

TAB 42

**THE ANIMAL PROTEIN PRODUCERS INDUSTRY (APPI) STATEMENT AT
THE FOOD AND DRUG ADMINISTRATION (FDA) PUBLIC HEARING OF
THE 'ANIMAL FEED RULE'**

9946 '01 NOV -5 A11:32

**Kansas City, Missouri
October 30, 2001**

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The Animal Protein Producers Industry (APPI) is the association of the United States rendering industry that is responsible for biosecurity and the establishment of programs to ensure feed ingredient safety, including animal proteins that are used as ingredients in livestock, poultry, aquaculture, and pet foods. In this capacity, the organization has followed the subject of bovine spongiform encephalopathy (BSE) from the report of the initial outbreak in the United Kingdom in 1986.

APPI is conscious of the complexity of the group of diseases collectively defined as the transmissible spongiform encephalopathies (TSEs), and fully recognizes the tentative nature of the science, and the fact that BSE is the first disease in the annals of regulatory medicine (animal or human) that a rule was written without a finite determination and affirmation of the cause of the disease. While this was unusual, APPI recognized at the time, that the uncertainty (ies) of the circumstances, mandated a necessity to establish a series of flexible controls that are in the best long term interest of animal and human health, and, as a result, supported the agency in its quest to format a rule that would preclude any likelihood of the transmission or amplification of the infectious agent of BSE, and ultimately the protection of the country's public health.

About 16 years after the initial report of BSE, we are still discussing the varied nuances of the disease including the current questions posed by the agency in their consideration of options including aspects/concepts for modification, if applicable, of the existing rule.

While the complex issues and unanswered concerns of BSE mandate caution, the record clearly indicates that the instituted controls in the U.S. starting in 1986 immediately after the confirmatory diagnosis, and continuing in a constant manner to recently promulgated regulations of the Animal and Plant Health Inspection Service (APHIS) imposing import restrictions are effective. Cumulatively, government policies are working and provide ample assurances that adequate constructive measures and controls are in place to ensure the safety of animal protein feed ingredients destined for the feed/food chain.

This assurance analogy is best exemplified by the final rule that became effective on June 5, 1997, and commonly referred to as the "animal feeding regulation." This comprehensive rule has addressed the potential hazards/risks associated with the

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disease and thus established a visionary protocol to prevent the likely transmission and/or amplification of the infectious agent, considered by the majority in the scientific community to be a prion, a protein. This becomes a new addition to the world of causative agents of complex neurodegenerative diseases, the transmissible encephalopathies.

The rule was an excellent proactive response for public health protection at the time it was written, and in the absence of any changes in the risk factors in this country remains so to this day. The regulating agency (CVM, FDA) developed a systematic method for education, inspection for compliance, and enforcement, and collaborated with the States to assure success of the spirit and intent of the rule. APPI, therefore, as an organization, sees no need for any modification(s) or a reopening of the objectives or contents of the rule. Retrospectively, the risk factors in the U.S. for a BSE "incident" are actually the lowest since the associated links to the outbreak was first described in late 1987 – 1988 by epidemiologists in the U.K. This has been affirmed in peer review professional journals by APHIS, USDA officials, and in the Service's own brochures and publications.

In summary, the epidemiological case definition for the BSE outbreak in the U.K. has been clearly articulated by the following postulates. For an indigenous case of BSE to occur, the simultaneous presence of three factors is required: 1. A large sheep population in relation to that of cattle, with a sufficient level of endemic scrapie; 2. Conditions of rendering that allow the survival of significant amounts of infectivity; and 3. The use of substantial quantities of meat and bone meal from affected sheep or cattle, in cattle feed.

The addition of a fourth factor applies to countries without the disease, and has obvious relevance for the United States. Countries without BSE may also acquire it by the importation of live animals that could be incubating the infectious agent of the disease, or the importation of contaminated meat and bone meal that could be subsequently fed to susceptible cattle. Fortunately, our established rules in the past fifteen years have addressed the potential risks from a worst-case assessment, thus creating an impenetrable firewall to prevent the likely transmission and amplification of the infectious agent of BSE, and as a result, the protection of animal and human health in the U.S., which constitutes the letter of the rule.

APPI is committed to the success and compliance with rules that advance the principles of biosecurity, sustainable animal agriculture, food safety, and the protection of human health. We pledge our resources to make that commitment a reality by working with FDA to achieve that objective. The organization treasures this opportunity to comment and commends the agency for its effort at transparency in the consideration of options.

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