USDA

Backgrounder

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Government Actions to Prevent Bovine Spongiform Encephalopathy in the United States

BSE Risk Assessment

In April 1998, the U.S. Department of Agriculture (USDA) entered into a cooperative agreement with Harvard Universityís Center for Risk Analysis, School of Public Health, to begin an analysis and evaluation of the Departmentís measures to prevent bovine spongiform encephalopathy (BSE). The risk analysis reviewed current scientific information, assessed the ways that BSE could potentially enter the United States, and evaluated existing USDA regulations and policies to prevent the spread of BSE within the United States if it were to occur.

While the study was being conducted, both USDA and the Food and Drug Administration (FDA) continued to take actions to monitor for BSE and maintain preventative regulatory measures.

BSE Pathways Into the United States and Government Actions To Prevent BSE

BSE has not been diagnosed in the United States, and the Government has worked proactively to keep it that way through prevention, education, research, surveillance, and response measures.

Prevention: The U.S. government has identified pathways through which BSE could enter the United States and has implemented preventative control measures.

The primary pathway would be through importing the BSE agent. This could be through imports of live cattle, animal tissues, and animal byproducts or ruminant feed imports from BSE-affected countries.

Imports of Live Cattle, Animal Tissues, and Animal Byproducts: Since 1989, USDA's Animal and Plant Health Inspection Service (APHIS) has prohibited the importation of live ruminants (cattle, sheep, goats, etc.) from countries where BSE is known to

Key Facts for U.S. Consumers about BSE

No confirmed cases of BSE have ever been found in the United States despite more than 11 years of active surveillance. Because of controls put in place by the United States government, it is highly unlikely that domestically produced food purchased in the United States would be contaminated with the BSE agent.

Consumers should know:

- USDA prohibits the import of any ruminant meat products originating in countries identified as having BSE or at risk for having BSE. This includes ruminant products used in human, animal, and pet foods.
- Milk and milk products, which are not considered to be at risk, continue to be imported into the United States from countries identified as having BSE or at risk for having BSE. To date, experiments have shown that milk from BSE-affected cattle has not caused infections in the same species or in other test animals.
- Dietary supplements and certain cosmetic ingredients containing materials derived from cattle originating in any country where BSE has been found or is at risk for being found are excluded from the United States.

exist in native cattle. Other products derived from ruminants – such as meat-and-bone meal, meat meal, bone meal, and blood meal, fetal bovine serum, tankage (dried animal residues), offal (organs such as brain and liver and trimmings such as tails and hooves), fats, and glands – are also prohibited from entry, except under special conditions or under USDA permit for scientific or research purposes. These restrictions were initially imposed on the United Kingdom in 1989, and, as subsequent countries identified BSE in native animals, the same restrictions were immediately applied to those countries.

On December 12, 1997, APHIS extended these restrictions to include all of the countries in Europe due to concerns about widespread risk factors and inadequate surveillance for BSE.

As of September 10, 2001, APHIS also imposed import restrictions on Japanese ruminants and ruminant products due to a confirmed case of BSE in that country.

(A complete list of all countries/areas either affected by BSE or at-risk for BSE can be found at: http://www.aphis.usda.gov/NCIE/country.html).

APHIS also monitors cattle that were imported from European countries and Japan before the ban on imports from those countries went into effect. Cattle were imported from the United Kingdom and Ireland prior to 1989, from continental Europe between 1996 and 1997, and from Japan between 1993 and 1999.

A total of 334 cattle were imported from the United Kingdom between 1981 and 1989. As of November 16, 2001, three of these animals are still alive. All are under quarantine and are carefully monitored by APHIS personnel on an ongoing basis. No evidence of BSE has been found in any of these imported animals.

Animals from other European countries have also been traced. A total of 162 animals were imported from Ireland between 1981 and 1989. None of these animals are still alive. A total of 46 cattle from continental European countries were imported between 1996 and 1997. All of these animals have been traced, and five are still alive. Movement of these animals is restricted, and they are being closely monitored by APHIS personnel.

To date, no evidence of BSE or any other transmissible spongiform encephalopathy (TSE) has been detected in these imported animals. APHIS continues to attempt to purchase the remaining imported animals for diagnostic research purposes.

A total of 242 cattle were imported from Japan between 1993 and 1999. As of November 29, 2001, 214 of these cattle had been located. Of these 214, 24 have died or gone to slaughter and 40 were exported.

Feed Imports: Epidemiological data suggests that the outbreak and spread of BSE was caused by a common source material involving animal feed containing contaminated meat-and-bone meal as a protein source. The disease may have originally been caused by feeding cattle rendered protein produced either from the carcasses of scrapie-infected sheep or from cattle with a previously unidentified TSE. Changes in rendering operations in the early 1980's may have permitted an infectious TSE agent to survive the rendering process. The resulting contaminated meat-and-bone meal could then have been fed to cattle, eventually resulting in the epidemic.

A pathway for the BSE agent to enter the United States could be through the import of meat-and-bone meal or feed from BSE-affected countries. Both FDA and USDA have taken action to prevent potentially contaminated feed products from entering the United States. These actions have addressed both direct imports of ruminant-derived protein products and also the potential of cross-contamination of other feed and protein products.

As outlined previously, since 1989, APHIS has prohibited the importation of live ruminants and other ruminant products from countries where BSE is known to exist in native cattle. These restrictions included prohibitions on the importation of ruminant-derived protein products such as meat-and-bone meal. On Dec. 12, 1997, APHIS extended these restrictions to include all of the countries in Europe.

As of December 7, 2000, APHIS prohibited all imports of rendered animal protein products, regardless of species, from BSE-restricted countries. This decision followed the recent determination by the European Union that feed of non-ruminant origin was potentially cross-contaminated with the BSE agent. The restriction applies to protein products originating, rendered, processed, or otherwise associated with

protein products originating from BSE-restricted countries. The same type of rendered product of ruminant origin has been prohibited from BSE-restricted countries since 1989.

FDA also announced an import alert on Jan. 20, 2001, allowing its inspectors to detain shipments of animal feed (including pet food), animal feed ingredients, and other products of animal origin intended for human or animal use from countries where BSE is known to exist in native cattle and all European countries.

Mammalian Protein in Ruminant Feed: A pathway for the amplification of BSE, were it to enter the United States, is through the use of contaminated ruminant protein in ruminant feed. To protect the American cattle population from consuming potentially affected meat-and-bone meal, should it ever be introduced into this country, FDA has, since August 4, 1997, prohibited the use of most mammalian protein in ruminant feeds. FDA's regulation also requires feed manufacturers to use appropriate procedures and control systems to ensure that feed for ruminants does not contain the prohibited mammalian tissue.

To ensure that industry is complying with the animal feed regulation, FDA, with assistance from State feed control officials, conducted inspections of more than 10,000 firms between January 1998 and October 2001. Inspected firms include feed mills, ruminant feeders, dairy farms, renderers, protein blenders, feed haulers, and distributors. Ninety percent of all of the inspected FDA-licensed feed facilities were found to be in compliance with the regulation, and 84 percent of feed mills not licensed by FDA were found to be in compliance. (To mix the more potent forms of medicated articles into feed, a feed mill must be licensed by FDA.) Additionally, 93 percent of the 174 renderers handling prohibited materials were in compliance. The compliance of rendering plants is particularly important because they are the source of most domestic meat-and-bone meal.

To continue its comprehensive efforts to prevent BSE in the United States, FDA is conducting additional inspections, and is re-inspecting facilities that were found not to be in compliance upon initial inspection. Sites initially found not in compliance have shown a high percentage of compliance upon re inspection. Based on the evaluation of the inspections conducted from 1998 through 2001, FDA will revise its compliance strategy to meet its goal of 100 percent compliance with the feed regulation.

Meat and Meat Products: It is thought that variant Creutzfeldt-Jakob Disease (vCJD) was introduced to people through the consumption of meat products contaminated with brain and spinal cord from cattle infected with BSE. Accordingly, should BSE ever enter the United States, meat products contaminated with the BSE agent would be the most likely cause of the spread of vCJD in this country.

In cattle naturally affected with BSE, the BSE agent has been detected only in brain tissue, in the spinal cord, and in the retina. (BSE infectivity was also detected in the brain, spinal cord, dorsal root ganglia, trigeminal ganglia, bone marrow, and distal ileum [intestine] from experimentally infected cattle.) The BSE agent has not been found in muscle meat or milk.

Regulations established by USDA's Food Safety and Inspection Service (FSIS) set strict limitations on what can be defined as meat. Under regulations established in the Federal Meat Inspection Act, meat includes skeletal muscle; as well as the tongue, diaphragm, heart, and esophagus. Brains and spinal cord are <u>not</u> allowed as components of boneless meat. (These products are considered to be safe to eat since BSE has not been diagnosed in the United States. However, these products, when used as components in food, must be clearly identified on the label. Bone-in meat, such as a T-bone steak may have spinal cord attached to the bone.)

Product derived from advanced meat recovery (AMR) systems is also defined as meat. AMR 's a process that uses machinery to separate edible meat from bones by scraping, shaving, or pressing the meat from the bone. AMR machinery is not permitted to break, grind, crush, or pulverize bones to separate meat, and bones must emerge intact and in natural physical conformation. Meat produced using this method is comparable in appearance, texture, and composition to meat trimmings and similar meat products derived by hand trimming of bones.

Meat produced from AMR systems cannot contain spinal cord tissue. FSIS verifies that establishments using AMR systems do not incorporate spinal cord tissue into the products as a consequence of the pressure used to force meat tissue from the bone.

Questionable products may be sampled by FSIS for analytical testing for the presence of spinal cord.

Mechanically separated meat, a batter-like product produced by forcing the bones and attached edible meat through a sieve or similar device to separate the bone from the edible meat tissue, by definition, is not considered to be meat. Because the process used to mechanically separate meat from the bone may result in a product containing some bone particles (generally no larger than the size of finely ground pepper), any product produced using this process must be labeled as “mechanically separated meat” in the product’s ingredients statement. Currently, spinal cord can be incorporated into this product.

Use of Bovine Products in Human Medicine: FDA has taken steps to protect human health by restricting the use of bovine products in medical products (such as drugs, blood, vaccines, and medical devices). In 1990, FDA intensified its review of new product applications for human medical products derived from or containing bovine sources. FDA recommended to manufacturers that they not purchase materials made from animal tissues or products that originated in a country where BSE has been diagnosed in native cattle.

In 1993, and again in 1996, FDA issued letters to the manufacturers of drugs, biologics and medical devices advising them that they should not use materials derived from cattle born, raised or slaughtered in countries where BSE is known to exist. Again in 2000, FDA reissued the same advice to manufacturers, including vaccine and other biological manufacturers, regarding bovine materials from countries with cases of BSE or countries with an undue risk of introducing BSE into the United States.

In August 2001, FDA issued guidance to blood collection establishments to reduce the theoretical risk of transmission of vCJD to those who receive blood products. Although there have been no reports of transmission of either the classical form of CJD or vCJD through blood or blood products, FDA is making these recommendations until more is known about the risk.

These precautionary recommendations request that blood centers exclude the following donors: individuals who have been diagnosed with or are at increased risk for vCJD or any other form of CJD; those who resided in the United Kingdom for three or more cumulative months between 1980 and 1996; individuals who received transfusions or blood or blood components in the United Kingdom between 1980 and the present; those who have spent five or more cumulative years in France between 1980 and the present; U.S. military personnel, employees, and dependents who resided for six months or more in Europe between 1980 and 1996; whole blood donors who have lived cumulatively in Europe for five or more years from 1980 until the present; and those who have injected bovine insulin since 1980 (unless it can be confirmed that the product was not manufactured after 1980 from cattle in the United Kingdom).

Education: Both FDA and USDA have made major efforts to educate various stakeholders.

USDA has implemented education measures to ensure that veterinary practitioners, veterinary laboratory diagnosticians, industry, and livestock producers are knowledgeable about the clinical signs and pathology of BSE. As part of the continuing education effort, numerous briefings have been held for industry groups. In addition to press releases and factsheets, a videotape on BSE and an information packet have been distributed to all APHIS field offices, State and Federal field veterinarians, extension veterinarians, colleges of veterinary medicine, and industry groups.

Using an innovative, education-oriented partnership program, FDA continues enforcing the feed ban. FDA has sponsored workshops for State veterinarians and feed control officials from all 50 States, Puerto Rico, the U.S. Virgin Islands, and Canada. In addition, a joint satellite teleconference with the Association of American Feed Control Officials, the American Feed Industry Association, and the National Grain and Feed Association was broadcast in 1998 throughout the United States and into Canada to describe the requirements of the regulations and answer questions from callers. FDA has also developed an interactive CD-ROM that provides information on the regulation and what is expected of those to whom the regulation applies. The CD-ROM is available to FDA employees, the States, and the regulated industry.

Research: While current prevention strategies have been effective in keeping BSE out of the country, continued research is needed to validate and improve the efficacy of current prevention efforts and to provide new tools for use in prevention and control strategies to further reduce the risk of BSE in the United States.

Specific priorities for USDA's Agricultural Research Service (ARS) research include: antemortem diagnostics, development and validation of tests for central nervous system tissue (including comparative evaluation of existing tests), development and validation of tests for ruminant protein in feeds and other products, and development of improved methods to differentiate TSE types. ARS scientists continue to direct their efforts toward achieving these goals and conducting research on other identified issues, as funding permits.

Additionally, the National Institutes of Health (NIH) has long been conducting research activity on CJD and kuru, a related TSE in humans, and BSE in animals. In the 1960s and 1970s, the Nobel Prize-winning team at the NIH Laboratory of Central Nervous System Studies conducted experiments on the oral transmission of CJD, kuru, and scrapie.

Today, researchers in the United States and around the world are collaborating in the search for methods to detect, prevent, and treat prion linked diseases. NIH scientists are providing input to the investigation of vCJD cases in Europe and have developed a diagnostic test for the disease that can be performed before death.

Surveillance: APHIS leads an ongoing, comprehensive, interagency surveillance program for BSE in the United States. This surveillance has been in place since 1990. BSE is a reportable disease by accredited veterinarians. APHIS veterinary pathologists and foreign animal disease diagnosticians have received training, including training from their British counterparts, in diagnosing BSE.

Surveillance samples include field cases of cattle exhibiting clinical signs of neurological disease, cattle condemned prior to slaughter for neurologic reasons, rabies-negative cattle submitted to public health laboratories, neurologic cases submitted to veterinary diagnostic laboratories and teaching hospitals, and sampling of cattle that are nonambulatory (downer cattle/fallen stock). Random sampling of non-ambulatory cattle has been conducted since 1993 as part of these surveillance efforts.

FSIS continues to cooperate with APHIS in conducting surveillance for BSE in the United States. FSIS inspection personnel perform inspections of all cattle prior to slaughter. Any cattle exhibiting signs of disease or abnormal posture or behavior are segregated and inspected by FSIS veterinary medical officers (VMOs), who are trained to recognize the signs of central nervous system (CNS) disorders in adult cattle. Any animals displaying signs of central nervous system impairment are condemned, and the meat is not allowed to be used in human food. Upon condemning an animal, FSIS notifies area APHIS Veterinary Services officers, who collect the brain sample and submit it to the USDAís National Veterinary Services Laboratories (NVSL) for testing. These brain submissions from cattle with evidence of CNS disorders are examined using both histologic examination and immunohistochemistry. NVSL began using immunohistochemistry in 1994.

As of October 31, 2001, 17,981 brains from the United States and Puerto Rico had been examined with no evidence of BSE or other TSE detected.

The Centers for Disease Control and Prevention (CDC) in Atlanta conduct surveillance for CJD in humans through examination of death certificate data for U.S. residents. Based on this surveillance, the annual incidence of classic CJD from 1979 to 1998 (not the new variant CJD related to BSE) remained stable at approximately one case per one million persons.

In addition to the ongoing review of national CJD mortality data, CDC conducted active CJD surveillance in its four established Emerging Infectious Disease Program areas (Minnesota, Oregon, Connecticut, and the San Francisco Bay area) and in a metropolitan Atlanta site during April and May 1996.

In 1996, CDC worked with the Council of State and Territorial Epidemiologists to initiate an ongoing follow-up review of clinical and neuropathology records of CJD decedents aged younger than 55 years who are identified through the national mortality data analysis. This age group is targeted for surveillance because, while CJD is normally found in people aged 60 and older, vCJD is generally found in younger individuals.

Also in 1996, the American Association of Neuropathologists (AANP), in collaboration with CDC, alerted its members about vCJD and requested reports of any possible cases. These continuing surveillance efforts have not detected vCJD in the United States. Enhanced CJD mortality surveillance also included the establishment of the National Prion Disease Surveillance Center in collaboration with the AANP.

In light of concern about the vCJD cases in the EU, CDC is working with the Council of State and Territorial Epidemiologists to expand current CJD surveillance. CDC is conducting pilot tests of enhanced surveillance efforts, including an active search for vCJD as described in the United Kingdom. This enhanced surveillance is coordinated through CDC's Emerging Infectious Disease Programs in Minnesota, Oregon, Connecticut, and California.

Response Measures: APHIS, in cooperation with FSIS, has drafted an emergency response plan to be used in the event that BSE is identified in the United States. The USDA has also worked cooperatively with the Department of Health and Human Services to coordinate response plans. In addition, APHISí TSE Working Group monitors and assesses all ongoing events and research findings regarding TSEs. APHIS continually revises and adjusts prevention and diagnostic measures as new information and knowledge is gained.

Future Initiatives to Prevent BSE and vCJD in the United States

Based on its preliminary review of the BSE risk assessment, USDA will take the following actions:

First, the risk assessment will be peer-reviewed by a team of outside experts to validate its scientific integrity. These experts will review the data inter pretation and evaluate the computer model to determine if it can be used easily by USDA scientists to evaluate "what if" scenarios.

Second, USDA will continue increasing the testing for BSE, with over 12,500 cattle samples targeted in fiscal 2002– up from 5,000 during fiscal 2001.

Surveillance is a critical part of our multifaceted strategy.

Third, USDA will soon announce in the Federal Register the availability of a policy options paper that will outline additional possible regulatory actions to limit the risk of BSE exposure. To ensure these options are science-based, they will be tested using the computer model developed by Harvard to see what impact they would have on further reducing risk.

These options will include:

- Prohibiting the use of brain and spinal cord from specified cattle in human food;
- Prohibiting the use of central nervous system tissues in boneless beef products, including meat from AMR systems; and
- Prohibiting the use of the vertebral column from certain categories of cattle, including downed animals, in the production of meat from AMR systems.

USDA will invite public comment on the options and then proceed with appropriate regulatory actions.

Fourth, USDA will issue a proposed rule to prohibit the use of certain stunning devices used to immobilize cattle during slaughter.

Fifth, USDA will publish an advance notice of proposed rulemaking to consider disposal options for dead and downer animals, because such animals are considered an important potential pathway for the spread of BSE in the animal chain.

For More Information

For questions concerning BSE, BSE surveillance and agricultural import bans, contact APHIS
Media Inquiries: (301) 734-7799
Technical Inquiries: (609) 259-5825
APHIS Web site: www.aphis.usda.gov

For questions concerning food safety, AMR, or mechanically separated meat, contact FSIS
Media Inquiries: (202) 720-9113
Technical Inquiries: (202) 690-6566
Consumer Inquiries: Call USDA's Meat and Poultry Hotline at 1-800-535-4555. In the Washington, DC, area, call (202) 720-3333. The TTY number is 1-800-256-7072.
FSIS Web site: www.fsis.usda.gov

For questions concerning CJD, vCJD, and other human TSEs, contact CDC
Media Inquiries: (404) 639-3286
FDA Web site: www.fda.gov

For questions concerning animal feed regulations, use of animal tissues in medicine, and blood, contact FDA
Media Inquiries: (301) 827-6250
Technical Inquiries: (301) 827-2950
FDA Web site: www.fda.gov