IFDA
international foodservice distributors association

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Government Relations / Educational Services

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Docket Clerk
Food Safety and Inspection Service
U.S. Department of Agriculture
Docket #03-038IF
Room 102
Cotton Annex
300 12th and C Street, SW
Washington, D.C. 20250-3700

03-038IF
03-038IF-26
David M. French

Re: Docket #03-038IF; IFDA Comments on Interim Final Rule Regarding Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems

Dear Sir or Madam:

The International Foodservice Distributors Association (IFDA) appreciates the opportunity to submit these comments regarding the Food Safety and Inspection Service (FSIS) interim final rules on Bovine Spongiform Encephalopathy (BSE). IFDA is a trade organization representing foodservice distributors throughout the U.S., Canada, and internationally. IFDA's 140 members include broadline and specialty foodservice distributors that supply food and related products to restaurants and institutions in the "food away from home" business. IFDA members operate more than 550 facilities, and sell more than $64 billion in food and related products to the fastest growing sector in the food industry. Formerly a division of Food Distributors International, IFDA was established as an independent trade association on January 1, 2003.

With the recent finding of BSE in Washington State, it is imperative that the U.S. government implements all necessary measures to prevent human exposure to materials that can cause BSE and the human form of the disease, new variant Creutzfeldt-Jakob disease (nvCJD). Such measures will not only serve to protect human health, but will also instill consumer confidence in the U.S. beef supply, both domestically and internationally. The measures implemented by FSIS in the interim final rules go a long way toward these goals. To that extent, IFDA strongly supports the agency's interim final rules.

This comment will address the interim final rule, "Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems." This rule significantly impacts existing AMR production in two ways. First, it amends the definition of "meat" to expressly provide that meat may not include significant portions of bone and related components, or any amount of central nervous system (CNS-type) tissue (brain, trigeminal ganglia, spinal cord, or dorsal root ganglia). Second, it establishes acceptable raw material and finished product specifications and mandates written control procedures/recordkeeping requirements for AMR production. Failure to comply with raw material and finished product specifications will result in the following:

- If skull or vertebral column from cattle 30 months of age or older is used, the product is adulterated and cannot be used for human food;
- If skull or vertebral column from cattle less than 30 months is used and either the raw material or finished product contains CNS-type material, the product cannot be used in meat food products but could be used in edible rendering'
- If finished product fails to meet calcium or iron criteria, the product cannot be labeled as meat.

*Ban on skull and vertebral columns from cattle 30 months of age or older.*

IFDA strongly supports the agency's decision to ban the use of skull and vertebral columns from animals 30 months of age or older in beef AMR production. AMR systems remove skeletal meat tissue from bone through the use of hydraulic pressure. Although the BSE agent has never been found in the bones of the skull or vertebral column of cattle, these parts contain the highest risk tissues for BSE – the brain, spinal cord, and dorsal root ganglia. If vertebral columns or skulls from cattle 30 months or older are used as raw materials in AMR systems, it is possible that these potentially infectious tissues can be incorporated in meat. It is because of this reason that the Harvard Center for Risk Analysis identified AMR systems as one of the most significant pathways for human exposure to the BSE agent.

Although some beef AMR processors have asserted that AMR systems can be operated in a manner to prevent CNS-type tissue from being incorporated in the beef AMR product, the compliance history regarding AMR systems has proved otherwise. Specifically, in a 2002 Beef AMR survey, FSIS found that a majority of AMR processors had difficulty keeping spinal cord and dorsal root ganglia out of their AMR products. Overall, FSIS found that approximately 76% of the establishments whose AMR product was tested had received positive laboratory results for spinal cord, dorsal root ganglia, or both in their final beef AMR products. Moreover, thirty-five (35) percent of AMR products sampled tested positive for spinal cord, dorsal root ganglia, or both. Since this survey, FSIS and AMR processors have taken actions to prevent the incorporation of CNS-type tissue in AMR product. However, the agency continues to find CNS-type tissue in randomly scheduled samples. Prohibiting the vertebral column and skull from cattle 30 months of age or older from being used in beef AMR systems will ensure that the BSE agent does not become incorporated into AMR-derived product.

In the preamble to the interim final rule, FSIS requested comments on whether the agency should modify the rule to address the fact that, in rare instances, BSE has been confirmed in cattle younger than 30 months. IFDA does not support modifying the interim final rule at the present time. While Japan reported a few positive findings of BSE in cattle younger than 30 months of age, these rapid test results were never confirmed by immunohistochemistry, the gold standard for BSE testing. Moreover, in Europe, of the cattle that developed clinical BSE in the field, only 0.01% was less than 30 months of age. It is believed that feeding ruminants high doses of the BSE infectious agent caused these rare cases. Unlike Europe, the U.S. does not have a BSE problem because ruminant to ruminant feeding has been banned since 1997. Finally, limiting the raw material specifications for AMR systems to cattle aged 30 months or older is consistent with international standards set by the Office International des Epizooties (OIE).

Notwithstanding, should expanded surveillance testing in the United States demonstrate that BSE is present in the U.S. and circulating, IFDA would suggest that FSIS re-evaluate the 30-month age limitation. On February 4, 2004, an international panel of experts (hereinafter "International Review Team") issued a report assessing the FSIS interim final rules. The International Review Team concluded that the FSIS ban on vertebral columns and skulls greater than 30 months was in accordance with OIE standards for a minimal risk country. However, it also recommended that if it is determined that the U.S. is no longer a minimal risk country because of a high prevalence of BSE, vertebral columns and skulls over 12 months of age should be prohibited in AMR systems.

*Ban on the use of AMR product in meat food products if raw material or finished product contains CNS-type tissue or finished product fails to meet calcium or iron criteria.*

IFDA also supports the agency's ban on the use of beef AMR product in meat food products if skulls or vertebral columns from animals less than 30 months are used and raw materials or finished product contains CNS-type tissue, or the finished product fails to meet calcium or iron criteria. Beef AMR product that contains CNS-type material or excess quantities of bone solids or bone marrow (as measured by calcium and iron content) do not comply with the definition of "meat." To that extent, beef AMR product containing CNS-type material or excess quantities of calcium or iron should not be permitted in meat food products.

*Enforcement*

While IFDA supports the agency's current rule on AMR, it should be recognized that the rule will only be effective if properly implemented and enforced. In this regard, IFDA commends the agency for issuing in a timely manner Notices and guidance materials regarding the determination of age of animals, removing the vertebral column and skull at slaughter and boning facilities, preventing cross contamination, and testing

AMR product for the presence of CNS-type tissue, bone, and other bone related components. IFDA encourages the agency to remain diligent in providing guidance to beef establishments on the requirements of the rule and verifying that establishment procedures are effective in complying with the interim final rule. Should establishments repeatedly violate the interim final rules on AMR, swift and effective enforcement action should be taken. Specifically, a repeat violator should not be permitted to conduct operations until it can demonstrate compliance with the interim final rule.

Moreover, IFDA suggests that the agency routinely evaluate the results of its compliance samples to determine if beef AMR processors are complying with the interim final. If it appears that beef AMR processors are unwilling or unable to comply with raw material and finished product specifications on a consistent basis, the agency should re-evaluate whether AMR systems should continue to be permitted.

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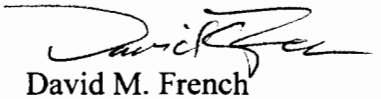
Once again, IFDA appreciates the opportunity to comment on the FSIS interim final rules. IFDA commends the agency for acting swiftly and proactively in issuing the final rules and looks forward to working with the agency to ensure that the U.S. food supply remains the safest in the world.

Respectfully submitted,



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