oppose FDA providing oversight of the integrity of private sector, fee-based certification programs – if it is requested to do so – we caution the agency to secure the necessary assurances so that its role is not misused to create winners and losers in the marketplace. Simply put, we do not believe a feed manufacturer's voluntary business decision on whether or not to participate in such certification schemes should imply that its feed products are any safer or less safe than those that do not.

FDA also asks about the use of analytical tests capable of detecting mammalian protein in ruminant feed. *[Question 13]* The NGFA believes such tests should be employed by FDA as an enforcement tool only if they have been demonstrated to accurately and repeatedly differentiate between prohibited and non-prohibited mammalian material – including blood, milk and gelatin products – without resulting in false positives. Such tests also should be compatible with the existing FDA-approved equipment clean-out and sequencing procedures that have been a hallmark of the medicated feed current good manufacturing practice regulations.

To conclude our statement, I would now like to ask Mr. Gottula to present our thoughts on operations-related questions posed by FDA.

Thank you. FDA asks several questions concerning whether it should amend its BSE-prevention rule to require dedicated facilities or transportation equipment. *[Question 4]*

The NGFA believes strongly that the decision of whether to utilize dedicated facilities to manufacture ruminant feed is a decision that should be made by individual companies, based on the practicality of doing so given the types of feed they manufacture and customer preferences. In this regard, the NGFA, as part of its BSE-Prevention Policy, has recommended as a 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.

It is our understanding that many feed manufacturers have made such a business decision, either because they believed it was the best way for them to comply with the FDA rule or because of preferences from customers or insurance carriers. But for some feed manufacturers, using dedicated plants or equipment may be impractical given the lines of feed they manufacture. For this reason, we believe it would be inadvisable and costly for FDA to mandate such a requirement.

The NGFA also does not believe FDA should require dedicated transportation equipment for hauling feed or feed ingredients containing prohibited mammalian protein. *[Question 5]* Doing so would increase delivery costs and disrupt operating efficiency, which in fact has occurred under just such a requirement imposed in South Dakota. The NGFA is taking proactive steps to address transportation-related issues associated with the FDA rule. Earlier this year, we established an Animal Protein Transportation Task Force, which I chair, that has drafted a set of best management practices for transporting animal and plant protein in compliance with the FDA rule. The task force consists of representatives from the animal feed, rendering, rail and truck, and soy processing industries. The draft best management practices, which are under review by the task force, identify procedures for using dedicated transportation fleets; customer-assigned equipment; and clean-out procedures if hauling both prohibited and non-prohibited mammalian material in the same conveyance. They also cover loading and receiving procedures applicable to transportation providers, plant and animal protein suppliers and feed manufacturers. Once finalized later this year, we will be disseminating these procedures widely to companies within the relevant industries, as well as to FDA and states, and encourage that they be adopted.

FDA also poses two questions on labeling. One asks whether the agency should require labels to identify the specific mammalian species from which the protein source was derived. *[Question 11]* The other asks whether to amend the BSE caution statement to identify specific ruminant species that are banned from being fed products containing prohibited mammalian protein. *[Question 12]*

The NGFA strongly opposes changing either of these labeling requirements. We believe one of the strengths of the current rule is that the labeling and caution statements are well understood by feed manufacturers and feeder-customers. Changing them could well create new confusion and well as result in excessive costs for the feed manufacturing industry because of the resultant labeling changes, with little offsetting benefit.

Concerning the identification of specie-specific mammalian protein on labels of all feed, the NGFA strongly supports the continued use on feed labels of the "animal protein products" collective term as recognized by AAFCO. Collective terms are extremely useful and cost-effective for feed manufacturers because they allow various ingredient sources that have a similar function to be interchanged based upon least-cost formulations, without having to change the list of individual ingredients on preprinted feed bags or tags.

The NGFA is unaware of any misuse of the "animal protein product" collective term" that would justify a change to specie-specific ingredient labeling. In terms of ensuring compliance with the BSE-prevention rule, it is the presence – or absence – of the caution statement that feeders and feed manufacturers look for to determine if the feed is appropriate for ruminant species.

We also have not seen how such a change would improve the efficiency of the inspection process, as inspectors still would be expected to review records to verify the source of animal or plant proteins being used in feed. If a customer requests such clarification, there are other less-costly methods – including written and oral communication – to provide such information.

We also believe that a requirement to change the caution statement to identify each type of ruminant is unnecessary and again would impose labeling costs on feed manufacturers and their customers. Commercial feeding of sheep, goats, bison, elk and deer are relatively niche, specialty markets whose feeders fully understand that they are feeding ruminant animals.

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