

STATEMENT

BY

STEPHEN SUNDLOF, D.V.M., Ph.D.

DIRECTOR, CENTER FOR VETERINARY MEDICINE

FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE

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FOREIGN COMMERCE, AND TOURISM

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## Introduction

Mr. Chairman, Members of the Committee, thank you for the opportunity to participate in today's hearing on measures by the Federal government to prevent bovine spongiform encephalopathy (BSE) or "Mad Cow Disease," from occurring in the United States (U.S.). I am Dr. Stephen Sundlof, Director, Center for Veterinary Medicine, Food and Drug Administration (FDA or the Agency).

Let me state at the outset that currently we have no evidence of BSE in the U.S. and FDA and other Federal agencies are working diligently to keep it out of the U.S. FDA has been actively involved nationally and internationally in efforts to understand and prevent the spread of BSE. FDA collaborates extensively with its sister Public Health Service agencies, the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH), relevant agencies within the U.S. Department of Agriculture (USDA), the Customs Service, and many other Federal and State agencies, as well as with affected industries and consumer groups.

## Background on BSE and variant Creutzfeldt-Jakob disease (vCJD)

BSE belongs to the family of transmissible spongiform encephalopathies (TSEs) diseases. TSEs are a group of transmissible, slowly progressive, degenerative diseases of the central nervous systems of humans and several species of animals. Animal TSEs include, for example, bovine BSE in cattle, "scrapie" in sheep and goats, "chronic wasting disease" (CWD) in deer and elk, feline spongiform encephalopathy in cats, and mink spongiform encephalopathy in mink. Scrapie and CWD are found in the U.S. to a small extent in certain herds of these animals.

Human TSEs include kuru, a disease of the South Pacific Fore people and Creutzfeldt-Jakob disease (CJD or "classical" CJD), which occurs throughout the world, including the U.S. (where it occurs at a stable rate of about one per million population per year) and new variant CJD (vCJD), which was first reported in the United Kingdom (U.K.) in 1996. It is believed that vCJD may be acquired from eating food products containing the BSE agent, and there is strong epidemiological and laboratory evidence for a causal association between vCJD and BSE. The onset of illness in the first case of vCJD, occurred in early 1994. As of April 2, 2001, 97 probable or confirmed human cases of vCJD were reported in the U.K., three in France and

one in Ireland. The absence of confirmed cases of vCJD in geographic areas free of BSE supports a

causal association. There is no evidence to date of vCJD in the U.S. There is no known treatment for any TSE, and they are all fatal.

BSE has a prolonged incubation period in cattle, ranging from three to eight years; for vCJD in humans, the incubation period is unknown, but is at least five years and could extend up to 20 years or longer. BSE was first discovered in the U.K. in November 1986. Epidemiological evidence established that the wide-spread amplification of BSE throughout many of the British cattle herds was related to the production and use over many years of BSE-contaminated meat-and-bone meal that was fed primarily to young calves. The original source of the BSE outbreak is uncertain.

The vast majority of BSE cases have been reported in the U.K. About 180,000 cases of BSE have been confirmed there in more than 33,000 herds of cattle. The U.K. epidemic peaked in January 1993 at nearly 1,000 new cases per week. Surveillance in Europe has also led to the identification of cases of BSE in Belgium, Denmark, France, Ireland, Liechtenstein, the Netherlands, Portugal, Switzerland and most recently, in Germany, Spain and Italy.

European countries have instituted a variety of public health control measures, such as BSE surveillance, the culling (removal from the herd) of sick animals, the banning of specified risk materials, the banning of animal proteins in animal feed, or a combination of these, to prevent potentially BSE-infected tissues from entering the human food chain.

### **FDA Protections**

Many FDA regulated products contain bovine products, including food, animal feed, drugs, vaccines, tissues, dietary supplements, cosmetics, medical devices, and there also are theoretical concerns about transmitting CJD and vCJD through the human blood supply from a donor infected with CJD or vCJD. At this time there is no documented transmission of CJD or vCJD through blood/blood products. FDA has a long-standing commitment to consumer protection involving BSE and vCJD.

The focus for FDA and its Federal and State partners in other agencies has been prevention. Using the best science known at this time, the U.S. has an aggressive, multi-faceted program in place to try to prevent the establishment and spread of BSE within the U.S. FDA's restrictions on certain cattle feed ingredients and its import restrictions on various items and products are critical parts of this program.

## Cattle Feed Restrictions, Inspections and Education

As I have stated, rendered feed ingredients contaminated with the BSE agent are believed to be the means by which BSE is amplified in cattle herds. The amplification is most closely associated with feed for cattle, particularly young calves that include ingredients processed from remnants of slaughtered animals, such as meat-and-bone meal, which may harbor the agent that causes BSE. Although the material is cooked, the BSE agent can survive.

In order to prevent the spread of BSE through feed, in August 1997, FDA published a regulation that prohibits the use of most mammalian protein in the manufacture of animal feeds for ruminants (Title 21, Code of Federal Regulations (CFR) Part 589). Even though there is no evidence of BSE in the U.S., FDA prohibited this feeding practice so that we established in our country feeding practices consistent with the best epidemiological knowledge available to prevent the spread of this disease throughout the U.S. cattle herd should it get into the U.S. With the strong support of renderers, cattle owners, feed manufacturers, and feed lot owners, FDA launched a compliance and education program, including a rigorous inspection program. The goal of these efforts is to achieve as

close to 100 percent compliance with the labeling, record keeping, and contamination avoidance provisions of this new regulation as soon as possible. FDA recognizes that there were some early problems with compliances, as cited in the General Accounting Office's (GAO) report, "Controls Can Be Strengthened to Reduce the Risk of Disease Linked to Unsafe Animal Feed" (GAO/RCED-00255).

FDA and State regulators have conducted over 10,000 inspections of renderers, feed mills, ruminant feeders, dairy farms, protein blenders, feed haulers, and distributors since January 1998. On first inspection, about three-quarters of these establishments were found to be in compliance. Most of the establishments that had problems during the first inspection were found in compliance upon re-inspection.

FDA is continuing its compliance efforts by conducting additional inspections and re-inspecting non-compliant facilities. In January 2001, FDA field offices were issued an assignment to re-inspect 834 firms that were not in full compliance with the rule. Of 184 re-inspections conducted by April 2, 2001, only one firm continued to be out of compliance.

Education is also an extremely important part of the compliance program. FDA has sponsored workshops attended by State veterinarians and feed control officials from all 50 States, Puerto Rico, the U.S. Virgin Islands, and Canada. In addition, FDA has held briefing sessions with trade associations and consumer groups, and has developed additional guidances for complying with the regulation.

### **Import Controls**

FDA and the USDA's Animal and Plant Health Inspection Service (APHIS) work in close cooperation with the Customs Service on items related to imports.

APHIS establishes and enforces import restrictions covering animals and animal products offered for import into the U.S. to prevent the importation of foreign exotic diseases. Beginning in 1989, APHIS has taken several actions to ban animals or products under their jurisdiction because of concerns about BSE.

FDA issues Import Alerts and Import Bulletins regarding problems or potential problems with imported products under FDA's jurisdiction. FDA coordinates its Import Alerts and Bulletins closely with APHIS. The Agency has issued the following:

- On September 1, 1992, FDA issued Import Bulletin 99-B03, alerting field units to imports, from BSE countries, of animal by-products and regulated products containing animal by-product ingredients.
- On October 19, 1994, FDA issued Import Alert 17-04 (replacing the 1992 Import Bulletin) calling for the detention, without examination, of bulk shipments of high-risk bovine tissues and tissue-derived ingredients from BSE countries (at that time this included the U.K., France, Ireland, Oman, Switzerland, and Portugal). FDA updated this alert whenever APHIS revised the list of BSE countries it included at 9 CFR § 94.18.
- On January 24, 2000, FDA updated the existing Import Alert 17-04, which called for detention of bulk shipments of high-risk bovine tissue from BSE countries to include

countries in most of Europe, following APHIS's extension of import restrictions to those countries.

- On December 20, 2000, FDA issued Import Bulletin 71B-02, alerting FDA field personnel of the APHIS restrictions on animal feed ingredients from 31 countries, and instructing them to coordinate entry review with their local APHIS office. This Import Bulletin was cancelled on January 23, 2001, after the issuance of Import Alert 99-25.
- On January 20, 2001, FDA issued Import Alert 99-25, which instructed FDA field personnel to detain animal feed, animal feed ingredients, and other products for animal use consisting of, or containing, ingredients of animal origin from the 31 countries where BSE is known to exist and/or have less restrictive import requirements than those that would be acceptable in the U.S.
- On March 1, 2001, FDA issued Import Bulletin 99B-14, alerting FDA field personnel that APHIS further prohibited the importation into the U.S. of certain edible ruminant products from Europe, Oman, and BSE at-risk countries. The Bulletin advises that FDA entry review should include assessment of product ingredients to determine whether they

contain or may contain ruminant material subject to the APHIS prohibition.

**Protecting FDA-Regulated Medical Products and Dietary Supplements**

FDA also has taken steps to protect medical products (such as drugs, blood, vaccines, and medical devices) for human use. Since 1993, FDA also has sent a number of letters to manufacturers of FDA-regulated products providing guidance on the use of bovine materials from countries affected by BSE and taken other actions.

- In 1993 and again in 1996, FDA requested that manufacturers of FDA-regulated products intended for humans not use bovine-derived materials from BSE countries.
- In September 1997, FDA released a Guidance for Industry, "The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE) in FDA-Regulated Products for Human Use." FDA recommends that gelatin-containing products such as candy or capsules imported from the 31 countries identified as having BSE or at risk for having BSE be manufactured under

specific guidance. Gelatin is to be made from non-BSE herds and use only specific parts of BSE-free animals.

- In April 2000, FDA's Center for Biologics Evaluation and Research (CBER) issued a letter to manufacturers of biological products reminding them of the Agency's strong recommendations not to use materials derived from ruminant animals from countries where BSE is known to exist. This action was taken as a result of learning that its recommendations regarding the sourcing of bovine materials for the manufacture of vaccines had not been followed in at least one instance.
- In May 2000, CBER requested that all vaccine manufacturers review the source for all bovine-derived materials used in the manufacture of their products, including bovine derived material used to prepare working cell and seed banks.
- In July 2000, assessments of risk and recommendations regarding additional vaccines manufactured with bovine derived materials that had been obtained from European countries on the USDA list were discussed in a meeting held in July 2000 between CBER's Vaccines and Related Biological Advisory Committee and FDA's TSE Advisory Committee. The

joint committees concluded that for licensed products, the risk to recipients, if any, was theoretical and remote and outweighed by the benefits of the vaccines. The joint committees, nonetheless, recommended that if bovine materials were found to be used in vaccine production that manufacturers change sources. They also agreed with CBER that if the working cell and seed banks were derived (after January 1, 1980) using bovine materials from countries on the USDA list, manufacturers re-derive those cell and seed banks using bovine materials from countries not on the USDA list. Manufacturers have agreed to, and have begun implementing, all of these changes.

- In November 2000, FDA sent a letter to manufacturers and importers of dietary supplements. The letter states the Agency's strong recommendation that firms manufacturing or importing dietary supplements that contain specific bovine tissues take whatever steps are necessary to assure themselves and the public that such ingredients do not come from cattle born, raised, or slaughtered in countries where BSE is known to exist. Since 1992, FDA has issued four letters to the dietary supplement industry to make sure the industry was aware of the problem and that they should be taking appropriate action.

FDA inspects manufacturers of FDA-regulated products to determine if manufacturers are following the Agency's current recommendations as part of current good manufacturing practices. In addition, as applications for new products or changes to products are submitted, FDA ensures that the recommendations are being followed, if those products are required to have FDA clearance prior to marketing in the U.S.

### **Protecting the Blood Supply**

In November 1999, FDA issued guidance to blood centers to reduce the theoretical risk of transmission of vCJD to recipients of blood products. This precautionary measure recommended procedures for deferring potential donors who may have been significantly exposed to BSE due to travel or residence in the U.K. FDA's present guidance recommends that blood centers exclude potential donors who have spent six or more cumulative months in the U.K. between January 1, 1980, and December 31, 1996, from donating blood. Further revision to this guidance may be forthcoming as new information becomes available regarding other countries' BSE experiences.

### **TSE Advisory Committee**

FDA has constituted a TSE Advisory Committee, which is composed of non-government experts in TSE matters and meets publicly on at least a semi-annual basis. This committee was chartered originally in 1995. The purpose of the TSE Advisory Committee, as with all of our advisory committees, is to consider policy and scientific issues and then provide FDA with insight and recommendations. One standing agenda item of this committee is review of current regulations and guidance to prevent exposure of the U.S. population to the agent(s) of BSE/TSE through blood, tissues, and other regulated products. FDA's TSE Advisory Committee recently offered advice on revising the guidelines to include potential donors who have lived an aggregate of ten years in France, Ireland and Portugal. FDA is developing revisions to its current industry guidance and will consider the advice of the committee.

#### **Interagency Coordination of TSEs Issues**

Protecting the U.S. from BSE and all TSEs are top priorities of the Department of Health and Human Services (DHHS or Department). Secretary Thompson has made BSE one of his priorities, and has initiated a process to strengthen coordination of BSE/TSE activities across the Department.

In January 2001, FDA established an Interdepartmental Steering Committee for BSE/TSE Affairs. This committee is chaired by the Acting Commissioner of FDA and includes representatives of: CDC, FDA, NIH, USDA (FSIS, APHIS, FAS), the U.S. Trade Representative, the Office of Management and Budget, the Customs Service, the Department of State, the Department of Defense, the State Association of Feed Control Officials, the National Association of State Departments of Agriculture, and the White House Office of Science and Technology Policy.

The committee assures:

- Ongoing coordination between agencies.
- Integrated contingency planning for the possibility that a case of BSE or of vCJD might be found in the United States.
- Identification and action on high priority cross-departmental issues in the U.S. regarding BSE and vCJD.
- Coordination of risk communication plans by the various agencies.

DHHS BSE/TSE activities can be divided into four major components: Surveillance, Protection, Research and Oversight. Surveillance for human disease is primarily the responsibility of the CDC. Protection and Surveillance of animals, feeds, and

foods are responsibilities of FDA, which it shares with USDA. Research is primarily the responsibility of NIH, although FDA also conducts important research. Oversight is primarily the responsibility of the DHHS Office of the Secretary.

Within the Department, there also is a Public Health Service Blood Safety Committee (BSC) that is chaired by the Assistant Secretary for Health, who serves as the Blood Safety Director for the Department. The BSC includes among its members the directors of CDC, FDA, NIH, and the DHHS Assistant Secretary for Planning and Evaluation. The purpose of this committee is to enable threats to the safety or availability of the blood supply to be brought immediately to the highest levels of DHHS. The BSC has been convened on an urgent basis to review proposed recommendations to defer blood donors at risk of transmitting BSE by virtue of prior residence in the U.K. The BSC also met to consider issues relating to the development of CJD at an unusually young age in a hunter who had been a long time plasma donor. In addition, members of this group met to review issues related to the discovery of a poorly characterized TSE that recently appeared in flocks of East Freisian sheep, which had been imported to Vermont from Europe. The group stands ready to be convened for similar matters in the future.

The Department intends to ensure timely, accurate, thorough, and clear communication to the public about the nature and extent of the threats posed by BSE/TSE and about the actions that each agency of government is taking to protect the public from these threats. FDA has announced that it will hold a public meeting for consumers on BSE on April 16, 2001, in Washington, D.C. The purpose of this meeting will be to inform the public about FDA's BSE-related activities and to hear from various consumer groups about their concerns with and suggestions for addressing the challenge of BSE.

### **Conclusion**

Let me close by again stating that currently there is no evidence that BSE or vCJD exists in the U.S. Working together with many counterpart agencies in the U.S., around the world and with various industry and consumer groups, FDA will continue to work to protect the health of the American people and of our animal population by acting to minimize the risk of BSE introduction or spread into the U.S.

Thank you again for the opportunity to testify.