

Testimony of

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**Government & Industry Programs to Prevent BSE
from Entering the U.S.**

before the

Subcommittee on Consumer Affairs, Foreign Commerce & Tourism
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Mr. Chairman, members of the Subcommittee, my name is Richard Sellers. I serve as vice president for feed control and nutrition for the American Feed Industry Association (AFIA). Thank you for the invitation to be here today to explain how the feed industry views U.S. efforts to prevent so-called "mad cow disease" from entering the U.S.

AFIA commends you, Sen. Fitzgerald, for calling this hearing. This forum gives both the federal government and animal agriculture the opportunity to describe our actions and demonstrate our collective commitment to keeping bovine spongiform encephalopathy (BSE) out of the U.S.

I respectfully request, Mr. Chairman, that AFIA be allowed to provide the full text of its statement, along with several pieces of documentation, for the formal record of this hearing.

AFIA is the national trade association representing more than 75% of the primary livestock, poultry and pet food sold annually in the U.S. AFIA's membership of nearly 700 companies is supported by 30 national, state and regional associations. Together we represent more than 5,000 facilities in all 50 states.

Food safety and consumer confidence in this nation's production of foods of animal origin is AFIA's highest priority. We share this priority with every group sitting at this witness table and with every agriculture organization and company in this room today.

We are all justifiably proud that no case of BSE has ever been detected in the U.S., and we are united in our resolve that an effective marriage of government and industry actions will continue to keep the U.S. BSE-free.

This consensus extends well beyond mere philosophy or lipservice. AFIA, the American Meat Institute, the National Renderers Assn., the National Cattlemen's Beef Assn., the National Milk Producers Federation, the American Sheep Industry Assn., and others have worked consistently and collectively for more than a decade to ensure that government actions – and programs instituted by industry – create not only the necessary "firewalls" to prevent BSE introduction to the U.S., but also reinforcement or redundancy to these government safety initiatives.

Dollars and Restraint Needed

AFIA calls on Congress today to do two things to help industry and government live up to their joint commitment to keep the U.S. BSE-free. First, Congress must ensure adequate funding is available to the Food & Drug Administration's (FDA) Center for Veterinary Medicine (CVM) and the U.S. Department of Agriculture's Animal & Plant Health Inspection Service (APHIS) and other federal agencies. These monies are needed to conduct government BSE prevention and control programs in the most effective manner possible.

This funding is necessary to increase and accelerate research on prion disease transmission, to find quick diagnosis and analytical test methods, increase manpower and technology at U.S. ports of entry to detect prohibited products and animals from entering the U.S., and should the unthinkable occur, contain any BSE outbreak to prevent any spread.

Second, we urge Congress to assist industry and government in making sure that public discussions of BSE are free of hyperbole, emotional exaggeration and inaccuracies. This hearing is an important step in making sure the public record on BSE prevention ---- is accurate and objective.

We must avoid at all costs mistakes made in Europe. We must take lessons from the European experience – adopting effective measures where justified by science – and constantly moving forward, ensuring the public is not the victim of demagoguery, grandstanding or propaganda.

AFIA'S Involvement in the World BSE Debate

AFIA's involvement in the battle to control and contain BSE goes back more than a decade to our initial consultations with sister organizations in Europe. These began in the late 1980s and early 1990s, as the BSE situation in the United Kingdom and continental Europe reached crisis proportions, both through independent meetings and through AFIA's role as an officer in the International Feed Industry Federation.

AFIA strongly supported the emergency USDA/APHIS ban on ruminant animals with confirmed cases of BSE in 1989, and likewise supported the expansion of the ban to include at-risk ruminant products from the same countries. AFIA advocated the formalization of these bans, as well as the intensified U.S. surveillance and testing that began here in 1990-93.

In 1996, based upon our consultations with international feed and scientific organizations and visits to European nations struggling to control the BSE outbreak, AFIA met with U.S. livestock and professional animal health groups. These discussions led to formation of a coalition, which announced a voluntary industry program to cease the use of ruminant-derived proteins in ruminant feeds. At the same, industry urged FDA/CVM and USDA/APHIS to accelerate their review to determine if additional regulations were needed to prevent the introduction of BSE to the U.S.

FDA announced in 1997 that it intended to ban the use of ruminant products in livestock feed. AFIA and the coalition of producer and scientific organizations successfully urged FDA to broaden its proposal on restricted proteins to include a restriction on all at-risk mammalian protein used in ruminant feeds.

This broadening of the federal restriction was needed for two reasons: First, all materials posing a potential risk to ruminant animal health needed to be segregated to use in non-ruminant feeds. Second, the broader ban recognized the logistical reality of the rendering, feed and feeding industries, and would not unnecessarily cause economic hardship nor take legitimate feed ingredients for non-ruminants out of the feed chain.

FDA opted to provide limited exceptions to the list of restricted use protein products (RUPP). These include blood, milk or gelatin products, and equine and porcine proteins derived from species not demonstrated to develop transmissible spongiform encephalopathies (TSE) naturally. AFIA supports the existing exceptions based upon sound science.

AFIA's Facility Certification Institute (FCI)

AFIA believes there cannot be too many industry or government science-based precautions, firewalls, or safety program redundancies when it comes to BSE prevention. Putting money, effort and manpower behind this belief, AFIA capitalized on its ongoing membership quality control programs and has modified its general Q/A recommendations to provide specific education and assistance to members and nonmembers relative to feed mill compliance with the government's RUPP rule.

AFIA's Board of Directors approved in early February creation of a third-party certification program to assure consumers of the continued safety of feed and food. This certification program was created as an entirely stand-alone entity -- the Facility Certification Institute (FCI). It provides the entire feed industry the opportunity to have facilities certified for compliance with the FDA's mammalian protein regulations.

AFIA created FCI, and its Certified Facility Program for RUPP, to incorporate FDA's inspection program for compliance with Title 21, CFR § 589.2000, *Substances Prohibited in Ruminant Feed*. The program is designed for an independent certifying agent to visit facilities which use restricted use protein products, as well as those that do not use these products. The agent reviews procedures, examines records and issues interim certifications to those facilities, when an inspection finds the facility meets the program's requirements.

FCI provides two levels of certification, based upon third party, in-plant inspections. Level 1 certified facilities do not use restricted use protein products in their ruminant feed manufacturing facilities. Level 2 plants use restricted use protein, but conform to FDA's regulations. FCI has contracted with certifying agents to handle the program, and is adding more trained personnel as demand dictates. All personnel have extensive feed industry/FDA compliance experience.

Upon certification, facilities are authorized to use one of two distinctive seals and the FCI logo, as well as statements regarding the program. These will be promoted widely as quality certification marks. The program is open to any feed manufacturing, rendering or related facility.

To date, over 100 feed and rendering facilities have received FCI certification, with 10-15 applications arriving daily. To provide farm and ranch customers additional service, all certified mills are listed on the Institute's website – www.certifiedfeed.org. In addition, if a facility loses or gives up its certification, that facility is listed separately. Facilities are also required to notify their customers if they surrender their certification for any reason. Likewise, if a facility is found in violation of federal or state rules during a government inspection, it is required to notify FCI.

FCI is designed to grow into other areas needing third party certification as needed. It represents the organization which will contract for certifications, invoicing and processing and form links and partnerships with other groups and organizations to further strengthen its mission, which is to provide certification with integrity.

FDA Compliance Reporting

AFIA shares FDA/CVM's goal of 100% compliance with the RUPP rule as quickly as possible, as witnessed by our industry third party certification program.

The most recent FDA/CVM compliance report shows substantial progress toward this goal. The report, released March 23, shows that of the estimated 1,290 licensed feed mills in the U.S., FDA has inspected 1,069, and of that universe, 397 mills (37% the licensed mills inspected) report handling RUPP materials.

Of those 397 mills, 99% are in compliance with recordkeeping requirements, i.e. where they bought RUPP materials, in which feeds it was mixed, and to whom those products were sold; 87% have a written in-plant program to prevent commingling, and 85% were in compliance with labeling requirements, i.e. "do not feed to ruminant animals".

There are approximately 6-8,000 non-FDA licensed feed mills in the U.S., and FDA/CVM has conducted inspections of nearly 5,100. About 1,800 mills report handling RUPP materials. Again, more than 99% of these facilities are in compliance with recordkeeping requirements, 82% are in compliance with requirements for written plans to prevent commingling, and 67% are in compliance with labeling requirements

It should be noted FDA/CVM began these inspections over three years ago, and published its interim "compliance report" in January 2001. This report, taken on its face, reflected high compliance with paperwork and recordkeeping requirements, but less successful compliance with labeling requirements and required written programs to prevent commingling.

AFIA believes this compliance report reflects an evolving government compliance inspection program, one coordinated between and among the FDA/CVM and state inspection programs under contract to the federal government. Anecdotal field reports indicate some inspected facilities were made aware of deficiencies, corrected them on the spot, but showed up as "out of compliance" on reports to FDA.

This report has generated customer and media attention. As for the general media, covering an issue as technically complex as BSE is understandably difficult, especially given the amount of unresolved scientific debate and "urban myth" that has sprung up around the issue. However, media must take a responsible approach to its reporting of this animal health issue – you'll note I did not say "food safety issue." Media must resist the temptation to demonize ingredients, practices, industries and food products. What the public needs is straightforward factual reporting on this issue. There is no room for journalistic shortcuts.

Conclusion

AFIA believes the mandate is clear: A marriage of science-based federal government and industry proactive measures is the working mechanism to prevent BSE from entering the U.S.

The firewalls, reinforcements and redundancies to ensure prevention include the following:

- FDA/USDA/Customs Service enforcement of import controls on animals, meat products and animal byproducts
- FDA/CVM's rules prohibiting the feeding of restricted use protein products
- FDA/CVM in-plant compliance inspections on its restricted use protein products rule
- APHIS is conducting on-going animal, tissue and brain testing
- Industry has initiated private third party certification of rendering facilities
- Industry has initiated private third party certification of feed facilities
- Industry has initiated livestock sales affidavit programs on livestock feeding
- Industry has initiated certification to retailers on ingredient, feed and feeding compliance

These measures are working, and are adequate to control BSE introduction to the U.S. However, vigilance and continued innovation are required as situations and scientific evidence may shift.

Congress can assist these efforts dramatically by insuring that FDA, USDA and other federal agencies are adequately funded to conduct research, testing and diagnostics development and other necessary research on prevention, detection and containment of this animal disease.

Congress can also assist industry in assuring that public debate over BSE is accurate, measured and fact-based. We must avoid the hysteria that has led to food panics and Europe.

AFIA stands by the joint industry statement issued by 12 animal agriculture and scientific organizations in January of this year.

“...(W)e affirm our commitment to effective implementation and enforcement of sound, science-based measure to prevent BSE in the United States...Active surveillance has not revealed a single case of BSE. BSE regulations have a firm scientific foundation. They reflect the wisdom of careful consideration and open debate. Surveillance and enforcement in the U.S. have been vigilant.”

And, Mr. Chairman, let me add, industry support and innovation, will continue.

Thank you again for the invitation to appear here today. I'll answer any questions you may have.