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May 4, 2004

FSIS Docket Clerk Docket #03-025IF Room 102 Cotton Annex 300 12<sup>th</sup> Street, SW. Washington, DC 20250-3700

## To Whom It May Concern:

The Institute of Food Technologists (IFT) is the premier scientific and educational society serving the food science and technology field. Founded in 1939, IFT is a not-for-profit organization whose mission is to advance the science and technology of food through the exchange of knowledge. IFT has a long, stable track record of contributing to the development of food science and the food industry. IFT has nearly 26,000 members who represent a broad cross-section of food professions in industry, academia, and government throughout the world.

The Institute of Food Technologists provides comments pertaining to the U.S. Department of Agriculture's (USDA) recent Interim Final Rule 9 CFR Parts 309, 310, 311, 318 and 319, which addressed the Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle (Ref. 1). On March 15, 2004 the Animal and Plant Health Inspection Service (APHIS) released a BSE Surveillance Plan initiating expanded efforts to estimate the level of BSE in the United States (Ref. 2). IFT commends the efforts of USDA-APHIS to determine the true prevalence of BSE and to identify that population in the U.S. that is most likely to be infected with BSE prions. Proper development and implementation of the surveillance plan is essential to the future understanding of risks resulting from the presence of BSE in the U.S., as well as controls that now may be necessary to eliminate risks associated with the presence of this disease. However, the two documents (Interim Final Rule 9 CFR Parts 309, 310, 311, 318 and 319 and the APHIS BSE Surveillance Plan), taken together, present limitations that may hinder successful implementation of the surveillance plan.

In order to assure overall safety of the food supply and successful management of BSE in the U.S., IFT is providing comments in three critical areas as follows:

- USDAs surveillance plan is essential and must be implemented to the fullest extent in order to characterize prevalence of BSE and to provide for effective control of the disease in the U.S.
- Economic or other incentives should be provided to cattle producers to encourage them to present non-ambulatory disabled cattle for testing. The lack of control of any BSE positive animal by government authorities is likely to introduce a disposal problem of environmental concern.
- Further research is needed to characterize earlier stages of the disease, which might include testing younger animals along with the development of additional diagnostics for detection of infected SRMs and/or products that may have been contaminated with infectious tissue.

In our opinion, the condemnation program, as presented in the interim final rule, has inadvertently created a disincentive for farmers to present non-ambulatory disabled cattle to authorities, thereby excluding a segment of the high-risk population from the surveillance plan and creating potential for adverse environmental impacts. As suggested by the Secretary's Subcommittee on the United States' Response to the Detection of a Case of Bovine Spongiform Encephalopathy, supplemental measures to encourage compliance are needed (Ref. 3). For these reasons, IFT feels that it is in the best interest of both the U.S. government and the general public for USDA to offer economic or other incentives to cattle producers in an effort to maintain control of the non-ambulatory disabled cattle population and effectively administer the expanded surveillance plan.

Publication of an enhanced Surveillance plan signifies the important and noble intentions of USDA to characterize prevalence of BSE and to provide for the efficient control of the disease in the U.S. This new plan is essential to future BSE initiatives in the U.S. and should be implemented to the fullest extent. APHIS estimates the "high-risk" population to be 446,000 cattle consisting of the following: "condemned at slaughter for CNS signs; moribund; dead; injured or emaciated (FSIS data 2002); CNS abnormalities reported for foreign animal disease (FAD) investigations (APHIS data); died on farm for unknown causes; lameness, or injury that resulted in euthanasia; and cattle that died with signs of incoordination or severe depression (NAHMS data)." Of those 446,000 animals, some 251,500 are estimated to die on the farm each year, so that the nonambulatory disabled population addressed in the Interim Final Rule consists of approximately 194,000 cattle. The expanded surveillance plan aims to test between 201,000 and 268,500 of the 446,000 high-risk cattle (Ref. 2).

To accomplish USDAs surveillance objectives, it is imperative that USDA receive high-level cooperation from the cattle industry, especially from farmers/producers that generate older cows and cull bulls for harvest. Prior to the Interim Final Rule of Jan. 12, 2004, many cattle previously identified as nonambulatory and recumbent may have been delivered to slaughter facilities, at which point they would fall under USDA-FSIS jurisdiction for inspection. Since implementation of the Interim Final Rule, there exists no obvious financial or other incentive for farmers to notify authorities of possession of a high-risk animal. As a result, the likelihood that such animals will be tested for BSE is

greatly reduced, and the opportunities for losing control of potentially infected (with BSE prions) tissues during disposal are increased.

It is recognized that methods for disposal of carcasses and/or tissues that would provide for proper control of BSE prions are extremely limited. Incineration (Ref. 4) or use of a government controlled and operated landfill are two such options. Both of these have limitations regarding their use. There would be costs to the farmer associated with transporting the carcass, and capacities to handle large volumes might be limited. Furthermore, landfills are not readily available in all parts of the country and some have limitations pertaining to the acceptance of biological wastes.

A lack of testing and subsequent control by government authorities of any BSE positive animal or tissue is likely to introduce a disposal problem of environmental concern (Ref. 4). Cattle processing produces several billion pounds of livestock mortalities, which has resulted in existing disposal issues for the industry (Ref. 5). As discussed previously, non-ambulatory disabled cattle represent a substantial fraction of the target population that will further exacerbate disposal problems in the future. Depressed animal protein markets have forced renderers to enact collection fees ranging from \$7 a head for calves to \$10 per head for cattle over 500 pounds. According to a Sparks report, approximately 55% of all cattle mortalities do not go to renderers (Ref. 5). All of these factors contribute toward the convenient disposal of carcasses, which might include one with BSE, but would not provide for destruction of prions and could result in environmental problems.

IFT recognizes and is encouraged by the recent request by FSIS for further data on salvage values and disposal costs (Ref. 6) because we are concerned that such expenses will create economic disincentives that may lead the farmer to seek alternate means of disposal that are not proven to effectively deal with BSE prions. Additional disposal methods of concern are composting, burial, and abandonment of potentially infected carcasses. Some states have regulations governing these disposal practices, but it should be recognized that such regulations were enacted prior to recognition of BSE in the U.S. Each of these practices continues to be followed and is problematic with respect to destruction of the infectious prion.

Firstly, no practices to ensure destruction of prions through composting have been established. Furthermore, composting is labor intensive and expensive. Burial costs are estimated at \$7.50 to \$15.00 per head (Ref. 5). Coupled with factors such as lack of equipment required for burial and seasonal problems associated with frozen ground, farmers sometimes abandon carcasses on remote parts of the farm. Abandonment of carcasses, burial, or composting is not effective means of destroying prions. These methods do not control dissemination of prions in the environment (e.g., in the water table) and may result in the introduction of infective material to the cattle population (via compost that is utilized as fertilizer for feed crops), thereby continuing to proliferate this disease.

Potential for reintroduction of prionic material was demonstrated via work by Brown and Gajdusek (Ref. 7) in which scrapie infectivity was shown to persist for several years in the environment. That study demonstrated potential for significant negative environmental and disease-status impacts. There must be complete destruction and/or control of tissues potentially infected with prions, which cannot be accomplished via abandonment, burying, or composting as means of disposition. We believe that programs being implemented by USDA should be modified to recognize and consider this potential major environmental hazard.

Current USDA regulations (9 CFR 309.13) require that condemned livestock be euthanized by the official establishment to which they are presented and disposed of according to section 314. Section 314.1 requires that condemned carcasses and SRMs be disposed of by "tanking", also known as inedible rendering; a process that has not been demonstrated to deactivate the BSE prion (Ref. 8). If facilities are not available for tanking, then the carcasses may be disposed of by other means, including incineration or denaturation using activated charcoal, carbolic acid, cresylic disinfectant, a mixture of one part FD&C No. 3 green coloring, 40 parts water, 40 parts liquid detergent and 40 parts citronella, or any other proprietary material approved by the FSIS Administrator (Ref. 1). As a precaution, all condemned cattle and SRMs must be handled as though infected with BSE, which is known to be extremely resistant to inactivation (Refs. 9, 10). However, to the best of our knowledge, the aforementioned denaturation methods, currently recommended by USDA as a means of disposal, have not been scientifically validated as capable of destroying infectious prion proteins, thereby leaving a caveat for survival and dissemination of the infectious agent, and potentially to more cases of BSE.

The risk of BSE dissemination through inappropriate disposal is compounded by the fact that infectivity has been confirmed in tissues other than bovine brains and spinal cords, such as the distal ileum at six months of cattle age and the tonsils at ten months of cattle age (Ref. 1). Most cattle in the U.S. are slaughtered at less than thirty months of age (Ref. 11), and are therefore unlikely to develop clinical signs of BSE. Infected cattle not showing clinical signs of the disease would not be detected as part of the current revised surveillance program.

USDA itself is critical of current testing procedures because they may not detect infectivity of tissue, thereby allowing the possibility of false negatives (Ref. 1). Development of enhanced diagnostics would reduce such possibilities. One example of a seemingly applicable analysis technique is the use of sodium phosphotungstic acid to preferentially precipitate prions. Use of this method has been shown to increase Western blot sensitivity by up to three orders of magnitude (Ref.12, 13). USDA may want to study further the practical application of this technique for incorporation into existing methodologies as a means of enabling detection earlier in the disease cycle, thereby allowing for elimination of young infected animals that appear healthy.

Further research is needed to develop additional diagnostics for detection of infected SRMs and/or products that may have been contaminated with infectious tissue. Such diagnostics may also serve a dual purpose in the future in that they would allow for

testing of finished beef products to verify that no contamination with SRMs or prion proteins has occurred. Potentially infectious tissues are the subject of much public concern due to their broad usage in the food, dietary supplement and cosmetic industries. Development of such diagnostics, as suggested by the Secretary's Subcommittee on the U.S.' Response to the Detection of a Case of Bovine Spongiform Encephalopathy (Ref. 3), could go a long way toward further characterizing the amount of BSE infectivity present in the U.S. which, in turn, would allow development of efficient, improved mechanisms for controlling transmission of BSE within the beef population. Clearly, consumer confidence in the U.S. food supply would be improved if additional diagnostic capabilities existed.

In summary, the Institute of Food Technologists recommends that the programs being implemented by the USDA be modified to provide proper incentives to farmers that will help to ensure testing, and consequently, proper control and disposition of all non-ambulatory disabled cattle. Such incentives, along with improved diagnostics, will increase the effectiveness of the surveillance plan while improving efforts to avoid potential environmental hazards.

Sincerely,

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