

**National Advisory Committee on Meat and Poultry Inspection
October 12-13, 2006**

**Update on the Harvard Risk Assessment of Bovine Spongiform
Encephalopathy (BSE) Technical Meeting, July 25, 2006**

Purpose

This update is presented to the Committee to brief them on the Food Safety and Inspection Service (FSIS) technical meeting on the 2005 updated Harvard Risk Assessment of Bovine Spongiform Encephalopathy (BSE) held on July 25, 2006, in Washington, DC.

Background

In April 1998, USDA entered into a cooperative agreement with the Center for Risk Analysis within the Harvard University, School of Public Health and the Center for Computational Epidemiology at Tuskegee University to conduct a comprehensive investigation of the BSE risk in the United States. The report, referred to as the Harvard Risk Assessment of BSE, was completed in 2001, and was revised in 2003 after being peer reviewed.

Both USDA and the Food and Drug Administration (FDA) implemented measures to strengthen protections against BSE in the United States immediately following the discovery of BSE in a cow in Washington State in December 23, 2003. USDA then contracted with Harvard University in May 2004 to revise the Harvard Risk Assessment model to reflect information available through December 2003. Harvard submitted an updated risk assessment to USDA in June 2005, which was formally peer reviewed and finalized in October 2005.

Discussion

The 2005 updated Harvard Risk Assessment evaluates the risk of BSE spreading among cattle in the U.S. and the potential for humans to be exposed to contaminated tissue. Harvard analyzed the effects of the measures implemented by USDA and regulations considered by FDA and analyzed recommendations made by an international expert BSE panel that was convened to review the actions taken by the United States in response to the BSE case in Washington State.

The Harvard Risk Assessment explores the impact that introduction of BSE-infected cattle could have on the U.S. agricultural system over a 20 year period. Key predictions of this updated risk assessment include the number of additional new cases of BSE that could develop subsequent to the hypothetical introduction of infected animals into the U.S.; the amount of BSE infective agent potentially available in human food; and the

reproduction rate of BSE cases among U.S. cattle population. This risk assessment was used to conduct “what if” scenario analyses to evaluate the effectiveness of FSIS policy options to mitigate BSE food safety risks. Information from these scenario analyses were used along with a cost-benefit analysis to support FSIS proposed rulemaking to address BSE food safety risks.

At the July 25, 2006 technical meeting, the developers of the Harvard Risk Assessment explained the modifications that have been made to the risk assessment model and described the scenarios evaluated and the results of the risk assessment. Overall, the 2005 updated Harvard Risk Assessment indicates that by eliminating the most BSE-infectious tissue from human food, the ban on the use of specified risk materials (SRM) for human food has a substantial impact on potential human exposure. Eliminating this material from cattle feed could also have an important impact on the spread of BSE among cattle if steps are taken to ensure that such bans also cover dead stock.

FSIS made the 2005 updated Harvard Risk Assessment available to the public prior to the July 25, 2006 technical meeting. The public requested an extension of the public comment period to more fully review the risk assessment. FSIS extended the public comment period to October 27, 2006.

FSIS’ Office of Public Health Science, Risk Assessment Division (RAD) will consider all public comments related to the risk assessment, develop a "response to public comment document" for posting on the FSIS website, and revise the updated risk assessment accordingly. This version of the risk assessment will then be submitted to the USDA Office of Risk Assessment and Cost-Benefit Analysis (ORACBA) as part of the Regulatory Impact Analysis that accompanies FSIS’ proposed rule for BSE. RAD will conduct further scenarios analyses and may further revise the risk assessment depending on the type of comments received from USDA/ORACBA. Subsequently, the 2005 updated Harvard BSE Risk Assessment will accompany the FSIS proposed rule for BSE to OMB. The current Harvard Risk Assessment of BSE will be finalized by December 2006.

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