TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES ADVISORY COMMITTEE MEETING

February 12 and 13, 2004

Silver Spring, Maryland

Issue Summary, Topic #2

Update on Bovine Spongiform Encephalopathy (BSE) in the United States

ISSUE:

A recent case of bovine spongiform encephalopathy (BSE) was recognized in the United States. The case investigation and responses by the USDA and FDA will be presented as a basis for later discussion of "Models for Risk-Based Sourcing of Bovine Materials in FDA-Regulated Medical Products (Topic #3); and Minimizing Risks of TSE Agents in FDA-Regulated Medical Products (Topic #4).

Background

On December 23, 2003, the U.S. Department of Agriculture (USDA) announced a preliminary diagnosis of BSE in a single "downer" (nonambulatory disabled) dairy cow in Washington State. On December 25, the diagnosis of BSE was confirmed by the U.K. Veterinary Laboratories Agency, Weybridge, England, which serves as an international reference laboratory for diagnosis of BSE.

The BSE-positive cow was 6.5 years old when slaughtered on December 9. Before slaughter, the cow was nonambulatory, a condition attributed to complications from recent calving. The animal was examined by a veterinary medical officer of the USDA Food Safety and Inspection Service (FSIS) both before and after slaughter. After examination, the carcass was released as inspected and passed for human consumption. Tissues considered to be at high risk for the transmission of the BSE agent (brain, spinal cord, and small intestine) were removed from the carcass and sent for inedible rendering (product acceptable in feeds for non-ruminant animals). Because the cow was not ambulatory at slaughter, brain tissue samples were sent to the Veterinary Services Laboratory of the USDA Animal and Plant Health Inspection Service (APHIS) in Ames, Iowa, as part of the USDA-targeted surveillance program for BSE. On December 23, a presumptive diagnosis of BSE was made, based on the finding of histopathological changes in the brain and immunohistochemical detection of abnormal prion protein. The herd from which the cow had come was placed under a state hold order. USDA, in collaboration with the state, other federal agencies, and industry representatives (and later with the Canadian Food Inspection Agency [CFIA]), initiated investigations of potentially exposed cattle and of regulated products.

On December 24, FSIS recalled beef from cattle slaughtered in the same plant on the same day as the BSE positive cow. Some beef subject to the recall had been shipped to several establishments, which processed it further. Meat products manufactured from the recalled meat were distributed primarily to locations in Oregon and Washington, with smaller quantities distributed to locations in California, Idaho, Montana, and Nevada. FSIS continues to verify the distribution and control of the recalled products.

The U.S. Food and Drug Administration (FDA) and inspectors from Oregon and Washington have located known potentially infectious rendered products from the BSE-positive cow. The rendering plants that processed this material placed a voluntary hold on known potentially infectious products, none of which had left the control of the companies or entered commercial distribution as of January 7, 2004. The FDA continues to investigate FDA-regulated products related to the BSE-positive cow.

APHIS, in collaboration with CFIA, traced the birth of the BSE-positive cow to a farm in Alberta, Canada. On January 6, 2004, USDA and CFIA announced that DNA evidence had confirmed this traceback to Canada with a high degree of certainty. Records show that the BSE-positive cow was one of 82 animals from a Canadian herd cleared for shipment to the US; 81 of the cattle listed in the Canadian animal health certificate entered the U.S. on September 4, 2001, through Oroville, Washington. These cattle are being traced to determine their disposition or current locations. The BSE-positive cow gave birth to two live calves while in the U.S. The first was a yearling heifer on the same farm as the BSE-positive cow. The second was a bull calf in a group of calves at another location, a calf-feeding operation also placed under state hold. Because the bull calf could not be identified definitely, APHIS eliminated all calves at this site. Since the epidemiological investigation began, APHIS has developed criteria to determine additional cattle at-risk for BSE to be eliminated. USDA has successfully tracked many of the animals that entered the U.S. from Canada with the BSE cow and depopulated other animals in contact with the BSE cow. More than 100 brain samples from the depopulated adult animals have been examined for the presence of abnormal prion protein by rapid (ELISA) test and immunohistochemistry; all have been negative.

Additional Safeguards Recently Adopted by USDA and FDA to Reduce Further the Potential Risk of Future Exposures to the BSE Agent

1. USDA issued interim final rules on January 12, 2004 requiring immediate implementation of the following safeguards:

- Prohibits any material from "downer" cattle for human food

- Prohibits the use in human food of certain Specified Risk Materials (SRMs) that are known to harbor the highest concentrations of the infectious BSE agent. The following tissues are designated as SRMs: skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord, and dorsal root ganglia of cattle over 30 months of age and the small intestine of cattle of all ages

- Prohibits the use for human food of product known as mechanically separated beef, a product that may contain SRMs.

- Requires additional process controls for meat derived by the process known as advanced meat recovery (AMR) and prohibits the use of AMR processes on vertebral

column or skulls of cattle greater than 30 months of age. Meat obtained by AMR may be used for human food, but sampling procedures must be in place to ensure that neither spinal cord nor dorsal root ganglia are present in the final product.

-Prohibits slaughter of bovines by the use of air-injected stunning (pneumatic stun guns).

(Additional information on recent USDA rule making and notices can be accessed at www.fsis.usda.gov/oa/news/2004/bseregs.htm.)

2. FDA announced the imminent issuance of an interim final rule to institute the following changes:

- Prohibits the use of ruminant blood and blood products in feed for ruminants

- Prohibits the use of "poultry litter" as a feed ingredient for ruminants

- Prohibits the use of "plate waste" (uneaten meat and meat scraps collected from restaurant operations) as a feed ingredient for ruminants

- Minimizes the opportunities for cross-contamination of feeds intended for ruminants with feeds for non-ruminant animals by requiring that equipment, facilities and production lines be dedicated to the production of non-ruminant animal feeds if they use proteins prohibited in feeds for ruminants.

References

1. Centers for Disease Control and Prevention. Bovine spongiform encephalopathy in a dairy cow—Washington State, 2003. MMWR (Jan 9) 2004;52:1280-1285 http://www.cdc.gov/mmwr/PDF/wk/mm5253.pdf

2. U.S. Department of Agriculture. Animal and Plant Health Inspection Service. BSE Update - January 23, 2004. www.aphis.usda.gov/lpa/issues/bse/bse_update01-23-04.htm

3. Department of Health and Human Services News Release. Expanded "mad cow" safeguards announced to strengthen existing firewalls against BSE transmission. HHS News. January 26, 2004 www.hhs.gov/news/press/2004pres/20040126.html

4. U.S. Department of Agriculture Food Safety and Inspection Service. Prohibition of the use of specified risk materials for human food and requirements for the disposition of non-ambulatory disabled cattle; meat produced by advanced meat/bone separation machinery and meat recovery (AMR) systems; prohibition of the use of certain stunning devices used to immobilize cattle during slaughter; Bovine Spongiform Encephalopathy Surveillance Program. Interim Final Rules and Notice. 9 CFR Part 301, 309, et al. Federal Register 2004;69(7): 1862-1874 (Monday, January 12, 2004) www.fsis.usda.gov/OPPDE/rdad/FRPubs/03-025IF.pdf

Attachments

All above