

**January 2002**

# **MAD COW DISEASE**

## **Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts**

**G A O****Accountability \* Integrity \* Reliability**

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## Abbreviations

|      |                                         |
|------|-----------------------------------------|
| BSE  | bovine spongiform encephalopathy        |
| FDA  | Food and Drug Administration            |
| FMD  | foot and mouth disease                  |
| GAO  | General Accounting Office               |
| HHS  | Department of Health and Human Services |
| OIE  | Office International Des Epizooties     |
| TSE  | transmissible spongiform encephalopathy |
| USDA | United States Department of Agriculture |
| vCJD | variant Creutzfeldt-Jacob disease       |



United States General Accounting Office  
Washington, DC 20548

January 25, 2002

The Honorable Tom Harkin  
Chairman  
The Honorable Richard G. Lugar  
Ranking Minority Member  
Committee on Agriculture, Nutrition, and Forestry  
United States Senate

The Honorable Richard J. Durbin  
United States Senate

Bovine spongiform encephalopathy (BSE), commonly known as mad cow disease, is an always fatal, neuro-degenerative disease that has been found in cattle in 23 countries around the world. Cattle contract the disease through animal feed that contains protein derived from the remains of diseased animals. Scientists generally believe an equally fatal disease in humans—known as variant Creutzfeldt-Jacob Disease (vCJD)—is linked to eating beef from cattle infected with BSE. Just over 100 people have died from vCJD, which many scientists believe is difficult to contract. Both diseases have long incubation periods during which they are undetectable—2 to 8 years in cattle and possibly up to 30 years in humans. Countries with BSE have experienced large economic losses in both their beef exports and domestic beef sales. In Europe, more than 5 million head of cattle have been destroyed to thwart the spread of BSE since 1986, when it was first identified in the United Kingdom.

The U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) have primary responsibility for preventing the introduction of BSE-contaminated cattle, beef, and cattle-derived products (such as some dietary supplements) into the United States and the spread of the disease if it were to appear. In 1989, USDA began to identify countries from which cattle and cattle-derived products cannot be imported because of BSE concerns; since 1992, FDA has identified the foods, medical products, and other FDA-regulated products derived from cattle for which imports from those countries pose a potential risk. USDA and FDA screen imported shipments of such products. In 1997, to prevent the spread of BSE should it appear in a U.S. herd, FDA implemented a ban on animal feed. It prohibited the use of proteins from most mammals in

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feed for cattle and other ruminants.<sup>1</sup> The prohibited proteins may still be used in other animal feed, including pet food and feed for swine and horses. In addition, USDA inspects domestically prepared meat, and FDA oversees the manufacture of medical and other products to help ensure they do not contain potentially infective brain and spinal cord (central nervous system) tissue. To detect BSE in the estimated 97 million dairy and beef cattle in the United States, USDA implemented a surveillance program to conduct post mortem tests for BSE on the brains of certain adult cattle.

No cases of BSE-infected animals have been detected in the United States, but the continuing discovery of new cases in other countries, as well as a limited understanding of the disease and its prevention, have heightened concerns about the adequacy of federal efforts to keep BSE out of the United States. In light of these concerns, you asked us to (1) assess the effectiveness of federal actions to prevent BSE and ensure compliance with the animal feed ban; (2) assess the potential economic impacts and health risks if BSE were to be found in U.S. cattle; and (3) compare U.S. actions with actions taken in other countries to prevent the emergence or spread of BSE. As you also requested, we considered, to the extent feasible, a study by the Harvard Center for Risk Analysis and sponsored by USDA to examine the potential for BSE in the United States.<sup>2</sup> That study, issued in November 2001, concluded that BSE is extremely unlikely to become established in the United States and that, if introduced here, it would be eliminated within 20 years.<sup>3</sup> The authors acknowledged that those conclusions, which were based on a probabilistic simulation model developed for the study, could be influenced by a number of model assumptions that could not be verified with confidence—including assumptions about U.S. measures to prevent the introduction and spread of BSE. The study also states that the most influential sources of

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<sup>1</sup>Ruminants are animals with four-chambered stomachs including, but not limited to, cattle, buffalo, sheep, goats, deer, elk, and antelope.

<sup>2</sup>Independent of the Harvard study, in May 2001 the Animal Disease Risk Assessment, Prevention, and Control Act of 2001 (P.L. 107-9) required USDA to report on the risk to the United States from BSE, the effectiveness of current interagency BSE prevention efforts, and recommendations to reduce and manage the risks. USDA expects to issue its report later this year.

<sup>3</sup>*Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States*, Harvard Center for Risk Analysis, Harvard School of Public Health and the Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, Nov. 26, 2001.

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uncertainty regarding the spread of BSE “are related to compliance with the feed ban.” USDA plans to have the study peer-reviewed by a team of outside experts to validate its scientific integrity. We did not attempt to validate the model nor the assumptions Harvard made in applying the model to the United States. Also, we did not conduct an independent risk analysis of the potential for BSE to occur in the United States.

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## Results in Brief

While BSE has not been found in the United States, federal actions do not sufficiently ensure that all BSE-infected animals or products are kept out or that if BSE were found, it would be detected promptly and not spread to other cattle through animal feed or enter the human food supply. With regard to imports, the United States had imported about 125 million pounds of beef (0.35 percent of total imported) and about 1,000 cattle (0.003 percent of total imported) from countries that later discovered BSE—during the period when BSE would have been incubating. In addition, weaknesses in USDA’s and FDA’s import controls, such as inspection capacity that has not kept pace with the growth in imports, may allow BSE-infected products to enter the country. With regard to animal testing to detect BSE, although USDA has steadily increased the number of animals it tests, it does not include many animals that die on farms. Experts consider these animals a high-risk population. Concerning the feed ban, FDA has not acted promptly to compel firms to keep prohibited proteins out of cattle feed and to label animal feed that cannot be fed to cattle. We identified some noncompliant firms that had not been reinspected for 2 or more years and instances when no enforcement action had occurred even though the firms had been found noncompliant on multiple inspections. Moreover, FDA’s data on inspections are severely flawed and, as a result, FDA does not know the full extent of industry compliance. FDA acknowledges that it has not yet identified and inspected all firms subject to the ban. In terms of the public health risk, consumers do not always know when foods and other products they use may contain central nervous system tissue, which, according to scientific experts, could pose a health risk if taken from diseased animals.

The economic impacts of a BSE outbreak in the United States could be severe, according to federal economists. However, scientific experts believe the health risks are uncertain. In terms of the economic impacts, if BSE were discovered in U.S. cattle, beef exports and domestic beef consumption would drop. The severity and duration of the economic impact would depend largely on the number of animals affected, the U.S. response, and the public’s reaction. We could not extrapolate the potential impact on the U.S. economy by looking at the experiences of countries

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with BSE because perceptions about food safety risks vary from country to country, and the economic impacts of BSE on one country might not be applicable to another. Nonetheless, if BSE were found here, the economic impact on the \$56 billion beef industry could be devastating. Many consumers might refuse to buy domestic beef; beef exports could decline dramatically and sales in related industries—such as hamburger chains and soup and frozen dinner manufacturers—could be similarly affected. Concerning the health risks, if BSE-infected cattle were to enter the food supply, some people might develop vCJD. However, experts disagree about the number of people who would be affected. While many believe that vCJD is very difficult to contract, so that relatively few people would develop it, some experts believe that, because of the long incubation period, no one can predict whether few or many might contract vCJD.

The United States acted as many as 5 years earlier than other countries to impose controls over imports of animals and animal feed ingredients from countries that had experienced BSE. Similarly, U.S. surveillance efforts to test cattle brains for BSE met internationally recommended testing targets earlier than other countries. However, the United States has a more permissive feed ban than other countries—one that allows cattle feed to contain proteins from horses and pigs. FDA is reviewing whether these ingredients should continue to be allowed in cattle feed. Finally, as in most countries that are BSE-free, including the United States, cattle brains and other central nervous system tissue can be sold as human food.

This report makes recommendations to USDA and FDA to, among other things, strengthen enforcement of the feed ban, develop a coordinated strategy to identify resources needed to increase inspections of imported goods, and alert consumers when products may contain central nervous system tissue. In commenting on a draft of this report, FDA and Customs concurred with our recommendations. USDA largely concurred but said that labeling and warning statements should be reserved for known hazards.

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## Background

BSE and vCJD are among a group of diseases known as transmissible spongiform encephalopathies (TSE). Currently, there are no therapies or vaccines to treat TSEs, and a definitive diagnosis can only be made from a post mortem examination of the brain. The infective agent that gives rise to TSEs is generally thought to be a malformed protein, called a prion,<sup>4</sup>

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<sup>4</sup>Prions are neither viruses nor bacteria and contain no genetic material.

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which causes normal molecules of the same protein in the brain to become malformed.<sup>5</sup> Prions cannot be killed by conventional heat, irradiation, or chemical disinfection and sterilization procedures. The precise amount of material needed to cause disease is unknown but is generally thought to be very small.<sup>6</sup> TSE prions accumulate in central nervous system tissue—specifically the brain, spinal cord, and eye—but are also present in other body tissues of infected humans and animals. Other TSEs include Creutzfeldt-Jacob disease (in humans), scrapie (in sheep), transmissible mink encephalopathy, and chronic wasting disease (in elk and deer).

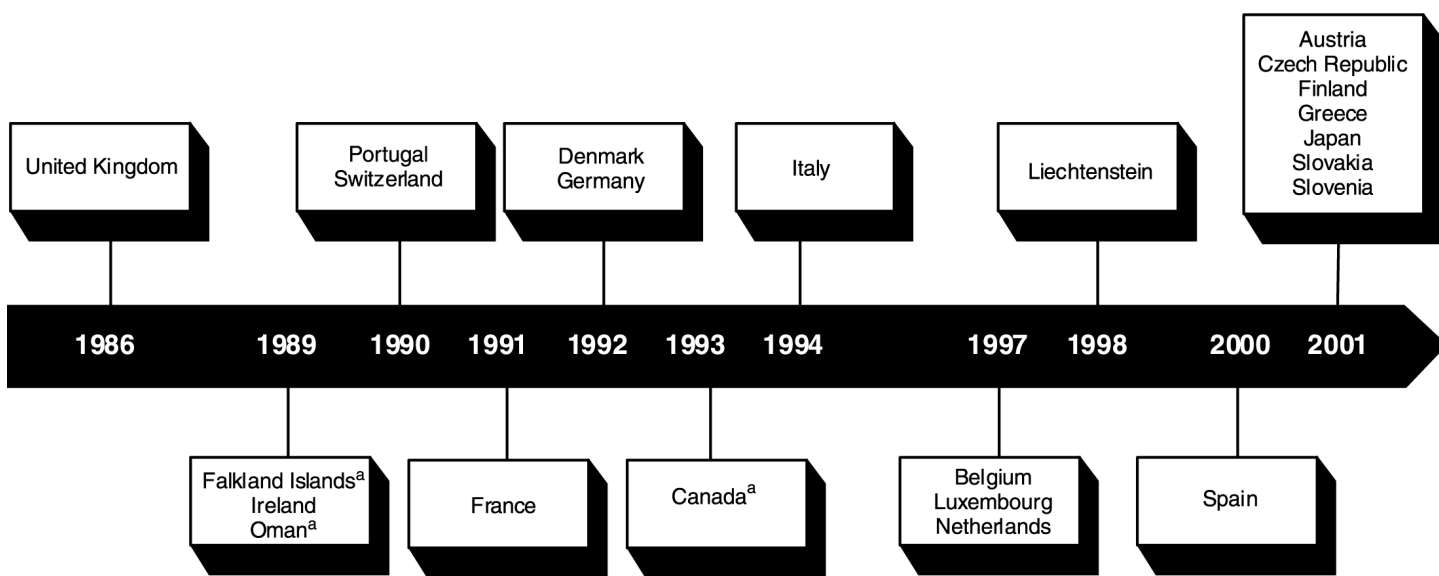
The original source of BSE is not known with certainty. However, evidence suggests that the practice of recycling the remains of diseased animals, specifically scrapie-infected sheep, into feed for livestock, including cattle, was responsible for the emergence and spread of BSE in the United Kingdom. In 1988, the United Kingdom banned the practice of feeding ruminant-derived protein to ruminants. Following this ban, the number of new cases of BSE-infected cattle declined from a high in 1992 of 32,280 new cases to a total of 1,312 cases in 2000, and to 526 cases as of September 30, 2001. About 2,500 cases of BSE have appeared elsewhere in 18 other European countries, as well as Oman, Canada, the Falkland Islands, and Japan, as a result of the exportation of contaminated feed and cattle (see fig. 1). The one BSE-infected cow found in Canada had been imported and was destroyed without entering the animal or human food chains. The BSE-infected cattle found in Oman (two animals) and the Falkland Islands (one animal) had also been imported.

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<sup>5</sup> The prion hypothesis is not universally accepted. Some scientists believe a virus or other conventional agent, as yet undetected, gives rise to TSEs.

<sup>6</sup> According to scientific experts at the European Commission, in careful feeding experiments less than one gram of brain tissue from an infected animal induced disease in all the recipient cattle. The infective dose depends heavily on characteristics of the host and the route of exposure. Consuming infected material is a less efficient means of inducing disease than injecting the material directly into the brain.

**Figure 1: Countries with Confirmed Cases of BSE, as of December 13, 2001**



<sup>a</sup>BSE found only in imported cattle.

Source: Office International Des Epizooties (world organization for animal health).

In 1996, experts in the United Kingdom reported the first cases of vCJD. They believed the victims contracted it by eating beef contaminated by central nervous system tissue from BSE-infected cattle. Although contamination of meat with central nervous system tissue could occur in many ways during the slaughtering and processing of cattle, the major suspect in these cases was meat removed by a system that mechanically recovered (by squeezing under pressure) the remaining meat left on carcasses after all accessible meat has been removed by knife. Prior to December 1995, when the United Kingdom banned the practice, mechanically recovered meat, which was included in many cooked meat products such as sausages, could legally have contained spinal cords. While scientists believe that at least several hundred thousand people may have eaten BSE-infective tissue, many believe vCJD is difficult to contract.<sup>7</sup> As of November 2001, 112 people have had vCJD, of whom just over 100 had died, nearly all in the United Kingdom.<sup>8</sup> Most vCJD victims

<sup>7</sup> According to FDA, millions of people in the United Kingdom may have been exposed to BSE.

<sup>8</sup> This figure includes 12 probable cases where confirmation will never be possible, according to officials in the Department of Health in the United Kingdom.

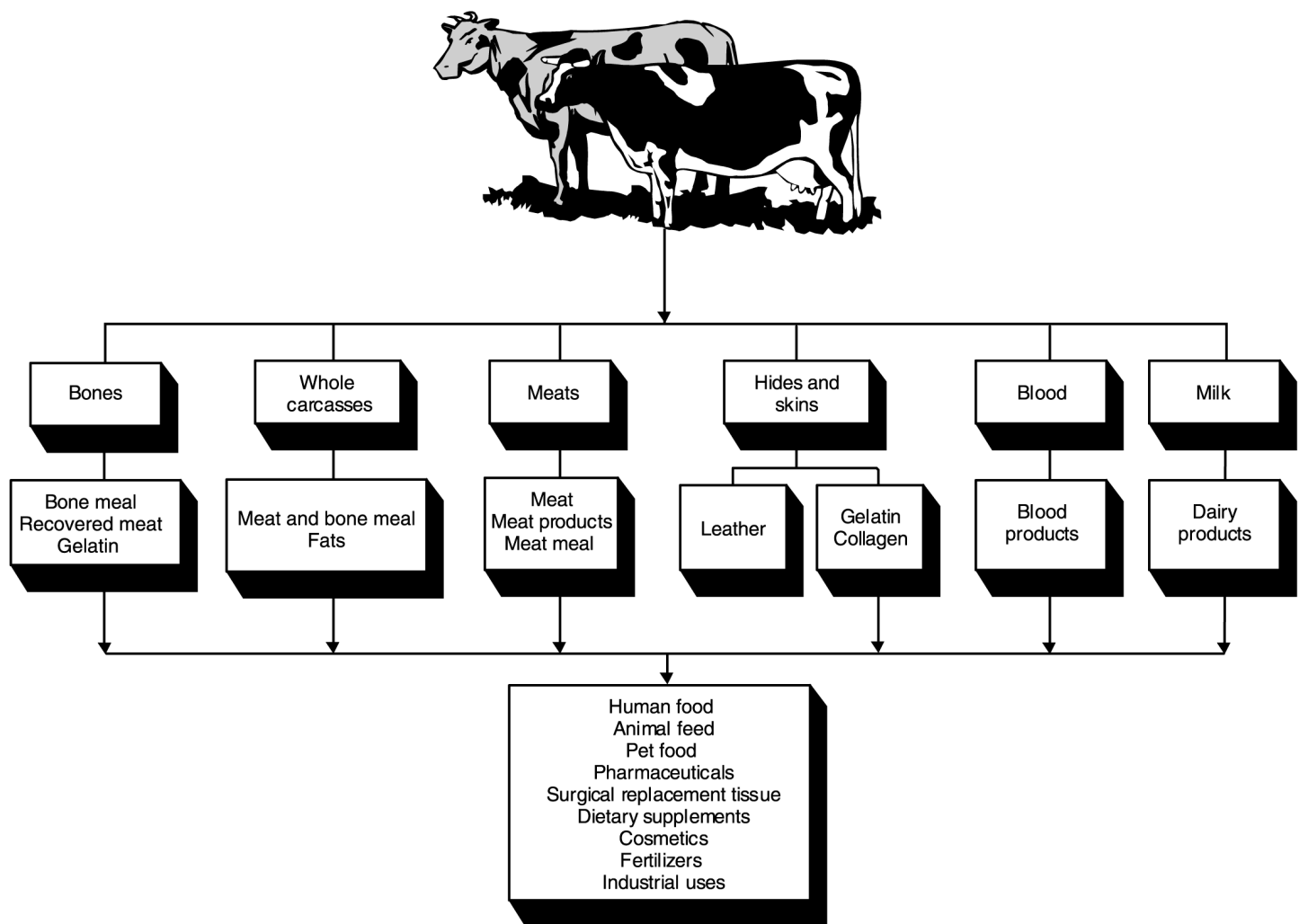
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have been young—the average age at death was 28—and half died within 13 months from the time they first showed symptoms.

As figure 2 shows, cattle provide meat and a wide array of consumer products. Many of these products may pose at least a theoretical risk for BSE infection. For example, dietary supplements, vaccines, cosmetics, and surgical replacement tissue, as well as gelatin, are produced from bovine carcasses, central nervous system tissue, and blood. The rendering industry in the United States and elsewhere recycles animals and animal tissues considered unfit for human consumption into, among other things, animal feed; diseased animals are routinely part of such recycling. The United States trades extensively in animals and the full range of animal products.

No test for BSE or TSE infectivity has been proven adequate for diagnosis in humans or animals before symptoms appear or for screening blood and other products. Tests to detect proteins from cattle in animal feed do not distinguish between milk and blood proteins that are allowed and meat and bone proteins that are not. Furthermore, methods to test animal feeds are based on the analysis of genetic material, bone, and protein, all of which are degraded or destroyed in the rendering process. The lack of unique genetic material associated with BSE prions has led scientists to look for other biological markers for the disease, such as accumulations of abnormal forms of the prion protein in various tissues. Development of valid, sensitive, rapid, and reliable tests for live animals is difficult because the specific agent has not been fully identified and elicits no detectable immune response. Furthermore, efforts are hampered by the limited scientific understanding of BSE and other TSEs, including when during the incubation period infectivity appears, what mechanism causes infection, and whether infectivity is ever present in blood.

**Figure 2: Examples of Products Derived from Cattle**



Four federal agencies are primarily responsible for overseeing the many imported and domestic products that could pose a risk of BSE and for surveillance programs designed to detect and monitor animal and human diseases:

- The U.S. Customs Service screens all goods entering the country to enforce Customs laws and laws for 40 other agencies.
- USDA's Animal and Plant Health Inspection Service monitors the health of domestic animals and screens imported animals and other products to protect animal health.

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- USDA's Food Safety Inspection Service monitors the safety of imported and domestically produced meat, poultry, and some egg products.
  - FDA, within the Department of Health and Human Services (HHS), monitors the safety of all other foreign and domestic food products (including dietary supplements and animal feed), as well as vaccines for humans, drugs, cosmetics, medical devices, and the human blood supply.

In addition, two other HHS agencies—the Centers for Disease Control and Prevention and the National Institutes of Health—monitor human health to detect vCJD should it appear and conduct research to better understand TSEs and the prions thought to cause them.

In August 1997, FDA banned potentially BSE-infective animal proteins in feed for cattle and other ruminants. Proteins are added to feed to promote animal growth and can be derived from a number of sources, including animal meat and bone meal, fishmeal, and plant products. The feed ban prohibits the use of most animal-derived proteins in cattle feed.<sup>9</sup> It also requires that, among other things, feed and feed ingredients that contain the prohibited proteins be labeled “Do not feed to cattle or other ruminants;” firms that handle both prohibited and nonprohibited feed and feed ingredients have procedures to ensure that the two are not commingled; and firms maintain records sufficient to track feed materials through their receipt and disposition for certain periods. The ban excludes animal blood and blood products, gelatin, plate waste,<sup>10</sup> milk and milk protein, and protein derived from pigs and horses (and other equines). Renderers, feed manufacturers and blenders, and feed distributors are subject to the ban.

Recent research on the ability of animals to be “silent” carriers of TSEs from another species raises questions about the advisability of including in feed for cattle, or other ruminants, proteins from animals such as pigs and horses that are currently not thought to be susceptible to BSE and other TSEs, according to researchers at the National Institutes of Health. Specifically, in November 2001 these researchers reported that even though mice experimentally infected with hamster scrapie did not develop clinical disease, infectivity persisted in the brains and spleens of the mice

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<sup>9</sup>Animal-derived protein may be used in pet food and in feed for horses, swine, other non-ruminant animals, and poultry.

<sup>10</sup>Plate waste is cooked meat offered for human food that is further heat processed.

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throughout their life spans.<sup>11</sup> Although available laboratory methods were not sufficiently sensitive to detect the infectivity in these mice, the researchers could infect other mice and hamsters with tissue from the original asymptomatic mice.

The European Commission—the executive and legislative body of the European Union<sup>12</sup>— has had its Scientific Steering Committee<sup>13</sup> conduct assessments of the geographical risk of BSE for countries that requested an assessment. Between July 2000 and November 2001 these scientific experts issued assessments for 49 countries, including the United States, which the experts stated was unlikely to have BSE, but they also stated that the possibility could not be excluded.

BSE differs greatly from foot and mouth disease (FMD). FMD is a highly contagious viral disease that primarily affects cloven-hoofed animals, including cattle, sheep, swine, and goats, and last appeared in the United States in 1929. In contrast to BSE, FMD does not threaten humans, rarely causes death in afflicted animals, and has an incubation period of 24 hours to 21 days. In addition, the virus that causes FMD can be killed using standard sterilization procedures. This report deals only with BSE. We also have a study underway, to be issued later in 2002, of federal measures to control the threat FMD may pose to U.S. livestock.

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## Weaknesses Exist in Federal BSE Prevention and Detection Efforts

The continuing absence of BSE in the United States today cannot be sufficiently ensured by current federal prevention efforts. The introduction and spread of BSE in the United States could stem from cattle and cattle-derived products imported from countries that subsequently developed BSE and from gaps in import controls, animal testing, and feed ban enforcement. As a result of these problems, consumers may unknowingly

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<sup>11</sup>R. Race, A. Raines, G.J. Raymond, B. Caughey, and B. Chesebro, "Long-term Subclinical Carrier State Precedes Scrapie Replication and Adaptation in a Resistant Species: Analogies to Bovine Spongiform Encephalopathy and Variant Creutzfeldt-Jakob Disease in Humans," *Journal of Virology*, Vol. 75, No. 21 (2001), pp. 10106-12

<sup>12</sup>The European Union is composed of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom.

<sup>13</sup>The Scientific Steering Committee provides scientific advice to the European Commission on matters related to consumer protection and health, including food safety.

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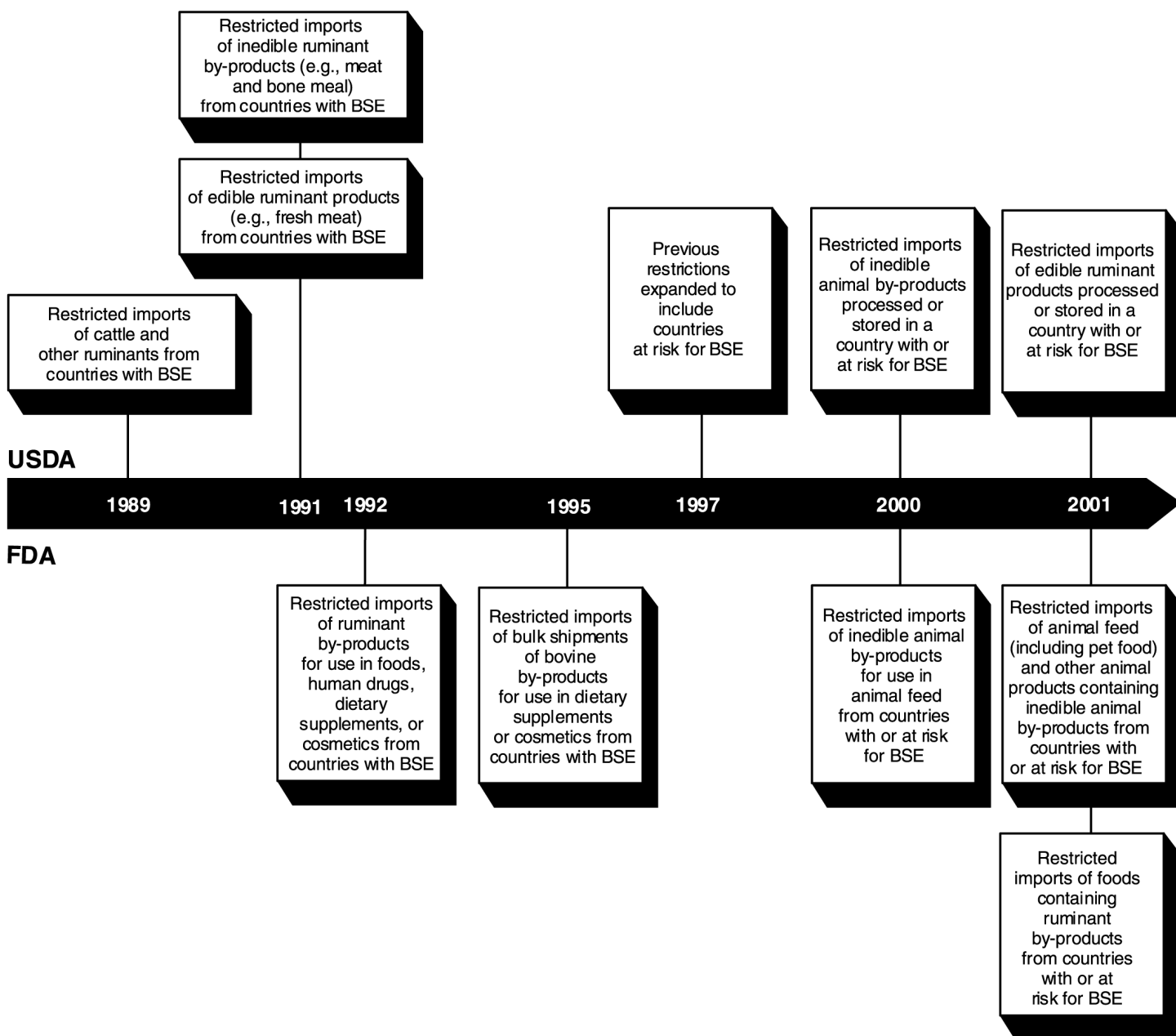
eat foods that contain central nervous system tissue from a diseased animal.

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**BSE-Risk Products May Have Entered the Country before BSE Emerged in the Exporting Countries or through Gaps in Import Controls**

Since 1989 and as recently as 2001, USDA and FDA have identified countries with BSE or at risk for BSE and issued import restrictions on cattle and other ruminants, and on products containing cattle- and ruminant-derived material from those countries. Figure 3 presents a timeline of the actions taken by USDA and FDA during that period.

**Figure 3: Agencies' Implementation of Restrictions to Prevent the Importation of Animals and Products at Risk for BSE**



Source: GAO analysis of USDA and FDA import restrictions.

Figure 4 shows the countries on which the United States currently imposes trade restrictions for BSE-risk items.

**Figure 4: Countries Restricted from Exporting Animals and Products at Risk for BSE to the United States**

|                        |                                              |
|------------------------|----------------------------------------------|
| Albania                | ◆ Luxembourg                                 |
| Andorra                | Monaco                                       |
| ◆ Austria              | ◆ Netherlands                                |
| ◆ Belgium              | Norway                                       |
| Bosnia and Herzegovina | ◆ Oman                                       |
| Bulgaria               | Poland                                       |
| Croatia                | ◆ Portugal                                   |
| ◆ Czech Republic       | Romania                                      |
| ◆ Denmark              | San Marino                                   |
| ◆ Finland              | ◆ Slovakia                                   |
| ◆ France               | ◆ Slovenia                                   |
| ◆ Germany              | ◆ Spain                                      |
| ◆ Greece               | Sweden                                       |
| Hungary                | ◆ Switzerland                                |
| ◆ Ireland              | The former Yugoslav<br>Republic of Macedonia |
| ◆ Italy                | ◆ United Kingdom                             |
| ◆ Japan                | Yugoslavia                                   |
| ◆ Liechtenstein        |                                              |

◆ Countries with reported cases of BSE.

Source: USDA regulations.

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Although federal agencies have acted to reduce the possible ways that BSE-infected animals or products could enter the country, the United States has imported about 1,000 cattle; about 23 million pounds of inedible meat by-products, including meat and bone meal; about 101 million pounds of beef; and about 24 million pounds of prepared beef products during the past 20 years from countries where BSE was later found. These numbers represent a fraction of total imports in each category—0.003 percent of cattle, 0.665 percent of meat by-products, 0.314 percent of beef, and 0.728 percent of prepared beef products. In light of the long incubation period for BSE (up to 8 years), the possibility that some contaminated animals or products have entered the United States cannot be ruled out.

The United States imported 334 breeding and dairy cattle from the United Kingdom between 1980 and 1989.<sup>14</sup> According to USDA, 173 of these animals could have been used in animal feed or entered the human food supply. In addition, the United States imported 443 breeding and dairy cattle from continental Europe between 1983 and 1997, some of which may also have been used in animal feed or in the human food supply. Since 1996, USDA has placed under quarantine any of these imported cattle it has found still alive. These animals are monitored and, when they die, USDA obtains brain samples to test for BSE. Thus far, all tests on these animals have been negative. As of November 16, 2001, three head of cattle from the United Kingdom and five from continental Europe were still alive and being monitored.

The United States also imported 242 cattle from Japan between 1993 and 1999. Japan reported its first case of BSE in September 2001. As of November 28, 2001, USDA had located 214 of these cattle. According to USDA, 24 of these cattle had gone to slaughter or to rendering,<sup>15</sup> 40 had been exported, and 150 were still alive. USDA has begun monitoring those animals and is attempting to locate the remaining 28 cattle.

In its evaluation of the potential for BSE in the United States, the Harvard study considered the ban on imports of cattle from the United Kingdom as one of the United States' key prevention measures. The study assumed

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<sup>14</sup>In 1989, USDA prohibited all imports of cattle and other ruminants from countries with BSE.

<sup>15</sup>Renderers recycle animals and animal tissues into, among other things, animal feed; diseased animals, unfit for human consumption, are routinely part of such recycling.

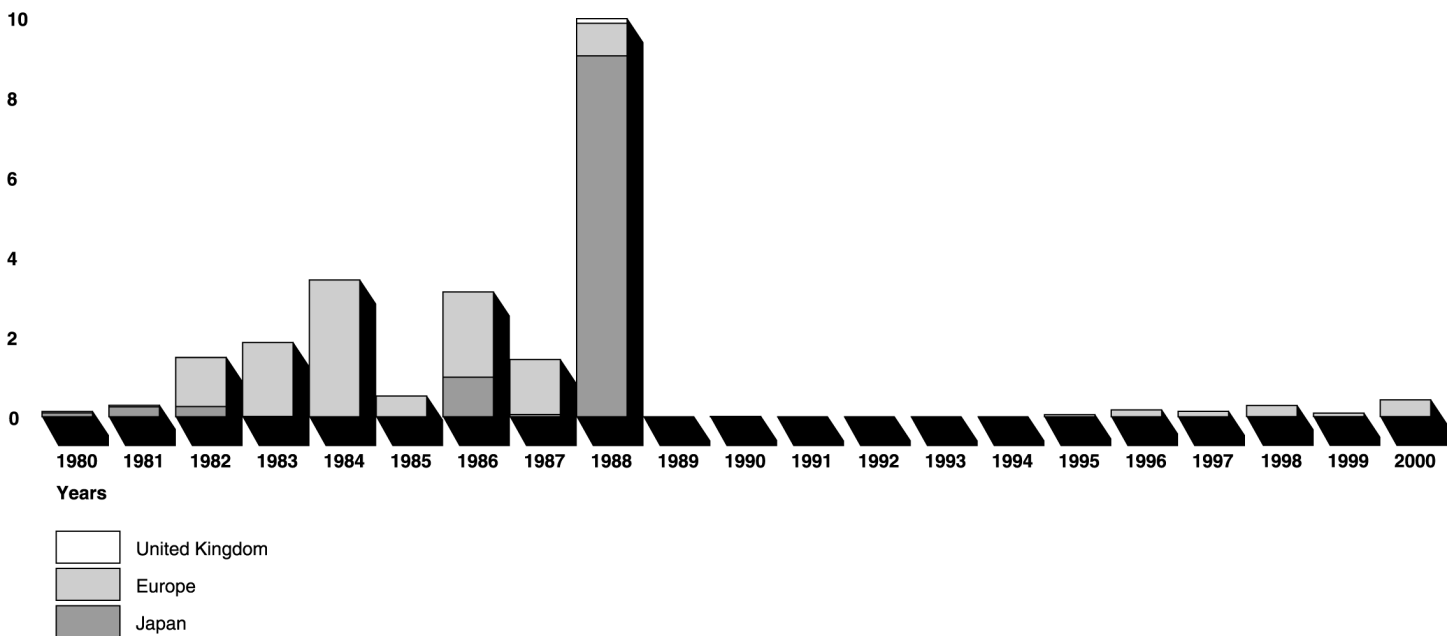
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that remains from some of the cattle imported from the United Kingdom could have been used in animal feed, food for human consumption, or both. Although more than 95 percent of the study's simulations, based on exposure to a low infective dose, resulted in no BSE cases in cattle, a few resulted in substantial numbers of cases. The study also assumed that cattle imported from continental Europe after 1996 had been traced and their movements controlled; it states that these cattle present virtually no risk for introducing BSE to the United States. However, the Harvard study did not take into account the 242 cattle imported from Japan between 1993 and 1999. The discovery of BSE in Japan occurred just before Harvard issued the results of its study.

The United States also imported about 23 million pounds of inedible meat by-products—which would include meat and bone meal and other animal-derived meals, flours, and residues—between 1980 and 2000 from countries later found to have BSE (see fig 5.). However, the amount of meat by-products derived from cattle is uncertain because the code Customs uses to classify such shipments includes by-products from cattle or other animals. Likewise, any meat and bone meal imported under that code could be from cattle or other animals. While experts, including the Harvard researchers, see the risk of exposure posed by these shipments as extremely low, if any cattle feed contained BSE-infected meat and bone meal, it could create an opportunity to contaminate U.S. cattle.

**Figure 5: Imports of Inedible Meat By-Products, Which Include Meat and Bone Meal and Other Animal-Derived Meals, Flours, and Residues, from Countries with BSE, 1980-2000**

12 Pounds in millions

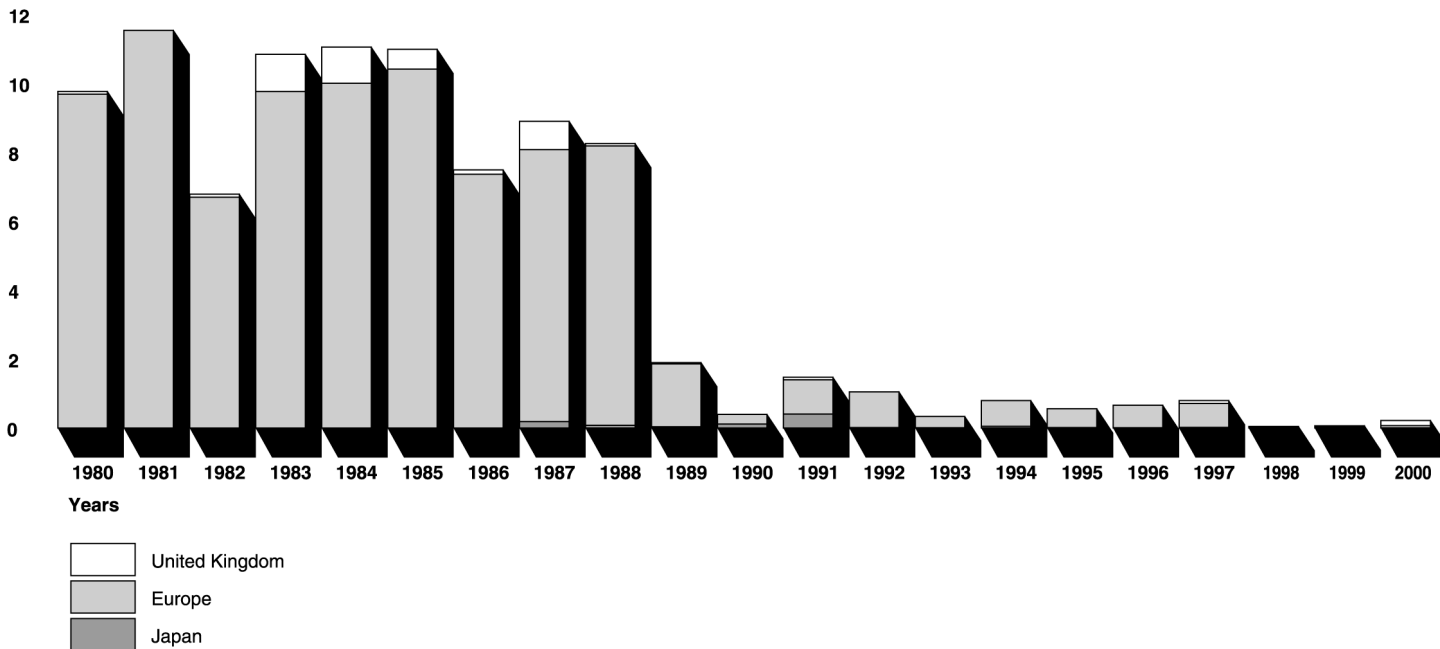


Source: GAO analysis of data from the International Trade Commission and the Departments of Commerce and Treasury.

The beef and prepared beef products that the United States imported from countries that later found BSE, were for human consumption. According to scientific experts, meat products could represent a risk to people who ate them if the meat came from a BSE-infected animal (see figs. 6 and 7). Until February 2001, USDA regulations allowed the import of beef and beef products from countries with BSE or at risk of BSE if the facility that processed the meat did not receive, store, or process ruminant material from a country with BSE or at risk for BSE.

**Figure 6: Imports of Beef and Edible Cattle Organs from Countries with BSE, 1980-2000**

14 Pounds in millions



Note: These trade data include beef only for the years 1980-1988; the data may include meat and organs from other bovines, such as bison, oxen, and buffalo, for the years 1989-2000.

Source: GAO analysis of data from the International Trade Commission and the Departments of Commerce and Treasury.

**Figure 7: Imports of Prepared Beef Products from Countries with BSE, 1980-2000**

5 Pounds in millions

4

3

2

1

0

Years



Note: Prepared products include, among other things, processed meat, such as sausage, and cured or pickled meat, such as corned beef. These trade data may include products from other bovines, such as bison, oxen, and buffalo.

Source: GAO analysis of data from the International Trade Commission and the Departments of Commerce and Treasury.

In addition to the BSE risk posed by past imports, a small but steady stream of BSE-risk material may still be entering the United States through international bulk mail. USDA inspectors at a New Jersey international bulk mail facility have begun using new x-ray technology that clearly distinguishes organic from inorganic matter to screen packages for products that pose a risk of animal and plant diseases. At this facility, we saw USDA inspectors seize one package that contained beef soup mix from Germany, one of the countries from which the United States restricts trade in beef products. Inspectors also showed us a package from Ireland that was labeled “cutlery,” but contained corned beef. From May through October 2001, USDA inspectors, using the new x-ray technology, screened about 7 percent (about 116,000) of the over 1.5 million packages that passed through the New Jersey facility. Of the screened packages, 570 contained one or more at-risk beef or beef-derived products. However, USDA does not screen packages at the New Jersey facility during the

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24 hours each week when inspectors are not on duty. According to the inspectors, the screening rate was low because only one or two inspectors are on duty at any time, and each has only seconds to visually inspect packages as they pass by on a conveyor belt. While all 14 international bulk mail facilities in the United States have some sort of x-ray technology that can distinguish organic from inorganic material, the new technology—used only at the New Jersey facility—provides greater accuracy and clearer imagery. The new technology is also compatible with the conveyor system and can be placed over the conveyor belt. USDA officials told us that the new x-ray technology would facilitate the inspection of international bulk mail arriving in the United States.

At-risk items may also slip through federal inspections at ports of entry. Customs often finds discrepancies with the accuracy of importer-provided information during its annual reviews of trade compliance and, as a result, BSE-risk products may not be flagged for further inspection. For example, Customs found a shipment of animal feed ingredients incorrectly classified as pet food by the importer. It also found a shipment of animal feed identified by the importer as originating in Canada that inspectors discovered originated in Switzerland. For fiscal year 1999, Customs reported that importer-provided information on shipments of live bovine animals (e.g., cattle, bison, and buffalo) was inaccurate in over 24 percent of samples taken. Information on shipments of fresh or frozen beef was inaccurate in over 21 percent of samples and on shipments of animal feed in over 24 percent of samples.

Additionally, the ever-increasing volume of imported shipments strains inspection resources for both FDA and USDA. In October 2001, we reported that during fiscal year 2000, FDA inspected about 1 percent of the over 4 million imported food entries under its jurisdiction.<sup>16</sup> Additionally, FDA inspected less than one percent of the more than 146,000 entries of imported animal drugs and feeds. FDA has acknowledged that the increased volume of imports has severely hampered its ability to inspect a sufficient portion of imports. Specifically, while imported shipments under FDA's jurisdiction have risen dramatically in recent years, the agency's inspection staff has remained almost static since 1992. Prompted by bioterrorism concerns, the Secretary of Health and Human Services requested \$61 million in October 2001 to hire 410 additional inspectors and

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<sup>16</sup>*Food Safety and Security: Fundamental Changes Needed to Ensure Safe Food* (GAO-02-47T; Oct. 10, 2001).

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other personnel to allow increased inspections of imported food products. In 1997 we reported that USDA's inspection workload had increased dramatically since 1990; we concluded that USDA had little assurance that it was deploying its limited inspection resources at the ports of entry that are most vulnerable to the introduction of pests and diseases.<sup>17</sup> USDA has acknowledged the lack of inspection coverage and, in the wake of foot and mouth disease outbreaks in Europe and other countries, authorized \$32 million in fiscal year 2001 to hire 350 new inspection personnel and additional canine inspection teams at U.S. borders and ports of entry.

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### USDA Tests Many Cattle Brains for BSE in Its Surveillance Program but Does Not Test Many from Cattle That Die on Farms

USDA began testing animal brains to detect BSE in domestic cattle in 1990. This surveillance program consists primarily of collecting and analyzing brain samples from adult cattle with neurological symptoms and adult animals that were nonambulatory at slaughter.<sup>18</sup> Testing animal brains is a key measure to detect BSE, and USDA's surveillance program should build on current efforts to increase the number of brain samples tested each year, according to officials from organizations representing the beef and grain industries, state officials, and consumers, as well as federal officials. As table 1 shows, the number of samples collected and tested by USDA in its surveillance program has generally increased each year.<sup>19</sup> The table also shows that a substantial portion of those samples have been taken from nonambulatory cattle since 1994, when USDA first began to collect this information. USDA has increased the portion of nonambulatory cattle because research has shown that this population includes animals that might have subtle neurological symptoms or injuries resulting from neurological impairment. In fiscal year 2001 these animals accounted for more than 90 percent of the 4,870 brains collected and tested by USDA. The remainder includes brain samples from animals rejected at slaughter for signs of neurological disease.

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<sup>17</sup>*Agricultural Inspection: Improvements Needed to Minimize Threat of Foreign Pests and Diseases* (GAO/RCED-97-102, May 1997).

<sup>18</sup>Nonambulatory or "downer" animals include primarily animals that are unable to walk for various reasons ranging from broken limbs to neurological diseases and some animals that died before slaughter.

<sup>19</sup>USDA also tests in its BSE surveillance program about 300 samples each year submitted by practicing veterinarians and veterinary schools and hospitals. Some of these samples come from cattle that displayed neurological symptoms but tested negative for rabies, another neurological disease.

**Table 1: Cattle Brain Samples USDA Collected and Tested for BSE in Its Surveillance Program, Fiscal Years 1994-2001**

| Brain samples tested                            | Fiscal year |            |            |            |            |            |              |              |
|-------------------------------------------------|-------------|------------|------------|------------|------------|------------|--------------|--------------|
|                                                 | 1994        | 1995       | 1996       | 1997       | 1998       | 1999       | 2000         | 2001         |
| Number from nonambulatory cattle <sup>a</sup>   | 199         | 223        | 266        | 219        | 344        | 651        | 1,895        | 4,464        |
| Number from ambulatory cattle                   | 296         | 242        | 318        | 636        | 387        | 342        | 414          | 406          |
| <b>Total brain samples collected and tested</b> | <b>495</b>  | <b>465</b> | <b>584</b> | <b>855</b> | <b>731</b> | <b>993</b> | <b>2,309</b> | <b>4,870</b> |

<sup>a</sup>According to USDA, it did not track brain samples from cattle that had died on farms; the few that were taken would have been counted in with the nonambulatory cattle.

Source: GAO presentation of USDA data.

In addition to increasing the sample size and the number of nonambulatory cattle tested, USDA has broadened its testing efforts. USDA tests samples using two complementary laboratory methods and conducts surveillance for two TSEs—scrapie in sheep and chronic wasting disease in deer and elk—that already exist in the United States. USDA officials and many scientific experts believe surveillance and eradication of scrapie and chronic wasting disease is important, in part, because of the suspected link between scrapie in the United Kingdom and the appearance of BSE, and because both have been experimentally transferred to other species.

Although USDA has strengthened its surveillance efforts, the program does not include many samples from cattle that die on farms. Scientific experts consider these animals a high-risk population because they are generally older and the reasons for their death are often unknown.<sup>20</sup> USDA told us that efforts to obtain samples more systematically from such animals are limited largely by the dispersed nature of the domestic livestock industry, the lack of adequate laboratory capacity to conduct the tests, and the lack of sufficient staff and time to collect the samples. When animals die on farms they may be buried on the farm, taken to landfills, or collected by renderers who recycle animals and other animal tissues into, among other things, animal feed. In 1998 USDA implemented a cooperative program with the rendering industry to ensure that carcasses of animals condemned at slaughter for signs of neurological disease are held until test

<sup>20</sup>Older animals are at risk because, if infected, they have lived long enough for disease symptoms to appear.

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results are completed. Under this program, USDA may share the expenses to store or dispose of carcasses during the testing period. USDA was not able to provide us with information on how frequently the program has been used, but it has been used only sporadically, according to USDA officials and the USDA veterinarians and renderers we spoke with in nine states and Puerto Rico.

In its evaluation of the potential for BSE in the United States, the Harvard Center for Risk Analysis included animals that die on farms as a potential source of BSE exposure. According to their simulation model, excluding from the rendering process those animals that die on farms significantly reduces the potential for cattle to be exposed to BSE through animal feed. Harvard's report also notes that farmers may not be willing to send animals displaying neurological symptoms to slaughter, thereby reducing the likelihood that infected animals would be inspected by USDA at slaughterhouses. Once dead, these animals might be rendered, as assumed in the simulation model, or disposed of on farms. According to USDA officials, when the Harvard study was issued to the public, the Secretary of Agriculture announced plans to more than double the number of BSE tests conducted in FY 2002 to more than 12,000.

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## FDA's Enforcement of the Feed Ban Is Limited and Inspection Data Are Flawed

Federal and state officials and the scientific community agree that if BSE were to be found in a U.S. herd, a well-enforced feed ban would prevent its spread to other herds. State inspectors (who conduct about 80 percent of inspections) and FDA inspectors document their feed ban inspections on inspection forms. FDA headquarters compiles and maintains this information in a database, and it provided to us the information in that database through October 26, 2001. According to FDA's data, more than 12,000 inspections have been conducted since 1997 at more than 10,000 firms,<sup>21</sup> including renderers, feed manufacturers, feed haulers, and distributors, as well as at on-farm feed operations. According to FDA's October 2001 quarterly update that summarized results of feed ban inspections, 364 firms were out of compliance. In addition, FDA believes that not all firms that should be subject to the ban have been identified and inspected, at least 1,200 or more based on industry estimates (see table 2). However, we could not verify these data because we found significant flaws in FDA's database, which we discuss later in this report.

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<sup>21</sup>FDA carries out feed ban inspections in 12 states and has entered into partnership and contract arrangements with the other states to conduct feed ban inspections.

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**Table 2: FDA Feed Ban Inspection and Compliance Information**

| Type of firm                         | FDA's estimate of the universe of this type of firm | Number of firms inspected | Number of firms out of compliance |
|--------------------------------------|-----------------------------------------------------|---------------------------|-----------------------------------|
| Renderers                            | 264                                                 | 264                       | 13                                |
| FDA-licensed feed mills <sup>a</sup> | 1,240                                               | 1,240                     | 42                                |
| Other feed mills                     | 6,000-8,000                                         | 4,835                     | 228                               |
| Other firms <sup>b</sup>             | At least 4,237 (universe unknown)                   | 4,237                     | 81                                |
| <b>Total</b>                         | <b>At least 11,741</b>                              | <b>10,576</b>             | <b>364</b>                        |

Note: Because of the severe flaws in FDA's inspection database, we were unable to verify these data or use the database for analysis of oversight and enforcement.

<sup>a</sup>Feed mills that must be licensed by FDA because they handle restricted medicines.

<sup>b</sup>Other firms include feed blenders, on-farm mills, and feed haulers.

Source: FDA's Center for Veterinary Medicine Update, Oct. 30, 2001.

FDA did not take prompt enforcement action to compel firms to comply with the feed ban. When we began this study, in April 2001, the only enforcement action FDA had taken was to issue two warning letters in 1999.<sup>22</sup> The first letter was issued in May 1999—21 months after inspections began.<sup>23</sup> However, since inspections began in 1997, FDA has reported hundreds of firms out of compliance—most often for failure to meet requirements to label feed that contained prohibited proteins or for including prohibited proteins in cattle feed. In our analysis of individual inspection forms, we found several instances in which firms were out of compliance in repeated inspections, yet FDA had not issued a warning letter. We also found instances in which firms were out of compliance but had not been reinspected for a year or more—and in some cases for more than 2 years.

Between February and November 2001, FDA issued warning letters to another 48 firms. In addition, 17 firms voluntarily recalled feed, including 9 that had been issued a warning letter. As of November 30, 2001, FDA or states had reinspected 33 of the total of 50 firms that had been issued

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<sup>22</sup> A warning letter generally represents FDA's first official notification to a firm that FDA has found one or more products, practices, processes, or other activities violate its regulations.

<sup>23</sup> Five firms also voluntarily recalled mislabeled or potentially contaminated feed during 1999.

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warning letters (2 in 1999 and 48 in 2001). Six of the firms were still out of compliance on reinspection. FDA has no enforcement strategy for feed ban compliance that includes a hierarchy of enforcement actions, criteria for actions to be taken, time frames for firms to correct violations, and time frames for follow-up inspections to confirm that violations have been corrected.

According to FDA, rather than taking enforcement actions, it has emphasized educating firms subject to the feed ban about the ban's requirements and working with those firms to establish cooperative relationships. FDA reported that some states might have taken enforcement actions, including requiring firms to recall noncompliant feed. However, FDA does not track enforcement actions taken by states; therefore, it does not know the extent of such actions.

Even if FDA were to actively enforce the feed ban, its inspection database is so severely flawed that—until corrected—it should not be used to assess compliance. Nonetheless, FDA uses the database to manage and oversee compliance, respond to congressional inquiries about compliance, and keep industry and the public informed.

From our review of FDA's database of 12,046 feed ban inspection records (as of October 26, 2001), we found records lacked unique identifiers, were incomplete, contained inconsistent or inaccurate information, and were not entered into the database in a timely manner. Examples of the severe flaws we found include:

- Entries for 5,446 inspections—or about 45 percent of all inspections—lack information to uniquely identify individual firms. As a result, the data cannot be used to reliably determine the number of firms inspected, compliance trends over time, or the inspection history of an individual firm. In at least one case, the same unique identifier had been applied to six different firms and, in another case, a firm had two unique identifiers. In addition, we found 232 cases in which one or more inspections of the same firm lacked the unique identifier.
- Entries for 301 inspections of firms that handle prohibited proteins contain no response to whether feed was properly labeled; entries for 438 inspections of firms that handled both prohibited and non-prohibited proteins had no response to whether prohibited proteins were included in feed intended for cattle.
- Entries where responses to questions about feed labeling or whether prohibited proteins were included in feed intended for cattle indicated that the firms were in compliance; however, inspectors' notes contained in

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other sections of the database contradicted the responses and indicated the firms were not in compliance.

- Inspections were not entered into the database. In assessing the warning letters, we discovered references to inspections that do not appear in the database. In fact, the inspection record for the firm that received the first warning letter—in May 1999—does not appear in the database.
- Inspections were not entered into the database in a timely fashion. We found several instances where inspections dating back to 1998 and 1999 were not entered into the database until mid to late 2001—too late for FDA to reinspect in a timely fashion if violations existed. Also, too much time had passed for FDA to reliably clarify inconsistent or conflicting information or obtain answers to questions left blank on the inspection forms. Moreover, any compliance information FDA reported to congressional overseers and others would not have been reliable.
- Several states did not use FDA’s inspection form, but instead used their own state-developed forms. Because the questions were different, certain assumptions had to be made when these data were entered into FDA’s database. The HHS Office of Inspector General noted, in a June 2000 report, that many FDA agreements with states, whose inspectors conducted about 80 percent of feed ban inspections, do not ensure that states routinely provide FDA with standardized information on the inspections they conduct.<sup>24</sup> In September 2001 FDA revised the inspection form and asked states to use the revised form. States are free to ask other questions during the inspections, but FDA has also asked them to include FDA’s questions in FDA’s format.
- The database is incomplete. It does not include all firms subject to the feed ban. FDA officials relied on the personal knowledge of state and FDA field staff and on membership lists from industry groups to identify and locate firms. However, our review of membership records for the National Renderers Association—for the years 1998 to 2001—disclosed 21 rendering firms that were not in FDA’s database. According to association records, those firms process meat and bone meal and other products that could contain proteins subject to the feed ban.

FDA did not count data entries with blanks—no responses—in the selected data fields it uses when it reports on compliance. Therefore, when FDA provided compliance information to the Congress—and when it publishes that information electronically—the data are misleading and the number of firms identified as out of compliance are undercounted. For

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<sup>24</sup>*FDA Oversight of State Food Firm Inspections: A Call for Greater Accountability* (HHS-OIG, June 2000, OEI-01-98-00400).

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example, for the 364 firms identified as out of compliance in FDA's October 2001 update—the source for information in table 1 above—FDA assumed that all entries with blanks in the compliance fields were in compliance. However, we found entries where firms had blanks in the data fields FDA used, yet contained inspector comments in other fields showing that the firms were not in compliance. FDA also did not include these firms on published lists of noncompliant firms. About half of the inspection records contain inspector comments. On those entries where blanks also existed, the inspector comments showed that firms were in compliance in some instances and out of compliance in others.

An FDA official told us that the database was not originally intended to track compliance of individual firms, but rather to guide the agency's efforts to educate firms subject to the ban by illustrating particular states or practices that needed more intensive focus. However, FDA has no information system other than the inspection database to track compliance with the feed ban.

FDA has not placed a priority on oversight of the feed ban. From the implementation of the feed ban in August 1997 until early 2001, one person in FDA's Center for Veterinary Medicine was responsible for feed ban management. Although state and FDA District Office inspectors conducted the inspections, this individual designed the inspection form, compiled inspection data, and made enforcement decisions—in addition to that individual's other duties. Furthermore, the inspection form had not been pretested—a standard practice to ensure that questions are interpreted and answered consistently.

In the course of our review, FDA attempted to clean up the database so that it could serve as an accurate management tool. However, in October 2001, FDA turned that effort over to a contractor to (1) review the completeness of the feed ban inspection database to ensure that findings have been captured, including written comments by the inspectors on inspection forms; (2) analyze the data and present the findings in a report; and (3) review the current enforcement strategy to determine program strengths and weaknesses and to make recommendations for improvements that will better support FDA's compliance goals. FDA expects this work to be completed by February 2002. Also in October 2001, FDA entered into a separate contract to reconfigure the data so that they can be incorporated into FDA's primary database for all other inspection activities. Work on the two contracts is to be carried out concurrently. This work is to be completed in the spring of 2002.

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In evaluating the potential for BSE in the United States, the Harvard study noted that the feed ban is key to preventing the spread of BSE. It added, however, that the effectiveness of the feed ban is somewhat uncertain because compliance rates are not “precisely” known. Harvard’s simulation model assumed the feed ban was compromised to some extent by on-farm feeding of prohibited proteins to cattle and by some noncompliance with the requirement that feed containing prohibited protein carry a warning label. The study’s observations underscore the importance of the problems we found in FDA’s oversight and enforcement of the feed ban.

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### Consumers Cannot Tell Which Beef Products May Contain Central Nervous System Tissue

Some consumers in the United States regularly eat cattle brains and central nervous system tissue. Brains are a routine part of the diet in several cultures. Eating such foods would not pose a safety concern unless they were from a BSE-infected animal. However, most consumers would not realize that central nervous system tissue could be found on many beef cuts and in several beef products.<sup>25</sup> For example, bone-in meat cuts, such as T-bone steaks, are stripped directly from the animal’s vertebrae and may contain portions of the spinal cord. Many other edible products, such as beef stock, beef extract, and beef flavoring, are frequently made by further processing (e.g., boiling) the skeletal remains (including the vertebral column) of the carcass after most of the meat has been removed. USDA officials told us that they would expect to find central nervous system tissue in these foods.

However, based on food quality—not food safety—concerns, USDA does prohibit central nervous system tissue in beef products that are labeled as meat and that are made using technology that mechanically removes meat from the bones of slaughtered animals in a way that approximates deboning by hand. Products made from meat using this technology include sausages and hot dogs. USDA has found central nervous system tissue in meat that was mechanically removed using a technology known as advanced meat recovery systems. USDA estimates that 28 beef processing plants use this technology and, in 2000, recovered 257 million pounds of beef. According to a beef industry official, this technology recovers up to 10 additional pounds of meat per carcass.

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<sup>25</sup>USDA is responsible for overseeing the health of cattle and ensuring the safety of fresh and processed beef and beef products, while FDA is responsible for ensuring the safety of many edible products made from cattle, including bouillon, flavorings, and dietary supplements.

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Because it is not a food safety issue, USDA has not rigorously enforced its prohibition against the presence of central nervous system tissue in meat extracted by using the advanced meat recovery system technology. Since 1997, USDA has tested a total of 63 beef samples from 18 of the plants that use this technology. Of those samples, 12 tested positive for central nervous system tissue. USDA has not tested beef samples from the other plants that use the technology in at least 4 years. When its tests found central nervous system tissue in samples, USDA did not track to ensure that the processing plants relabeled the contaminated meat products as something other than meat.

USDA plans to use the Harvard study to help it determine whether the presence of central nervous system tissue should be a food safety matter—whether all or some central nervous system tissue should be considered unsafe for human consumption. The Harvard study notes that a ban on the use of spinal cords, brains, and vertebral columns in human food or animal feed significantly reduced the risk of exposure in its simulation model. As part of its evaluation of the implications of the study, USDA will issue a Federal Register Notice after January 2002 to solicit comments on, among other things, the safety of the advanced meat recovery technology and any meat that comes from the vertebral column.

In addition, FDA's TSE Advisory Committee—composed of USDA, National Institutes of Health, Centers for Disease Control and Prevention, and other federal experts, as well as academic scientists and medical experts, and consumers—recommended, in October 2001, that FDA consider taking regulatory action to ban brains and other central nervous system tissue from human food because of the potential risk of exposure to BSE-infected tissue. According to FDA, it is considering banning central nervous system tissue from the foods it regulates as well as from cosmetics and over-the-counter drugs. FDA told us it is taking this action to ensure that consumers are protected from consuming BSE-contaminated products. Representatives of two consumer groups we interviewed expressed concern that central nervous system tissue remains a part of food generally and that the use of advanced meat recovery technology could expose consumers unknowingly to such tissues.

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## The Economic Impacts of a U.S. Outbreak Could Be Severe, and the Health Risks Are Uncertain

If BSE were discovered in U.S. cattle, beef exports and domestic beef consumption would drop, damaging many sectors of the economy, according to federal economists. If the infected cattle were to enter the food supply, some people might develop vCJD.

The economic impacts of a BSE outbreak in the United States would include the direct impacts on certain sectors, such as the beef and livestock industries, and indirect impacts on related industries, such as the animal feed and restaurant industries. In addition, an assessment of economic impacts would include costs relating to the public sector, such as farmer compensation payments, increased spending on research and development, and increased costs to government agencies.<sup>26</sup> While the extent to which economic impacts would pass from one sector to another is unclear, these effects would eventually channel through to several sectors of the economy. Figure 8 lists the sectors and some of the likely qualitative impacts within each sector in the event of a BSE outbreak in the United States.

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<sup>26</sup>For the most part, these costs represent transfer payments from the public sector or taxpayers to farmers and other related industries.

**Figure 8: Economic Sectors That Would Be Affected if BSE Were Found in the United States**

### **Private sector effects**

#### **Farmers**

- Decreased market prices and output
- Increased costs of slaughtering and disposing of animals
- Increased costs of cattle feed
- Increased prices and output for substitute meat products (e.g., poultry, pork, and fish)

#### **Meat industries**

- Lost markets and increased disposal costs for beef packers<sup>a</sup>
- Lost markets for beef processors<sup>b</sup>
- Gained markets for other substitute meat industries

#### **Feed manufacturers**

- Lost raw materials
- Increased costs of raw materials (may pass on to farmers)

#### **Renderers**

- Lost markets
- Lost raw materials

#### **Retailers and wholesalers**

- Lost beef sales to downstream wholesalers and retailers
- Lost business for restaurants specializing in beef products
- Increased wholesale prices of substitute meat products

#### **Other related industries**

- Lost markets for cattle auction and transportation industries
- Possible increased costs of raw materials for pharmaceuticals, cosmetics, tannery and leather goods, and other related industries
- Lost markets and/or increased costs for manufacturers of products that contain beef extracts and broths
- Possible gained business for quality control/inspection services industries

### **Final consumption sector effects**

- Increased costs of imported beef products
- Increased costs of substitute meat products
- Increased costs of products from related industries
- Decreased costs of domestic beef and beef products

### **Public sector effects**

- Increased costs to subsidize certain livestock-related industries
- Increased costs for additional inspection and surveillance for BSE
- Increased costs for research on BSE and vCJD

### **Trade sector effects**

- Decreased exports of live cattle and beef in the short run
- Possible lost markets for beef exports in the long run
- Increased beef imports

<sup>a</sup>Beef packers slaughter cattle and other animals and package carcasses and large cuts for further processing.

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<sup>b</sup>Beef processors cut, slice, grind and package beef for consumers and for other end users, such as grocery stores, restaurants, and institutions.

Source: GAO analysis.

To date, however, there are no comprehensive economic studies of the total direct and indirect economic impacts of a potential BSE crisis in the United States. A complete assessment of these impacts is difficult to forecast given the uncertainties surrounding key assumptions, such as the source of the BSE, the number and timing of cases, and the public's reaction. For instance, if BSE were to enter the country through the importation of meat and bone meal rather than live cattle imports, the economic consequences could be more pervasive, because the meat and bone meal could potentially contaminate many cattle. Another difficulty in estimating impacts is the problem of determining how the increased costs of BSE would be passed on from the farmer to the final consumer in the beef-marketing channel. Moreover, studies that estimate losses due to BSE from other countries may not be totally applicable to the United States.

Food safety experts have noted that perceptions about food safety risks vary from country to country, and the consumer impacts of BSE in one country may not be applicable to another country. If BSE were found here, the economic impact on the \$56 billion beef industry and related industries could be devastating, according to USDA economists. For instance, consumers in the United States, in response to reports of BSE-infected cattle, may for a period of time restrict their purchases of beef and products containing beef. That response would be felt not only by the cattle and beef industries, but also by peripheral industries. For example, hamburger chains and soup and frozen dinner manufacturers could see dramatic declines in business.

Similarly, in international trade, a loss in beef exports may be more devastating for the United States than for other beef-producing countries. In particular, since the United States exports nearly 10 percent (by volume) of its total beef production (about 25 percent of total world beef exports), the trade sector is also critical in estimating total economic impacts.

As a first approximation, however, FDA officials estimated the direct effects to the beef and livestock industries based on a 1998 study of the economic impacts of the first year of the BSE outbreak in the United

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Kingdom.<sup>27</sup> They estimate that if the United States were to experience an outbreak as severe as the one in the United Kingdom, the beef industry could lose as much as \$15 billion in sales revenue. Specifically, these costs were based on the assumption that in the event of a BSE crisis, U.S. domestic and export demand would decrease by the same amounts as in the United Kingdom—a 24 percent decline in domestic beef sales and an 80 percent decline in beef and live cattle exports. In addition, the FDA estimated the livestock sector would incur a minimum of \$12 billion to slaughter and dispose of at-risk cattle. This estimate was based on an assumption that the United States would need to destroy about four times as many cattle as the United Kingdom. However, the FDA analysis did not include the offsetting effects of government payments, as occurred in the United Kingdom, shifts in consumer demand for other types of meat, or the effects on other related sectors of the economy. Overall, however, FDA noted that those firms primarily engaged in the production of beef products would incur severe economic disruption.

In terms of the health risks, if infected cattle were to enter the food supply, some people might develop vCJD; however, scientific experts disagree about how many people could develop the disease. Many experts believe that vCJD is difficult to contract and, therefore, that relatively few people would develop the disease. However, other scientific experts believe that, because of the long incubation period, no one can predict whether few or many might contract vCJD. According to some scientific experts in the United Kingdom, as many as 100,000 people in Europe may develop vCJD as a result of the BSE outbreak there. This could include Americans who lived in countries where BSE occurred. In addition to these direct health implications, an outbreak of BSE in the United States would carry an emotional toll on consumers who believe federal regulators will protect them from this devastating disease. Moreover, according to a National Institutes of Health scientist, the appearance of vCJD could cast doubt on the safety of organ donations and the U.S. blood supply.<sup>28,29</sup> Any health

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<sup>27</sup>Using an input-output model of the British agricultural economy, a study prepared by the Ministries of Agriculture, Fisheries, and Food, commissioned by United Kingdom agricultural departments and Her Majesty's Treasury, estimates that economic losses for the first year of the crisis in the United Kingdom were between \$1.07 and \$1.4 billion. *Economic Impact of BSE on the UK Economy*, by DTZ Piedad Consulting, March 1998.

<sup>28</sup>*BSE and vCJD: Background, Evolution, and Current Concerns*, Brown et al., *Emerging Infectious Diseases Journal*. Vol 7, No 1, Jan-Feb 2001.

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implications would translate into medical treatment and related financial and economic costs, such as lost productivity.

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## The United States Set Controls on Importing Animals and Met BSE Testing Goals Earlier Than Many Countries, but Its Feed Ban Is More Permissive

The United States prohibited the import of cattle and other ruminants 3 to 5 years earlier than many other countries. Its surveillance program to test cattle brains for BSE also met international targets for the number of animals tested earlier than many other countries. However, the United States has a more permissive feed ban than other countries—one that allows cattle feed to contain proteins from horses and pigs. FDA is reviewing whether these ingredients should continue to be allowed in cattle feed. Finally, as in most countries that are BSE-free, including the United States, cattle brains and other central nervous system tissue can be sold as human food.

The European Commission's Scientific Steering Committee has had scientific experts assess countries, including the United States, for the risk that BSE could enter the country through imported animals and feed and be spread through recycled animal proteins in feed. As of November 30, 2001, risk assessments had been completed for 49 countries. According to the scientific experts, most European countries are likely to have BSE, even if it has not yet been confirmed by surveillance testing, or to have BSE at a higher level of incidence than thought. The scientific experts assessed the United States as unlikely to get BSE, but indicated that the possibility could not be excluded. Table 3 presents the results of the 49 BSE risk assessments completed through November 30, 2001.

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<sup>29</sup>FDA monitors the BSE-related safety of the blood supply and has recommended deferring donors of blood and blood products based on exposure to the BSE agent, for example donations from individuals who traveled or resided in the United Kingdom for 3 or more months between 1980 and the end of 1996.

**Table 3: BSE Level of Risk Assessed for 49 Countries by European Commission Experts**

| <b>BSE risk level</b>                                              | <b>Number of countries (percent of total assessed)</b> | <b>European Union countries</b>                                                          | <b>Other countries</b>                                                                                                                                           |
|--------------------------------------------------------------------|--------------------------------------------------------|------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Highly unlikely – Level I                                          | 16 (32.7)                                              |                                                                                          | Argentina, Australia, Botswana, Brazil, Chile, Costa Rica, El Salvador, Namibia, Nicaragua, Norway, New Zealand, Panama, Paraguay, Singapore, Swaziland, Uruguay |
| Unlikely but not excluded – Level II                               | 12 (24.5)                                              | <b>Austria, Finland, Sweden</b>                                                          | <b>Canada</b> , Colombia, India, Kenya, Mauritius, Nigeria, Pakistan, <b>Slovenia</b> , United States                                                            |
| Likely but not confirmed or confirmed at a lower level – Level III | 19 (38.8)                                              | <b>Belgium, Denmark, Germany, France, Ireland, Italy, Luxembourg, Netherlands, Spain</b> | Albania, Cyprus, <b>Czech Republic</b> , Estonia, Hungary, Lithuania, Poland, Romania, <b>Slovakia, Switzerland</b>                                              |
| Confirmed at a higher level – Level IV                             | 2 (4.1)                                                | <b>United Kingdom, Portugal</b>                                                          |                                                                                                                                                                  |

Notes: Countries with reported cases of BSE as of December 13, 2001, are in bold type. BSE was found in Austria, Czech Republic, Finland, Slovakia, and Slovenia after their BSE risk assessments had been completed. Greece, the only European Union country that did not provide the data for an assessment, reported its first case of BSE in 2001.

Source: GAO analysis of 49 BSE risk assessments.

Using information on each country's past and present potential exposure and ability to stop the spread of BSE, the scientific experts qualitatively assessed the probability that an animal in a country is infected with BSE. The assessments relied on data voluntarily supplied by the countries and on discussions with the officials familiar with BSE prevention efforts from each country on (1) the potential import of BSE via live cattle or contaminated feed, (2) the adequacy of surveillance testing to detect the presence of BSE, (3) cattle feeding and rendering practices, and (4) the use of potentially infective tissue from cattle. The scientific experts also focused on the import of infected animals and animal feed as the only initial sources of infection and on animal feed as the only source of spread. The experts did not evaluate the risks from consumer products that could contain BSE-infected tissue. The scientific experts reported using a conservative, reasonable worst-case approach, whenever data or information from countries were insufficient. Based on our analyses of the 49 risk assessments, the United States compared with the other countries as follows in terms of the potential to import BSE, surveillance testing, cattle feeding practices, and use of potentially infective tissue.

- **Potential to import BSE.** The United States acted earlier than many countries to ban the import of cattle and meat and bone meal for use in

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cattle feed from the United Kingdom and other countries where BSE had appeared. The United States was one of three countries that banned trade in cattle from the United Kingdom by 1989; six other countries did so by 1994. Nine other countries had formal bans in place by 1996, the year that the United Kingdom stopped all trade in cattle. Actions to halt trade in cattle with other countries where BSE had appeared has been variable, and the United States and some other countries phased in restrictions as cases appeared.<sup>30</sup> Also, many of the assessed countries, particularly those in South America and in Africa, had little or no trade in cattle with the United Kingdom or other countries where BSE had appeared. With regard to the import of meat and bone meal for use in cattle feed, the United States banned imports from the United Kingdom in 1991 and phased in restrictions from other countries as cases of BSE appeared. While one country banned such imports from the United Kingdom as early as 1978, due to concerns about foot and mouth disease, a few countries imported significant amounts of meat and bone meal from the United Kingdom and other BSE countries as recently as 1999.

- **Surveillance testing to detect BSE.** The United States is one of three countries that reported meeting Office International Des Epizooties (OIE)-recommended cattle testing levels by 1994.<sup>31</sup> Most countries either had not met OIE levels at the time of their assessments or met the levels after 1994. However, nine countries, including six with BSE,<sup>32</sup> had started or planned to start targeting cattle that die on farms in their surveillance testing.<sup>33</sup> In their assessments of the United States and the other countries, the scientific experts most often recommended that countries improve surveillance largely by including tests of high-risk populations, such as animals that die on farms.
- **Cattle feeding practices (feed bans).** Of the 49 countries assessed, 41 had some sort of feed ban in place; however, those bans varied on the extent that they allowed protein from mammals in feed for cattle.

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<sup>30</sup>In 1997 the United States restricted trade in cattle and cattle-derived products, among other things, from most European countries, regardless of whether the countries had BSE.

<sup>31</sup>The OIE recommends minimum testing levels for BSE surveillance in countries based on the size of the adult cattle population.

<sup>32</sup>The six countries with BSE that have targeted testing animals that die on farms are Switzerland, Ireland, Portugal, France, the Czech Republic, and Slovenia.

<sup>33</sup>The three countries that do not have BSE that have targeted testing animals that die on farms are Estonia, Cyprus, and Singapore.

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Compared to other countries with a ban, the United States and 16 others allow at least some mammalian protein in feed for cattle. For example, the United States and Canada allowed cattle feed to contain protein from horses and pigs.<sup>34</sup> The remaining 24 countries with a feed ban (including 13 that have BSE) prohibit all mammalian protein in cattle feed, although 9 allow such protein in feed for pigs and poultry. Four of the 24 countries have more stringent bans that prohibit mammalian protein in feed for all farm animals—a practice the European Commission asked its member countries to adopt on a temporary basis in 2000. In the assessments, scientific experts found that the potential for commingling prohibited protein with cattle feed existed in most countries. Enforcing existing feed bans was the second most common recommendation made by the scientific experts. In October 2001, FDA officials held a public hearing to elicit comments on, among other things, whether the existing feed ban exemptions should be modified. As of December 17, 2001, FDA had not announced whether it would propose any changes to the ban.

- **Use of potentially infective tissue.** Most of the countries assessed that had not found BSE-infected cattle, including the United States, generally allowed the sale of brains and other central nervous system tissue in human food. Nearly half of the countries with BSE prohibited this high-risk tissue in human food, and at least three countries—the United Kingdom, Ireland, and Switzerland—banned mechanically recovered beef, such as that used in meat pies, that may contain central nervous system tissue and had been linked to vCJD. However, the Court of Auditors—the investigative agency for the European Commission—found that efforts by European Union countries to remove potentially high risk tissue from the human food and animal feed chains have not been fully implemented and that the countries could not reach agreement on what constituted high-risk tissue.<sup>35</sup>

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## Conclusions

BSE and vCJD are devastating, incurable, inevitably fatal diseases. If they enter the country, they can bring dire economic consequences to the cattle and beef industries. Therefore, forceful federal prevention efforts are

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<sup>34</sup>FDA allowed these exemptions either because scientific evidence had not shown infectivity in the protein sources or because the species involved were not known to contract BSE or other TSEs.

<sup>35</sup>*Special Report No 14/2001: Follow up on the Courts' Special Report No 19/98 on BSE Together with the Commission's Replies*, Sept. 30, 2001.

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warranted to keep BSE away from U.S. shores. Nevertheless, Customs has reported significant error rates in importer-provided information for BSE-risk shipments, import controls over bulk mail are weak, and inspection capacity has not kept pace with the growth in imports. Because of these import weaknesses—and because BSE may have entered in imports from countries that have since developed the disease—BSE may be silently incubating somewhere in the United States. If that is the case, then FDA's failure to enforce the feed ban may already have placed U.S. herds and, in turn, the human food supply at risk. FDA has no clear enforcement strategy for dealing with firms that do not obey the feed ban, and it does not know what, if any, enforcement actions the states may be taking. Moreover, FDA has been using inaccurate, incomplete, and unreliable data to track and oversee feed ban compliance.

Furthermore, if there is even a slight chance that BSE is incubating in U.S. cattle, consumer groups believe that the American public has the right to know when food and other consumer products may contain central nervous system tissue that may pose a risk to the food supply. The importance of informing consumers is heightened by concerns raised in the Harvard study and by FDA's TSE Advisory Committee regarding the potential public health risk posed by consuming such tissue. In addition, although USDA has been proactive in increasing the number of cattle brains tested, it does not test many animals that die on farms, even though it recognizes that older animals and animals that die from unknown causes are at higher risk for BSE.

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## Recommendations for Executive Action

To better ensure that the United States is protected from the emergence and spread of BSE, we make the following recommendations:

In order to strengthen inspections of imported products that could pose a risk of BSE, we recommend that the Secretaries of Health and Human Services and of Agriculture, in consultation with the Commissioner of Customs, develop a coordinated strategy, including identifying resource needs.

In order to strengthen oversight and enforcement of the animal feed ban, we also recommend that the Secretary of Health and Human Services direct the Commissioner of FDA to take the following actions:

- Develop a strategy, working with states, to ensure that the information FDA needs to oversee compliance is collected and that all firms subject to the feed ban are identified and inspected in a timely fashion.

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- Develop an enforcement strategy with criteria for actions to address firms that violate the ban and time frames for reinspections to confirm that firms have taken appropriate corrective actions.
  - Track enforcement actions taken by states.
  - Ensure that, as contractors modify the inspection database, they incorporate commonly accepted data management and verification procedures so that the inspection data can be useful as a management and reporting tool.

In order to help consumers identify foods that may contain central nervous system tissue, we recommend that, as USDA evaluates whether such tissue from cattle poses a health risk, the Secretary of Agriculture

- consider whether some interim action, such as public service announcements or caution labels or signs, might be appropriate to advise consumers that certain beef cuts and beef products may contain central nervous system tissue; and
- better enforce the existing labeling requirement for products that contain beef extracted using advanced meat recovery technology and contain central nervous system tissue.

Additionally, to further help consumers identify foods and other products that may contain central nervous system tissue, we recommend that the Secretary of Health and Human Services consider whether the products it regulates, including food, cosmetics, and over-the-counter drugs, should be labeled to advise consumers that the products may contain central nervous system tissue.

In order to strengthen the BSE surveillance program, we further recommend that the Secretary of Agriculture increase the number of tests from cattle that die on farms in the BSE surveillance program.

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## Agency Comments and Our Evaluation

We provided HHS, USDA, and Customs with a draft of this report for review and comment. HHS conveyed comments from FDA. FDA concurred with our recommendations and said the report highlighted some key areas where U.S. efforts to prevent BSE could be bolstered. FDA agreed that further improvements in compliance with the feed ban would reduce the risk of introducing and spreading BSE in the United States. However, FDA did not agree that it had misled Congress and the public in reporting on compliance. It is true, as FDA pointed out, that its June 22, 2001, transmittal of compliance information to the Chairman of the House Committee on Energy and Commerce “made an effort to identify the fact

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that there were reporting problems, including incomplete data, i.e., blanks.” However, we do not believe that caveat conveyed the extent to which the information could be inaccurate. In fact, noncompliance could be much higher than FDA reported, because FDA treated all firms with blanks on compliance questions as if they were in compliance, even though some of those records contained inspector comments stating that the firms were not in compliance. FDA’s transmittal to the Chairman did not disclose this. Therefore, we believe our report is correct in characterizing FDA’s data as misleading. FDA also disagreed with our conclusion that it had not placed a high priority on oversight of the feed ban. However, throughout our review, FDA repeatedly pointed out that one individual, along with that individual’s other responsibilities, designed the feed ban program, the inspection form, and the database to monitor inspections and, until January 2001, made all decisions regarding enforcement actions. FDA’s comments and our detailed responses are presented in appendix II.

USDA largely agreed with our recommendations and said that it will address them as it seeks public comment on any proposed regulatory changes. USDA stated that a portion of the funding it received to bolster USDA’s homeland security efforts in the January 10, 2002, Defense Appropriations legislation will be used to increase BSE surveillance. It plans to more than double the number of animals sampled and to obtain more samples from animals that die on farms. USDA also acknowledged its support for providing consumers with information on product contents and for an open process that allows consumers to make choices. However, USDA stated that labeling and warning statements should be reserved for known hazards, which BSE is not in the United States. In light of the experiences in Japan and other countries that were thought to be BSE free, we believe that it would be prudent for USDA to consider taking some action to inform consumers when products may contain central nervous system or other tissue that could pose a risk if taken from a BSE-infected animal. This effort would allow American consumers to make more informed choices about the products they consume. USDA’s comments and our detailed responses are presented in appendix III.

Customs concurred with the report and the recommendations as they related to Customs. Its letter is presented in appendix IV. USDA and FDA also made technical clarifications, which we incorporated as appropriate.

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As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies to the Secretaries of Agriculture and HHS, the Commissioner of Customs, and other interested parties. We will make copies available to others upon request.

If you have any questions about this report, please contact me or Erin Lansburgh at (202) 512-3841. Key contributors to this report are listed in appendix V.

A handwritten signature in black ink, appearing to read "Lawrence J. Dyckman". The signature is fluid and cursive, with the first name "Lawrence" written in a larger, more prominent script than the last name "Dyckman".

Lawrence J. Dyckman  
Director, Natural Resources  
and Environment

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# Appendix I: Scope and Methodology

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To address the effectiveness of federal efforts to prevent BSE or its spread, we focused on oversight activities in four key areas: import controls, compliance with feed rules, meat production, and disease surveillance. This included analysis of import data for calendar years 1980 through 2000 maintained by the U.S. Department of Commerce, the Treasury Department, and the International Trade Commission; analysis of FDA data on inspections for compliance with the feed ban for fiscal years 1997 through 2001; and review of USDA slaughter and meat processing procedures and BSE surveillance documents. To assess the effectiveness of compliance with the animal feed ban, we obtained and analyzed FDA's feed inspection database to determine the accuracy, completeness, and reasonableness of key data elements, and timeliness of data entry. We interviewed FDA and feed industry officials and reviewed various FDA documents, including BSE inspection forms, assignment memorandums for conducting BSE inspections, and listings of firms that were out of compliance and firms that received FDA warning letters. In addition, we reviewed FDA contract information for evaluating the existing data in the BSE inspection database and for cleaning up the data and incorporating it into the agency's main database. We did not independently verify the accuracy of trade data maintained by the International Trade Commission or inspection data maintained by FDA. We also visited two large ports of entry to observe procedures to screen shipments for BSE-risk products, one state to observe feed ban inspections, and another state to observe slaughter and advanced meat recovery operations.

To assess the potential health risks and economic impacts of a BSE outbreak in the United States, we met or spoke with federal and state officials, as well as academic experts, industry representatives, and consumer groups, and we reviewed scientific literature. Specifically, we interviewed USDA officials responsible for oversight of imported animals and products, meat, animal disease surveillance, and agricultural statistics; FDA officials responsible for oversight of the feed ban, vaccines and blood, food regulated by FDA, dietary supplements, and imported products; officials at the U.S. Customs Service, International Trade Commission, United States Trade Representative, Department of State, Centers for Disease Control and Prevention, and National Institutes of Health. In addition, we attended public meetings on BSE-related topics sponsored by FDA, HHS, and the American Meat Institute. We also discussed risks and impacts with representatives from the National Association of State Departments of Agriculture, American Association of Feed Control Officials, Center for Science and the Public Interest, Public Citizen, American Feed Industry Association, American Meat Institute, National Cattlemen's Beef Association, National Grain and Feed

Association, National Milk Producers Federation, National Renderers Association, Inc., and the Pet Food Institute. We interviewed officials at the Harvard Center for Risk Analysis and reviewed their report, *Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States*, issued in November 2001.

To compare federal efforts to those taken by other countries, we reviewed BSE risk assessments of 49 countries, including most major U.S. trading partners, prepared by the European Commission's Scientific Steering Committee. We compared the U.S. prevention efforts with those of countries that have not reported a case of BSE and with countries in which existing prevention measures did not prevent the emergence of BSE. We also reviewed evaluations of BSE prevention programs in member states of the European Union conducted by the European Commission's Food and Veterinary Office and the European Communities' Court of Auditors. We conducted our study from April through December 2001 in accordance with generally accepted government auditing standards.

# Appendix II: Comments from the Department of Health and Human Services

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

January 9, 2002

Mr. Lawrence J. Dyckman  
Director, Resources, Community,  
and Economic Development Division  
United States General Accounting Office  
441 G Street, NW  
Washington, DC 20548

Dear Mr. Dyckman:

Please find the enclosed comments from the Food and Drug Administration on the GAO draft report entitled, Mad Cow Disease: Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts (GAO-02-183).

The Agency also provided extensive technical comments directly to your staff.

The Agency appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

A handwritten signature in black ink that reads "BA Schwetz".

Bernard A. Schwetz, D.V.M., Ph.D.  
Acting Principal Deputy Commissioner

Enclosure

**FOOD AND DRUG ADMINISTRATION COMMENTS ON THE GENERAL ACCOUNTING  
OFFICE DRAFT REPORT ENTITLED, MAD COW DISEASE: IMPROVEMENTS IN THE  
FEED BAN AND OTHER REGULATORY AREAS WOULD STRENGTHEN U.S.  
PREVENTION EFFORTS (GAO-02-183)**

The Food and Drug Administration (FDA) welcomes the General Accounting Office's (GAO) draft report on Mad Cow Disease, also referred to as Bovine Spongiform Encephalopathy (BSE), and appreciates the opportunity to review and provide comments. In addition to FDA's response to GAO's specific recommendations, we have some general comments regarding the draft report.

GENERAL COMMENTS

The overall report highlights some of the key areas where U.S. efforts to prevent BSE could be bolstered. One such area highlighted is the enforcement by FDA of its mammalian protein feed ban (21 CFR 589.2000). While GAO states that federal actions alone cannot provide total assurance to prevent a BSE outbreak in the U.S., the findings of the Harvard Risk Assessment suggest that the levels of the feed ban compliance used in that model, along with the other federal BSE initiatives, is an effective measure in reducing risk. We agree that, as both the Harvard and the GAO reports indicate, further improvements in compliance with the feed ban will further strengthen BSE prevention efforts in the U.S. and will make the present small risk of introduction and spread even smaller.

GAO's report asserts that the United States has a more permissive feed ban than other countries—one that allows cattle feed to contain proteins from horses and pigs. When the feed ban rule was promulgated in 1997, FDA realized that U.S. risk factors were not equivalent to those of many European countries. If the U.S. had similar risk factors to these countries, mainly importation of similar quantities of potentially infective meat and bone meal (MBM) and cattle, or confirmed domestic cases of BSE, then it would follow that the U.S. should have a comparable feed ban. It should be remembered that the European temporary total ban was intended to address problems of cross-contamination in an environment in which BSE was known to exist or be highly likely to exist. The total ban was not directly related to a concern about infectivity from porcine or equine origin MBM, or from feeding MBM to non-ruminants. In October 2001, FDA sponsored a public hearing in Kansas City on the feed ban to have the opportunity to discuss with various stakeholders whether changes in the feed ban rule are needed and the evidence to support any such changes. The agency is currently evaluating the written and oral comments from that public meeting.

FDA does not believe Congress or the public was misled when FDA provided compliance information to the Congress and when information was published electronically as GAO indicates in the report. In FDA's June 22, 2001, response to Chairman Tauzin, we stated that, "Although FDA provided training in completion of the checklist, some reporting problems have been noted - including failure, in some cases, to complete all appropriate questions." FDA clearly made an effort to identify the fact that there were reporting problems, including incomplete data, i.e., blanks. FDA believes we were forthright in notifying the Congressional Committee that incomplete data was an issue in some cases, and, therefore, we do not think that the term "misleading" is a fair characterization in regards to reporting to Congress. As the GAO report acknowledges, FDA recognized the need for significant improvements in its data collection systems for enforcement of the feed ban rule, initiated those improvements, and is in the process of implementing them. We discuss further details of these systems improvements in responses to specific recommendations of this report.

FDA does not agree with GAO's conclusion that FDA has not placed a high priority on oversight of the feed ban. FDA began implementing the feed ban in FY 1998, and this task included training field personnel, educating the industry, and coordinating with states on inspections. This required nearly a whole new infrastructure from that which was previously in place to conduct inspections of manufacturers

See comment 1.

See comment 2.

See comment 3.

See comment 4.

engaged in the production of medicated animal feeds. No additional resources accompanied the development of the animal feed ban regulation to support the infrastructure to put such a feed ban in place. FDA had to divert significant resources from other enforcement programs and activities implement the feed rule and to evaluate whether additional protections are necessary.

GAO states that one person in FDA's Center for Veterinary Medicine (CVM) had responsibility for feed ban management. In actuality, FDA had a number of people involved in the development and management of the database, overseeing data entry, and preparing reports from the database. Compliance staff members were and still are available to answer questions from FDA, state, and industry, as well as congressional inquiries, and assist in compliance decisions. During FY 1998, CVM reprogrammed one-third of its field inspection resources so it could determine the extent of compliance with the feed rule. FDA had additional personnel providing scientific support and input into inspectional and compliance decisions.

#### GAO RECOMMENDATIONS FOR EXECUTIVE ACTIONS

**In order to strengthen inspections of imported products that could pose a risk of BSE, we recommend that the Secretaries of Health and Human Services and of Agriculture, in conjunction with the Commissioner of Customs, develop a coordinated strategy, including identifying resource needs.**

See comment 5.

#### FDA Comment

FDA agrees with GAO's recommendations, and has recognized the need for close cooperation with both the USDA agencies and the U.S. Customs Service in order to prevent the importation of products posing the risk of BSE. FDA's Import Program is the primary tool the Agency has to "control imports" of products potentially infected with or at high risk of infection with the agent associated with BSE (i.e., products "potentially tainted with mad cow disease"). On the issue of protecting the U.S. from BSE, FDA and the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) work together in close cooperation with the U.S. Customs Service (Customs), the Federal agency with primary responsibility for administering U.S. laws relating to imports. There currently exists working groups and a senior executive interagency steering committee on BSE that includes all three organizations. FDA is a participating agency on all of these groups, and, in fact, chairs the Senior Executive Interagency Steering Committee. A major goal of these groups is to ensure that imports of products potentially contaminated with the agent associated with BSE do not get into the U.S. Following is a brief overview of these groups and specific information on cooperation on imports.

An Interagency Steering Committee of senior officials assures ongoing coordination between agencies, especially in three main areas: integrated contingency planning in case BSE or variant Creutzfeldt-Jakob Disease (vCJD) disease is found in the U.S., identification of and response to potential vulnerabilities in the U.S. to BSE and vCJD, and coordination of risk communication plans by the various agencies. Organizations represented are: the Department of Health and Human Service's Assistant Secretary for Science Policy, FDA, the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), USDA's APHIS, Foreign Agricultural Service, and Food Safety and Inspection Service (FSIS), White House Office of Science & Technology Policy, U.S. Trade Representative, Customs, Department of State, Department of Defense (DOD), National Association of State Departments of Agriculture, and the Association of American Feed Control Officials.

An interagency working group on BSE started in 1996 with USDA's APHIS, FSIS and Agricultural Research Service (ARS), FDA, NIH, CDC, and DOD represented. The purpose of the group is to share information, evaluate ideas and issues, and take suggestions back to participating agencies. Although import issues have long been addressed in the interagency working group and agencies have coordinated

actions on import issues, to further strengthen coordination of import issues, an import subgroup to the interagency workgroup was formed to investigate and make recommendations relating to import issues. This import subgroup, consisting of representatives from APHIS, FDA and Customs has been meeting since January 2001, to enhance joint procedures to prevent the importation of BSE material into the U.S.

FDA, APHIS, and Customs have coordinated their response to the potential importation of BSE-related products. After APHIS issued their prohibition on the importation of BSE materials on December 7, 2000, FDA issued Import Bulletin 71B-02 requesting that FDA's field offices notify their local APHIS offices of any import suspected of containing BSE material.

FDA continues to coordinate activities among U.S. Customs, USDA/APHIS and FDA, and is leading the efforts for developing procedures for multi-agency operations. FDA has provided FDA product codes (those used in OASIS entry screening) to APHIS for their review, and has facilitated APHIS review of Customs HTS codes (used in Customs entry screening) which resulted in Customs issuing a directive to Customs field personnel on January 4, 2000, identifying specific HTS codes for products subject to the APHIS prohibition.

APHIS prohibition of BSE risk products of animal origin is currently the first line of defense to prevent such products from entering the U.S. FDA will continue to review entries of FDA-regulated products that consist of, or may contain, such products and ensure that APHIS has been notified of and has denied entry of such products as appropriate. FDA is continuing to review the admissibility of FDA-regulated products that could pose a BSE-related risk. This tri-agency cooperative effort has led to a multi-layered review process whereby each agency utilizes the strengths of their particular entry procedures to produce a composite system which is considerably more robust than any of the component.

- 1) Prior to vessel arrival, USDA examines vessel manifests for products identified as being of animal origin and takes appropriate action, based on the origin and the presence of USDA certificates (if any.)
- 2) When the entry is presented to U.S. Customs, the HTS code is screened against the list of potential products provided by USDA, and any suspect products are referred to USDA.
- 3) Entries subject to FDA regulation are then screened by FDA's entry review system (OASIS) and subsequent review of importers and brokers documents (if necessary.) Any products suspected of containing animal ingredients from a BSE country are referred to USDA for regulatory follow-up. FDA and USDA have developed a "fax-back" system to rapidly exchange entry information to facilitate this review.

On November 14, 2001, FDA hosted a satellite broadcast between FDA, USDA, and U.S. Customs to review this multi-layered system and assess its effectiveness. Participants included both headquarters and field personnel. Additional broadcasts will occur as deemed necessary. In addition FDA, USDA, and Customs staff remain in regular communication regarding current developments and emerging BSE risks. FDA is currently developing an import sampling assignment for FDA regulated products to make sure they are in compliance with 21 CFR 589.2000. This assignment is being coordinated with the USDA. We will continue development of a coordinated strategy with USDA and Customs to strengthen controls over imported products.

**Recommendation to develop a strategy, working with states, to ensure that the information FDA needs to oversee compliance is collected and that all firms subject to the feed ban are identified and inspected in a timely fashion.**

See comment 6.

FDA Comment

FDA agrees with GAO that the development, coordination, and constant improvement of a strategy for the oversight of state inspection activities is critical to the Agency's successful enforcement of 21 C.F.R. 589.2000, and has made extensive progress in implementing this recommendation. Even before issuing the regulations in 1997, FDA recognized that the states would play a significant role in inspections. FDA adopted this compliance strategy because the states know where these facilities are, have legal authority to gain access to them, and have enforcement tools that allow immediate control over violative product.

This strategic alliance with our state partners has produced major successes in terms of the inspectional coverage of those facilities covered by 21 C.F.R. 589.2000, with approximately 80% of the over 12,000 inspections conducted by state personnel. One issue raised in the report is the number of firms that are subject to the FDA regulation that have not yet been identified and inspected. The number of 6,000 to 8,000 unlicensed feed mills used by the agency in its compliance updates was an estimate developed in 1997 by consulting with a number of trade, industry and state officials and it encompasses a broad target of potential firms that may be in business. Since 1997, the feed industry has undergone an intensive consolidation. While there remains no definitive inventory of unlicensed establishments and there is no statutory registration requirement, the best estimate of the number of unlicensed firms on a national basis, is the existing inventory of firms that have been inspected (4,835). However, the agency shares the concern expressed in the report that all firms subject to this regulation should be inspected and in compliance with the requirements. Therefore, the agency has incorporated into its state contracts a requirement for each state to inventory all the firms in the state and reconcile these firms with the FDA's official establishment inventory of firms. Any new unlicensed feed mills identified are to be inspected as a priority by the state.

The core ingredient to this strategy is the longstanding relationship between the agency and the states regarding feed manufacturing and BSE issues. The agency has steadily increased the number of states working under contract with it since the regulation became effective. The regulation became effective in August 1997. In 1998, 15 states entered into a contractual agreement with the agency followed by 16 in 1999, 18 in 2000, 27 in 2001 and 34 in 2002. Part of this contractual agreement includes using the Agency's designated information collection forms and includes requirements for timeliness for data submissions.

In addition, to the states with contracts, the agency has developed partnership agreements to conduct inspections relating to the BSE regulations. Nine states entered into partnership agreements in 1998, 12 in 1999, 11 in 2000, 10 in 2001 and 9 in 2002. The partnership agreements generally provide similar data quality and timeliness as with contracts, however, the agency has preferred contracts since they provide the most effective means to oversee the quality and effectiveness of state inspections. FDA personnel conduct inspections in states that are not covered by either a contract or partnership agreement.

The agency works very closely with the states to coordinate their respective activities in regard to BSE inspections. This includes providing training, conducting joint inspections, work planning, sharing of inspection findings, coordination of recall and enforcement actions and auditing. The agency conducts a 50-state conference call on a quarterly basis that includes updates on BSE activities. In July 2001 and again in October 2001 specific FDA-State BSE meetings were conducted to discuss inspection and enforcement strategy. These meetings are continuing on a quarterly basis with the next meeting scheduled for February 19, 2002. The agency works closely with the American Association of Feed Control Officials (AAFCO) and the National Association of State Departments of Agriculture (NASDA) on BSE issues. FDA is represented on the AAFCO BSE task force and regularly consults with its state counterparts.

See comment 7.

**Recommendation to develop an enforcement strategy with criteria for actions to address firms that violate the ban and time frames for reinspections to confirm that firms have taken appropriate corrective actions.**

FDA Comment

FDA agrees with the need for a comprehensive enforcement strategy for BSE. FDA made enforcement guidance available on its web-site since 1998, issued specific guidance regarding inspectional assignments in 2001, and FDA's Office of Enforcement provided still more guidance to the field in early 2001. It should be noted that the agency does not have a unique enforcement strategy for every regulatory program. Generally, guidance contained in the Investigators Operations Manual (IOM) and the Regulatory Procedures Manual (RPM), along with procedures in place for ad hoc case review, are used to determine the hierarchy of enforcement action, the criteria for actions to be taken, the timeframes for firms to correct violations, and the timeframes for follow up inspections to confirm that violations have been corrected. However, because of the significance of ensuring industry's compliance with the BSE regulations, FDA is developing a BSE enforcement strategy that will be incorporated into a comprehensive BSE compliance program, the Feed Manufacturing Compliance Program. The compliance program, which is currently being drafted and is anticipated to be released in this fiscal year, will add additional detail for inspections, reporting and enforcement.

From a historical perspective, it should be noted that the 1998 strategy focused initially on education and attempted to establish a cooperative approach to implementing 21 C.F.R. 589.2000. In fact, the database, mentioned throughout this report, was not developed as a compliance tool but was developed to guide the agency's efforts to evaluate effected firms knowledge of the feed ban. However, as BSE began to spread throughout Europe, the database began to assume more functionality as a source of information about general compliance with the feed rule. Thus, both our own evaluations of our efforts to date coupled with the increasing demand for data caused us to make some mid-course changes to the database. In FY 2001, as part of a contingency fund request, we asked for additional resources both for database improvements and more expansive inspectional coverage. In addition, in FY 2002 we requested and received a substantial amount of resources to help us further improve our systems and inspectional and enforcement actions.

The agency however, has progressively increased its enforcement approach starting with the January 2001 assignment to the field that provided direct reference authority for issuance of warning letters. This increased emphasis on enforcement not only included giving the field authority to issue warning letters without prior approval from headquarters, but also advised the field to begin using seizures, injunctions and prosecutions to assure industry's compliance with the 21 C.F.R. 589.2000.

The agency's current position is that the federal feed ban regulation has now been in effect for more than four years. FDA and its state feed regulatory counterparts have conducted inspections of all known renderers, protein blenders, and feed manufacturers in the U.S., as well as a number of ruminant feeders. These inspections, which were conducted to ensure industry's understanding and compliance with the regulations, have led to recalls of more than 200 adulterated or misbranded products. The regulated industry should now be fully aware of the regulation, its requirements, and the need to comply with the regulation. The agency will continue to work with industry to enhance its understanding of the agency's policies and efforts to prevent the spread of BSE to the United States. The agency is responsible for ensuring industry's adherence to the regulation; and we are committed to using enforcement actions, if necessary, to meet this goal.

See comment 8.

**Recommendation to track enforcement actions taken by states.**

FDA Comment

FDA thanks the GAO for this recommendation. FDA needs to more fully evaluate the impact of this recommendation. FDA does not have the authority to require that all states track and report to FDA enforcement actions taken. Currently, state laws differ on what inspection and enforcement authorities each state has and the ability of each state to provide such information to FDA. We do strongly support the concept of voluntarily sharing inspection and enforcement actions taken by FDA and our state partners. This was one of the primary motivators for our quarterly FDA-State regulator BSE meetings to provide a forum to share such potentially confidential information.

**Recommendation that, as contractors modify the inspection database, they incorporate commonly accepted data management and verification procedures so that the inspection data can be useful as a management and reporting tool.**

See comment 9.

The agency agrees with this recommendation and has issued a statement of work for the contractor, Booz-Allen and Hamilton Inc., that incorporates accepted data management and verification procedures into the inspection database. The origins of this initiative started in May 2001 when the Acting Principal Deputy Commissioner of FDA tasked FDA's Director, CVM, and the Associate Commissioner for Regulatory Affairs to develop solutions to upgrade the database to enhance its ability to collect, analyze, and report out data in regard to inspections for compliance with 21 CFR 589.2000. A number of workgroups were tasked with developing short-term solutions to improve data quality and timeliness in regard to BSE inspections as well as to propose longer term solutions to incorporate existing data into existing agency compliance data systems. These workgroups began meetings in May 2001 on a biweekly basis and have completed their short-term assignment. FDA anticipates implementation of the longer-term integration with user acceptance testing of the new system in mid-February and production implementation in early March 2002. Specific short-term accomplishments included the designation of BSE coordinators in each district office to track and review inspection reports submitted by state or federal investigators for accuracy and completeness, incorporation of specific instructions for completion of the checklist, defining terminology to improve comprehension of the inspection form, revising and updating the questions to improve ease of completion, and reinforcing the need for quality control of all BSE data. These short-term accomplishments were completed in September 2001. Longer-term accomplishments included incorporating the existing database of checklist information into the existing Field Accomplishment Compliance Tracking System (FACTS) that includes unique identifiers for each firm. The new process incorporates edit checks to help ensure that data entered is complete and valid. The longer term objectives included:

- Providing the FDA with a centralized repository of BSE firms in support of its activities pertaining to ruminant feed regulations.
- Supporting the FDA in identifying firms under high-risk categories and by compliance program such as BSE for which a firm may be regulated and inspected.
- Providing FDA with an integrated and centralized repository of BSE related data including inspection checklists, inspection results, sample collections and compliance activities against non-compliant firms.
- Avoiding duplication of efforts in the tracking of BSE firms in different data systems.

The requirements of the system are described below:

BSE FUNCTIONAL REQUIREMENTS

• **BSE FIRMS REQUIREMENTS**

The following Table 3-1 describes the requirements for tracking BSE firms in FACTS.

**Table 3-1: BSE Firms Requirements**

| No. | Requirement Description                                                                                                                                                                                                                                                          |
|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.  | The system shall allow OEI Coordinators and Investigators to identify firms that are subject to BSE inspections.                                                                                                                                                                 |
| 2.  | The system shall allow a firm to be identified with multiple associations of Compliance Programs for which the firm may be inspected such as BSE, Prescription Drug User Fee Act (PDUFA), High Risk for HAACP, etc. In addition, firms may be identified by their level of risk. |
| 3.  | The system shall allow users to query BSE firms based on their inspection violations such as NAI, VAI, and OAI, their State and Home District.                                                                                                                                   |
| 4.  | The system shall display summary information of the firms identified in the query results. Information shall include FEI, firm name, address, inspection status, etc.                                                                                                            |
| 5.  | The system shall provide and display the counter hits of the query and the date the query is performed.                                                                                                                                                                          |
| 6.  | The system shall provide a link to the Inspection Results for the firm highlighted on the summary list.                                                                                                                                                                          |
| 7.  | The system shall allow query results for BSE firms to be generated through an output file or printed report.                                                                                                                                                                     |
| 8.  | The system shall provide access to the CVM Information Technology team for querying and viewing BSE firms in FACTS.                                                                                                                                                              |

• **BSE INSPECTION CHECKLIST REQUIREMENTS**

The following Table 3-2 describes the requirements for tracking BSE Inspection Checklist data in FACTS.

**Table 3-2: BSE Inspection Checklist Requirements**

| No. | Requirement Description                                                                                                                                                                                             |
|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.  | The system shall allow Investigators and BSE District Coordinators to enter, update, search and view BSE Inspection Checklist data.                                                                                 |
| 2.  | The system shall allow BSE Inspection Checklist data be entered only for inspections performed under BSE PACs.                                                                                                      |
| 3.  | The system shall allow users to enter information into FACTS from the hardcopy BSE Checklist form for inspections performed by State investigators.                                                                 |
| 4.  | The system shall link the firm inspection results to the BSE Inspection Checklist data. BSE Inspection Checklist data shall be accessible from the Inspections Results screen for a given firm and inspection date. |

**Appendix II: Comments from the Department  
of Health and Human Services**

| No. | Requirement Description                                                                                                                                                                                                                    |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 5.  | The system shall allow users entering BSE inspections results to update the firm name and address information, and operational status of the firm such as 'Inactive' and 'Out of Business'.                                                |
| 6.  | The system shall allow users to identify multiple BSE firm types such as Renderer, Feeder of Ruminant, FDA Licensed Feed Mill, On Farm Feed Mixers, etc.                                                                                   |
| 7.  | The system shall automatically flag the firm as BSE high risk firm when an inspection is reported under a BSE PAC and the firm was not previously identified as a BSE firm.                                                                |
| 8.  | The system shall not allow users to set the Inspection Status to 'Completed' or 'Awaiting Endorsement' if inspection was performed under a BSE PAC and BSE Inspection Checklist data has not been entered.                                 |
| 9.  | The system shall prompt and warn users if the inspected firm is identified as high risk for BSE but no BSE PAC has been reported under the Inspection Results when setting the Inspection Status to 'Completed' or 'Awaiting Endorsement'. |
| 10. | The system shall allow all FACTS users to view BSE Inspection Results and the related BSE Inspection Checklist data.                                                                                                                       |
| 11. | The system shall provide access to the CVM Information Technology team for viewing BSE inspection results and related BSE Inspection Checklist data.                                                                                       |
| 12. | In a future implementation, the system shall allow State Investigators to enter BSE inspection results and BSE Inspection Checklist data directly into FACTS through the State Access to FACTS application (SAF).                          |

**• BSE LEGACY DATA REQUIREMENTS**

The following Table 3-3 describes the requirements for reconciling CVM-BSE Firms with ORA Firms data. It also describes the requirements for transferring BSE Checklist data from the CVM Access application into FACTS.

**Table 3-3: BSE Legacy Data Requirements**

| No. | Requirement Description                                                                                                                                             |
|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.  | BSE firms identified in the CVM legacy system shall be reconciled with ORA firms and initialized as high risk BSE firms in the ORA Firms table.                     |
| 2.  | Initial list of ORA firms to be reconciled with CVM-BSE firms shall be identified based on inspections performed under BSE PACs.                                    |
| 3.  | CVM-BSE firms not found in the ORA Firms inventory shall be added to the ORA Firms table as Workload Obligation 'Yes'.                                              |
| 4.  | BSE Checklist data from CVM legacy system shall be transferred to the corresponding BSE inspection related tables in FACTS.                                         |
| 5.  | The CVM Information Technology team shall have access to generate ad hoc reports for BSE firms and BSE Inspection Checklist data from the FACTS Reporting database. |

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The following are GAO's comments on the Department of Health and Human Services' letter dated January 9, 2002.

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## GAO Comments

1. Our report acknowledged FDA's ongoing review but also notes that FDA has not set a date to announce a decision on the exemptions. The report also recognizes that recent research suggests the possibility of "silent" incubation in species not previously thought susceptible to TSEs. This research argues against waiting until BSE is found to strengthen measures shown to prevent the spread of the disease. As FDA notes, other countries strengthened their feed bans due to concerns about commingling prohibited and non-prohibited proteins. Such commingling is a common area of noncompliance in the United States.
2. As FDA points out, its June 22, 2001, transmittal of compliance information to the Chairman of the House Committee on Energy and Commerce "made an effort to identify the fact that there were reporting problems, including incomplete data, i.e., blanks." However, we do not believe that this caveat conveyed the extent to which the information could be inaccurate. In fact, noncompliance could be much higher than FDA reported, because FDA treated all firms with blanks on compliance questions as if they were in compliance. We found that over 700 inspection records for firms that handled prohibited proteins had blanks on compliance questions. In its response to the Chairman, FDA did not disclose that some of those records contained inspector comments stating that the firms were not in compliance. Nor did FDA disclose that, at the time it responded to the Chairman, it was aware of the need for "significant improvements in its data collection system for enforcing the feed ban." As a result, we believe the data were misleading.
3. We believe that the nature and severity of the problems we found in FDA's management, oversight, and enforcement of the feed ban point to insufficient attention by FDA management. Moreover, the fact that FDA gave all headquarters responsibility to one individual—as an add-on to that individual's other duties—is further evidence of the relatively low priority FDA gave to its regulatory responsibility.
4. Although FDA's field inspectors and state inspectors carried out the inspections, FDA headquarters tracked overall compliance with the feed ban and brought together data on FDA field and state compliance inspections. In meetings with FDA officials, we were repeatedly told

that a single person had designed the program and the database to monitor inspections and, until January 2001, made all enforcement decisions. While administrative and other support may have been available for this person, the overall design and direction of feed ban implementation rested with this individual. Moreover, because FDA had no other information system, the database that individual developed was FDA's only mechanism to monitor the program and track feed ban compliance.

5. Although FDA cites a number of high-level interagency policy and technical initiatives aimed at ensuring that BSE-risk products do not enter the United States, our recommendation is grounded in problems we found at the operational level. First, the high error rates in importer-provided information found by Customs are unacceptable. Second, the ever-increasing volume of imported shipments strains inspection resources at both USDA and FDA. Third, we observed or were told by federal field personnel about problems affecting USDA and FDA staff responsible for reviewing import documentation and conducting inspections of shipments. FDA staff told us that they need integrated information technologies, dedicated inspection facilities, and additional staff to effectively address their workload.
6. We do not agree that FDA has made extensive progress implementing our recommendation, based on the fact that it periodically meets with states on BSE-related issues and has increased the number of states under contracts to conduct inspections. With regard to its progress in identifying the universe of firms subject to the ban, our work shows that FDA's efforts have not been successful. In reports, FDA states that the number of on-farm feed mills, feed blenders, and feed haulers is still unknown. FDA also asserts that the feed industry has undergone extensive consolidation, but it has not reconciled the number of firms inspected with industry or state estimates. Although FDA asserts it has incorporated into state contracts a requirement to identify firms subject to the ban, the contracts we reviewed did not include such provisions. Moreover, as recently as May 2001, we found that FDA was adding to its database information on inspections conducted in 1998 by states under contract.
7. FDA agrees on the need for a comprehensive strategy for BSE but points out that it began an enforcement strategy in 1998. However, our review shows that the strategy did not contain criteria and timeframes for specific enforcement actions against firms that fail to comply with the feed ban, as our recommendation envisions. FDA's contention that

its initial approach was to educate firms does not explain its failure to take action against firms found out of compliance on repeated inspections. Now that the feed ban has been in effect for more than 4 years, FDA points out that inspections have resulted in more than 200 recalls. However, those recalls consist of actions taken by 22 firms, one of which accounted for about 150 recalls. By FDA's own estimates, more than 300 firms are out of compliance.

8. Regardless of variations in state laws, FDA has instructed states to provide specific information on the feed ban inspections they conduct. We believe FDA should request these states to also include information on enforcement actions taken as a result of those feed ban inspections.
9. While we agree that FDA has initiated efforts to increase the integrity and usefulness of the BSE inspection data, it has not taken the steps necessary to ensure that the inspection data are accurate and complete and recorded in a timely manner. For example, neither the steps listed in FDA's letter nor the terms of the contracts we reviewed include periodic assessment of error rates or controls to help ensure data entered are complete and accurate. Moreover, FDA's response does not address how the data on past BSE inspections will be merged with the Field Accomplishment Compliance Tracking System. Many of the firms have never before been subject to FDA oversight and would not have such control numbers to effectively merge the old and new data. Also, FDA has not included steps to capture timeliness of inspections, enforcement actions, and follow up, especially for past inspections.

# Appendix III: Comments from the Department of Agriculture

United States Department of Agriculture  
Comments on the Draft General Accounting Office Report:  
*Mad Cow Disease: Improvements in the Animal Feed Ban and  
Other Regulatory Areas Would Strengthen U.S. Prevention Efforts*

## General Comments

USDA will address the recommendations as we seek public comment for any proposed regulatory changes. We believe that GAO's intent in its recommendations is to strengthen our ongoing efforts to enhance public and animal health by innovative, science-based programs and activities. We agree that the USDA should continue to work with other government agencies and to target methods of adjusting our BSE prevention system based on new scientific findings and changing world events. The USDA has worked proactively for well over a decade to exclude BSE from the United States, and we have been committed to continual improvement all along the way. Our general responses to the recommendations are as follows:

1. In order to strengthen inspections of imported products that could pose a risk of BSE, we recommend that the Secretaries of Health and Human Services and of Agriculture, in consultation with the Commissioner of Customs, develop a coordinated strategy including identifying resource needs.

Response: We agree on the importance of coordination among government agencies and have been working closely to take a holistic approach to resource needs associated with BSE prevention and surveillance. The U.S. Government coordinates and plans ongoing activities and policies regarding BSE and other TSEs through technical working groups and an inter-agency policy planning committee.

For policy-level coordination, a strategic planning group, the Inter-agency BSE Steering Committee, has several responsibilities, including:

- Planning ways to minimize the spread of BSE and identify potential vulnerabilities in present policies,
- Clarifying jurisdictional issues,
- Improving communication between Federal agencies on TSE –related matters,
- Developing contingency plans and communication strategies for the public if a case of BSE or vCJD or BSE-contaminated animal feed were found in the United States.

Policy-level representatives participate from USDA, DHHS, Customs Service, USTR, DOD, State Department, the Office of Management and Budget, the White House Office of Science and Technology, the American Association of Feed Officials, the National Association of State Departments of Agriculture, and the National Assembly of Chief Livestock Health Officials.

A great deal of coordination and planning also takes place at the technical level among scientists working on BSE issues. APHIS, ARS, CDC, Customs, DOD, FAS, FDA,

See comment 1.

See comment 2.

FSIS, and NIH participate together on the Inter-agency BSE Working Group. Technical representatives from each participating agency discuss prevention activities, new science, and changing world events and coordinate efforts across agencies. In addition, the group holds annual meetings with Canadian and Mexican technical experts from counterpart agencies that cover animal health, public health, diagnostics, and research in those countries. These annual meetings have contributed to greater understanding and harmonization of TSE control and prevention policies among the three countries, which is crucial given the amount of trade taking place among the North American countries.

2. Consider whether some interim action, such as public announcements or caution label or signs, might be appropriate to advise consumers that certain beef cuts and beef products may contain central nervous system (CNS) tissue.

Response: The Harvard Risk Assessment indicates that the United States is highly resistant to the introduction and spread of the BSE agent in United States cattle herds due to existing Federal regulatory programs. Additional measures will be used to minimize human exposure to the BSE agent in the unlikely event that it is introduced in the United States. While the risk of consuming products containing the BSE agent may be minimal in the United States, providing consumers with information on product content indicates a transparent, open process that allows consumers to make choices about the products they consume.

While products may contain CNS tissue, this does not mean such tissue is infectious for BSE. Labeling and warning statements should be reserved for known hazards.

3. In order to strengthen the BSE surveillance program, we further recommend that the Secretary of Agriculture increase the number of tests from cattle that die on farms in the BSE surveillance program.

See comment 3.

Response: On January 10, 2002, President Bush signed into law the Defense Appropriations bill, which bolstered USDA homeland security efforts. This bill included \$105 million for USDA's Animal and Plant Health Inspection Service for pest and disease exclusion, detection and monitoring. A portion of these funds are being expended to increase BSE surveillance, and indeed USDA is already well on its way to the goal of testing 12,500 cattle brains this fiscal year, up from 5,200 last year, as recommended in the Harvard risk assessment. A focus of this increased surveillance is to obtain more samples from animals that die on farms.

Modern, properly equipped laboratory facilities are required to support testing. The Secretary of Agriculture has submitted a plan to Congress requesting funds to enhance USDA's laboratory infrastructure.

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The following are GAO's comments on the Department of Agriculture's comments received January 11, 2002.

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## GAO Comments

1. While USDA states that it agrees with our recommendation, in its discussion of policy-level coordination and strategic planning among various agencies, USDA does not fully address the substance of our recommendation. Our recommendation focuses on actions to strengthen the inspection of imported products at an operational level, including identifying resources needed to do so.
2. With regard to our recommendation to consider interim action to advise consumers when products may contain central nervous system tissue, USDA acknowledged its support for providing consumers with information on product content and for an open process that allows consumers to make choices. However, USDA stated that labeling and warning statements should be reserved for known hazards. We believe that it would be prudent for USDA to consider taking some action to inform consumers when products may contain central nervous system or other tissue that could pose a risk if taken from an infected animal, especially in light of the experiences in Japan and other countries that were believed to be BSE free. This would allow consumers to make informed choices about the products they consume. Caution labels or signs, if used, could facilitate more timely removal of products that could pose a health risk if BSE were to appear.
3. USDA states that it is more than doubling the number of animals sampled in its BSE surveillance program for 2002 and that it intends to obtain more samples from animals that die on farms. USDA notes that properly equipped laboratory facilities will be needed to support the increased surveillance. Because of this uncertainty, we are keeping the recommendation.

# Appendix IV: Comments from the Customs Service



## U.S. Customs Service

### *Memorandum*

DATE: January 14, 2002  
FILE: AUD-1-OP CN

MEMORANDUM FOR LAWRENCE J. DYCKMAN  
DIRECTOR, NATURAL RESOURCES  
AND ENVIRONMENT

FROM: Director,  
Office of Planning

SUBJECT: Comments on GAO Draft Audit Report Mad Cow  
Disease: Improvements in the Animal Feed Ban  
and Other Regulatory Areas Would Strengthen  
U.S. Prevention Efforts

Thank you for providing us with a copy of your draft report entitled "Mad Cow Disease: Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts" and the opportunity to discuss the issues in this report.

We have reviewed this report and concur with the Customs related recommendation.

We have determined that the information in the audit does not warrant protection under the Freedom of Information Act.

Thank you for the opportunity to review the draft report. If you have any questions regarding this report, please contact Ms. Cecelia Neglia at (202) 927-9369.

A handwritten signature in black ink, appearing to read "William F. Riley".  
William F. Riley

TRADITION



SERVICE



HONOR

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# Appendix V: GAO Contacts and Staff Acknowledgments

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## GAO Contacts

Lawrence J. Dyckman (202) 512-3841  
Erin Lansburgh (202) 512-3017

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## Acknowledgments

In addition to those named above, Cheryl Williams, James Dishmon, Stuart Ryba, Janice Turner, Jason Holliday, Barbara Johnson, Barbara El-Osta, and Carol Herrnsstadt Shulman made key contributions to this report.

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