TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES

ADVISORY COMMITTEE MEETING

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Issue Summary Topic #3

Models for Risk-based Sourcing of Bovine Materials in FDA-regulated Medical Products

Issue

FDA seeks discussion on potential models and strategies for risk-based sourcing of bovine materials from minimal risk BSE countries used in FDA-regulated medical products.

Overview

Bovine source materials are used in a variety of FDA-regulated medical products including drugs, devices, vaccines, blood products, and human cell and tissue based products. The emergence of bovine spongiform encephalopathy (BSE) in 1986 in the United Kingdom and its transmission to humans as variant Creutzfeldt-Jakob disease (vCJD) a decade later suggested that medical products containing bovine source material from a BSE country could potentially pose a risk for humans. To minimize the possibility of exposure to the BSE agent in regulated products in the United States, the FDA issued letters in 1993 and published guidance the following year recommending that manufacturers of medical products not use bovine source materials from countries designated by the USDA as having BSE. Several FDA centers have since provided guidance and letters to manufacturers clarifying the policy.

BSE risk assessments for the United States have generally concluded that the risk of BSE for the cattle population, including those used in the manufacturing of medical products, is low. A risk assessment completed by the Harvard Center for Risk Analysis in 2001(HCRA, 2001) indicated that, even if BSE enters the U.S.A., the disease would not become established because of current control measures. Among the most effective risk reduction measures cited in the report is the FDA 1997 feed rule prohibiting the feeding of most mammalian protein to ruminants. The Harvard study characterized the main pathways of BSE transmission, chief among which is the consumption by cattle of feed containing rendered meat-and-bone meal (MBM) from carcasses of infected animals. Potential routes for introducing BSE into the U.S.A. through imports of live ruminants (later rendered into MBM) were addressed in the modeling, and another potential pathway—the import of ruminant MBM or other products from BSE-infected animals—was included. The FDA feed ban was found to be especially effective in reducing the risk of exposure to the BSE agent for both cattle and humans in the U.S.A.

Given the recent confirmation of a BSE case on December 23, 2003 in Mabton, Washington, in a dairy cow imported from Canada, and a case in May 2003 in Alberta, Canada, the FDA would like the TSEAC to discuss the present risk reduction measures for FDA-regulated medical products as well as other potential approaches to reduce any residual risk. The finding of a case of BSE in the U.S.A. in a cow imported from Canada suggests that the BSE risk is low but not zero; recognition of that risk prompted reevaluation of BSE risk and stimulated additional risk-based BSE control efforts by USDA and FDA. On December 30, 2003, the USDA put forth new regulations to enhance existing protections of the human food supply (see summary for Issue #2)(USDA, 2003). These measures should further reduce any potential for human exposure to the BSE agent via food products. On January 26, 2004, the Department of Health and Human Services announced its intention to publish an interim final rule (DHHS, 2004) for animal feed that will prohibit the use of mammalian blood and blood products, poultry litter, plate waste in ruminant feed, and require the use of separate dedicated production and processing lines for prohibited and non-prohibited ruminant feed. These steps are aimed at further reducing the potential BSE risk to U.S. cattle.

Although these steps provide further protection, and the risk assessments support a very low risk of BSE in North American cattle, materials sourced from such cattle may potentially pose a small residual risk of containing the BSE agent. Cattle herds can be assembled from a variety of animals originating from different geographical locations, and raised and fed using very different practices. Manufacturers of medical products may not have information about the BSE risk profiles, such as age, herd and feed history, or the pedigrees of cattle from which source materials are derived. This might inadvertently permit use of materials from animals at higher risk of exposure to BSE in the production of medical products. To reduce this possibility, additional measures, such as use of certified herds, the use of animals under 24 or 30 months of age, and/or the use of rapid PrP testing for BSE might be considered either as a general measure or one for specific materials, products, or uses determined to present higher potential transmission risks. FDA seeks the Committee's discussion of its current risk reduction approaches for medical products as well as such additional and/or alternative approaches.

References

Harvard Center for Risk Analysis (HCRA). November 26, 2001. Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States, copy available at http://www.aphis.usda.gov/lpalissues/bse/bse-riskassmt.html

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