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Bovine Spongiform Encephalopathy (BSE, or “Mad Cow Disease”): Current and Proposed Safeguards

Updated October 13, 2005

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Summary

There have been two findings of bovine spongiform encephalopathy (BSE, or “mad cow disease”) in the United States, one identified in December 2003 in a Canadian-born cow, and one identified in June 2005 in a Texas-born cow.

Shortly after the first case of BSE was announced, U.S. Department of Agriculture (USDA) and other officials announced measures to improve existing safeguards against the introduction and spread of BSE. Previously, the major safeguards were: (1) USDA restrictions on imports of ruminants and their products from countries with BSE; (2) a ban on feeding most mammalian proteins to cattle and other ruminants, issued by the Food and Drug Administration (FDA); and (3) a targeted domestic surveillance program by USDA’s Animal and Plant Health Inspection Service (APHIS), the agency responsible for animal health monitoring and disease control.

Some argued that these safeguards were inadequate, as evidenced by the finding of the first U.S. BSE case and subsequent federal efforts to bolster protections. Most new actions announced by USDA on December 30, 2003, were under the purview of USDA’s Food Safety and Inspection Service (FSIS), responsible for the safety of most U.S. meat and poultry. These actions took effect in January 2004 and included (1) holding tested carcasses until BSE-negative results are obtained; (2) banning nonambulatory (“downer”) cattle from human food; and (3) banning certain additional animal parts from human food. USDA also increased work and spending on a national animal identification and tracking system, and undertook an enhanced BSE surveillance program, among other activities. On January 26, 2004, FDA announced planned changes to its safeguards, including additional bovine materials banned from the human foods and cosmetics it regulates; a ban on poultry litter, restaurant waste, and ruminant blood products from ruminant feed; and stricter oversight of feed manufacturing. In lieu of these changes, FDA on October 6, 2005, proposed a ban, in all types of animal feed, of some higher-risk cattle parts.

Many Members of Congress have closely followed these BSE developments. Hearings have been held on various aspects of the issue, and several legislative proposals have been introduced. Among the policy questions have been whether the expanded agency actions will protect further against BSE, whether they are scientifically sound, and what cost they will impose on consumers, taxpayers and industry. Also at issue have been whether USDA and FDA have effectively implemented and enforced the current safeguards; whether these safeguards will be sufficient to rebuild foreign markets’ confidence in the safety of U.S. beef; and whether other types of actions should be considered, among other questions. Additional U.S. BSE cases could affect these policy deliberations.

This report will be updated if significant developments occur. For regular updates on the BSE issue see CRS Issue Brief IB10127, *Mad Cow Disease: Agricultural Issues for Congress*, by Geoffrey S. Becker.

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Bovine Spongiform Encephalopathy (BSE, or “Mad Cow Disease”): Current and Proposed Safeguards

Introduction

Overview

Bovine spongiform encephalopathy (BSE or “mad cow disease”) is a fatal degenerative neurological disease of cattle. It is believed to be caused by an abnormal protein, called a prion. It is in the family of related diseases referred to as transmissible spongiform encephalopathies, or TSEs. TSEs include scrapie in sheep and goats, chronic wasting disease (CWD) in deer and elk, and Creutzfeldt-Jakob disease, or CJD, in humans. BSE is believed to be spread to cattle in feed, but not transmitted directly from one animal to another in a herd.

Worldwide, BSE has been found in more than 187,000 animals, approximately 183,000 of them in the United Kingdom (UK), where the disease was first detected in 1986. Most of the rest occurred elsewhere in Europe. Twenty-six countries have reported cases of BSE, but the total number of annual cases has declined steeply since their peak in 1992 in the UK.

BSE is thought to be transmissible to humans who eat contaminated beef, causing a variant form of CJD (variant or vCJD) that was first recognized in 1996 during the BSE outbreak in the UK. About 160 people have been diagnosed with vCJD since 1986, most of them in the UK. As of September 2005, no persons have been reported to have contracted vCJD in the United States.¹

As of October 2005, BSE had been reported in six cattle in North America, one in an imported animal and the other five in native-born animals:

- **In December 1993**, Canada reported BSE in a cow imported from the UK in 1987, around the height of the outbreak there;

¹ By contrast, the U.S. Centers for Disease Control and Prevention (CDC) has estimated that foodborne diseases cause approximately 5,000 deaths each year in the United States. Many are caused by such bacteria as *Campylobacter*, *Cryptosporidium parvum*, *Escherichia coli* O157, *Listeria*, *Salmonella*, and *Yersinia enterocolitica*. For more information and sources, see CRS Report RL31853, *Food Safety Issues in the 109th Congress*, by Donna U. Vogt.

- **On May 20, 2003**, Canada announced the first native case, found in a Black Angus beef cow that was born in Saskatchewan in March 1997 and presented for slaughter in Alberta in January 2003;
- **On December 23, 2003**, USDA announced the first U.S. case, in a Holstein dairy cow born in Washington state that was born in Alberta in April 1997;
- **On January 2, 2005**, Canada confirmed BSE in an Alberta dairy cow born in October 1996;
- **On January 11, 2005**, Canada confirmed BSE in an Alberta beef cow born in March 1998;
- **On June 24, 2005**, USDA confirmed the first native-born U.S. case, in a 12-year-old Brahma cross cow from a Texas ranch. This animal had first been killed and tested in November 2004, when BSE was initially ruled out, but subsequent retesting of brain tissue in June 2005 determined the presence of BSE.

Beef Recalls

First U.S. Case: On December 23, 2003, upon the announcement of a BSE-positive cow in Washington state, FSIS requested a voluntary recall of 10,410 pounds of meat traced to the affected animal and 19 others slaughtered and processed along with it.² The agency announced that upon reviewing slaughter records for the BSE-positive cow, it had determined that high-risk materials — the animal’s brain, spinal cord and lower intestine (“distal ileum”) — had been removed at slaughter, and that the muscle meats that passed inspection posed an “extremely low likelihood that the beef contained the infectious agent that causes BSE.” Further, the agency stated:

According to scientific evidence, the tissues of highest infectivity are the brain, spinal cord, and distal ileum. All were removed from the rest of the carcass at slaughter. Therefore, the meat produced were cuts that would not be expected to be infected or have an adverse public health impact. The recall is being conducted out of an abundance of caution.³

Most of the recalled product was distributed to stores in the West, and primarily in Oregon and Washington, according to various news reports. These reports indicated that some individuals already had consumed meat from the affected production lot, consisting of the positive cow and others slaughtered with it on December 9, 2003. USDA’s February 9, 2004, release observed that additional beef was mixed in with the originally recalled beef products at several points in the distribution network. This caused the Department to expand the recall to approximately 38,000 pounds.

Second U.S. Case: Material from the second U.S. BSE cow — first suspected of the disease in November of 2004 but not confirmed until June of 2005 — did not enter the food or feed supply, according to USDA. The cow had been delivered to a Texas plant where its remains would have been processed into pet food, according to USDA officials. However, these remains were held during testing for BSE and ultimately were incinerated. So no beef recall was necessary.

In the first U.S. case, USDA stated that virtually no risk to public health existed. However, the Department announced a voluntary recall of thousands of pounds of beef that had entered the food supply as a precautionary measure, and also conducted an extensive epidemiological investigation into how the cow likely contracted BSE

² USDA, “FSIS Update Of Recall Activities,” release, Feb. 9, 2004, on the Internet at [<http://www.fsis.usda.gov/OA/recalls/prelease/update067-2003.htm>]. A Class II recall “is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product,” according to the release. USDA does not have explicit statutory authority to mandate meat recalls or to initiate recalls on its own. However, some believe that because USDA has the power to withdraw inspection, effectively keeping meat from the food supply, such mandatory authority is implied. For more information about meat inspection and slaughter practices, see CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*, by Geoffrey S. Becker.

³ “FSIS Update Of Recall Activities.”

and whether other animals also might have the disease. During this investigation, which was officially concluded on February 9, 2004, more than 700 cattle at 11 facilities were destroyed and 255 of those were tested for BSE, all with negative results. The 255 were deemed “of interest” because they could have been from the source herd in Alberta, Canada.⁴

In the second U.S. case, USDA said that no material from the animal entered the food or feed supply. The epidemiological investigation, completed in late August 2005, attempted to trace all adult animals that left the index farm (the Texas ranch) after 1990 and all progeny born within two years of the BSE cow’s death. Sixty-seven animals still on the index farm were killed and tested, all negative for BSE. USDA determined that 200 animals of interest had left the farm, 143 of which were slaughtered. Only two others were found alive; one was not tested because its age ruled it out as a suspicious animal, and the other tested negative. Of the rest, 34 were presumed dead, one was known dead, and 20 were untraceable. USDA also was interested in two calves born to the BSE cow, but due to recordkeeping gaps, it had to trace a total of 213 calves to try to eliminate the calves of interest. None were found alive to test (most were fed and slaughtered for beef).⁵

Officials also conducted investigations into the source of the feed consumed by the infected animals, because feed containing infective ruminant material (i.e., meat and bone meal from rendered cattle) was considered the most likely source in all of the cases. All but one of the North American BSE animals were born before both the United States and Canada in 1997 instituted similar but separate bans on the use of most mammalian proteins in cattle feed; the other animal was born in Canada more than six months after the ban was implemented there.

The North American BSE reports prompted widespread debate over the effectiveness of U.S. (and Canadian) safeguards against BSE. These safeguards generally have been implemented incrementally over a number of years, not only as a response to its emergence in Great Britain and spread to other countries, but also to evolving scientific evidence about this relatively new disease, its causes, and means of transmission. Many animal health experts inside and outside of government assert that these regulatory developments do not constitute a “piecemeal” approach to addressing the BSE threat but rather an increasingly unified system of overlapping and complementary safeguards.

⁴ USDA, *Final BSE Update — Monday, February 9, 2004*. Included in the 255 were 28 of the 80 cattle that had entered the United States with the cow that tested positive for BSE. Because of a lack of records, only 28 of these 80 other imports were positively identified, contributing to the need for the wider investigation and destruction of more animals. For an overview of the current BSE situation, see CRS Issue Brief IB10127, *Mad Cow Disease: Agricultural Issues for Congress*, by Geoffrey S. Becker. For a timeline, see CRS Report RL32932, *Bovine Spongiform Encephalopathy (BSE, or “Mad Cow Disease”) in North America: A Chronology of Selected Events*, by Geoffrey S. Becker.

⁵ USDA officials had reported, on July 27, 2005, another possible case of BSE, but on August 3, 2005, they announced that confirmatory tests were negative for the disease. For the most recent information on this animal and for other USDA statements on BSE issues, see [<http://www.aphis.usda.gov/lpa/issues/bse/bse.html>].

Some critics, nonetheless, have questioned whether these safeguards are providing adequate protection against BSE. Also at issue have been whether their costs to taxpayers and industry are justified; whether such steps are defensible scientifically and will restore foreign markets' confidence in the safety of U.S. cattle and beef; and whether other types of regulatory and/or legislative actions should be considered, among other questions.

Safeguards in Place Prior to December 2003

In the wake of the far more extensive BSE outbreaks in the United Kingdom starting in 1986, U.S. officials had, by the late 1980s, begun erecting what they and beef industry leaders had termed the “three firewalls” to keep the disease out of the United States and to contain it immediately if it should occur here:

- Restrictions on imports of ruminants and their products from countries with BSE;
- A ban on feeding most mammalian proteins to cattle and other ruminants; and
- A targeted domestic surveillance program.

A number of critics argued that this system was inadequate. Government officials acknowledged that the system was not fail-safe, but asserted that it was scientifically defensible and kept the risks of BSE — to both U.S. agriculture and human health — at extremely minimal levels. Among other evidence, they cited reviews they commissioned by the Harvard School of Public Health's Center for Risk Analysis (the “Harvard study”) concluding that the safeguards were sound and would reinforce each other in preventing the spread of isolated BSE cases, should they arise.⁶ It should be noted that the Harvard study was a mathematical model that used assumptions based on existing evidence whenever possible. The study did, however, consider protections provided by each of the firewalls and a variety of scenarios in which they could be challenged.

Additional Safeguards After December 2003

Despite official reassurances that the U.S. beef supply and cattle herds were safe, the first appearance of BSE in the United States ignited a more vigorous debate on the U.S. safeguards. It also spurred USDA officials to announce, on December 30, 2003, a number of major new actions aimed at strengthening BSE protections. These additional actions, the Secretary of Agriculture stated, had been under consideration for some time prior to confirmation of the U.S. BSE case. They are discussed at greater length later in this CRS report. The new actions included:

- Holding carcasses of tested animals until BSE-negative results are obtained (notice, January 12, 2004, *Federal Register*);

⁶ Joshua Cohen et al., *Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States*, Nov. 2001, revised Oct., 2003, Harvard Center for Risk Analysis, School of Public Health, at [http://www.aphis.usda.gov/lpa/issues/bse/bse_initiatives.html]. (Hereafter cited as Cohen, Harvard study.)

- Banning nonambulatory (“downer”) cattle from entering facilities that slaughter them for human food (interim final rule, January 12, 2004, *Federal Register*);
- Keeping additional animal parts considered to be at higher risk — such as central nervous system and several other tissues of older animals — from the human food supply (interim final rule, January 12, 2004, *Federal Register*);
- Prohibiting certain meat plant practices such as air injection stunning and some types of mechanical deboning operations (interim final rule, January 12, 2004, *Federal Register*);
- Working on a national system to identify and track individual animals from their place of birth to slaughter; and
- Naming an international scientific panel to review the government’s BSE response and recommend any needed improvements (The panel’s findings are discussed below).

On January 26, 2004, FDA announced it would publish changes to its own BSE safeguards, such as banning a number of bovine materials from the human foods and cosmetics it regulates; banning poultry litter, restaurant plate waste, and ruminant blood products from ruminant feed; and tightening feed manufacturing procedures and oversight. In the July 14, 2004, *Federal Register*, FDA published jointly with USDA an advance notice of proposed rulemaking (ANPR) asking for public input “on additional measures under consideration to help prevent the spread of BSE.” Significantly, the FDA stated that it “has reached a preliminary conclusion that it should propose to remove *Specified Risk Material* (SRM) from all animal feed and is currently working on a proposal to accomplish this goal.”

On October 6, 2005, FDA published its long awaited proposed rule to tighten feed restrictions, by banning, from all animal feeds, some higher-risk cattle parts (i.e., some SRM). Some have criticized FDA over both the pace and adequacy of these proposed changes (a final rule is not anticipated until 2006). FDA officials have defended their rulemaking, noting that they needed to fully consider the latest scientific advice, and consider, in addition to the safety aspects, a rule’s impact on affected industries and on the environment. (For details on these developments, see later sections of this report).

International Review Team Findings

The international panel of BSE experts released its findings on February 4, 2004.⁷ The panel (the “International Review Team” or IRT, a subcommittee of a

⁷ USDA, *The Secretary’s Foreign Animal and Poultry Disease Advisory Committee’s Subcommittee Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE)* (continued...)

USDA advisory committee on animal diseases) concluded that it is probable that material from other infected animals imported earlier from Canada and possibly Europe has been rendered and fed to U.S. cattle, likely causing indigenous infection here. Although the panel observed that many of the government actions taken so far had been effective and conformed to international standards, it nonetheless recommended additional steps. These included further tightening animal feeding rules by FDA, and more extensive testing of cattle, to gain a better understanding of the prevalence of any BSE here.

Some BSE experts and consumer groups welcomed findings from the report. Others in the beef, feed, and related industries responded that the IRT had exaggerated the risks based on faulty assumptions, and had not properly distinguished between the BSE situation in North America and the far more extensive problems experienced in Europe. Some claimed that the panel report contradicted other scientific findings, such as a three-year examination of the U.S. BSE situation by the Harvard Center for Risk Analysis.

On February 23, 2004, a full committee of USDA advisors concurred with some of the subcommittee recommendations, and questioned others. The full committee recommended that the Harvard Center review the subcommittee's report in light of its prior risk analysis.⁸

The additional actions taken by USDA and FDA in 2004 were intended not only to reassure consumers and protect livestock health, but also to calm foreign markets, most of which had quickly banned the entry of U.S. cattle and beef products after December 23, 2003. (A number of major markets continue to do so as of September 2005.) More actions are possible; a discussion of each major safeguard follows.

Trade Restrictions

With few exceptions, countries with BSE can trace the first case(s) to importation of affected animals or infected by-products. In this section, U.S. import controls to prevent BSE are examined, within the context of internationally accepted standards. For a discussion of economic issues and impacts on the U.S. beef trade following the discovery of BSE, see CRS Report RS21709, *Mad Cow Disease and U.S. Beef Trade*, by Charles E. Hanrahan and Geoffrey S. Becker.

Worldwide, 24 countries, including the United States, had reported one or more indigenous cases of BSE, and another two reported only imported cases, as of July 2005. The United Kingdom (UK), where BSE was first reported, has experienced

⁷ (...continued)

in the United States, Feb. 4, 2004, at [<http://www.aphis.usda.gov/lpa/issues/bse/bse.html>], hereafter referred to as the USDA Subcommittee report or the IRT report.

⁸ USDA, *Report of the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases: Measures Relating to Bovine Spongiform Encephalopathy in the United States*, Feb. 23, 2004, at [<http://www.aphis.usda.gov/lpa/issues/bse/bse.html>], hereafter referred to as the USDA Advisory Committee report.

some 183,000 of the approximately 187,000 cases worldwide, and most of the rest have been found elsewhere in Europe. Annual BSE cases peaked in the UK in 1992 at more than 37,000, and have been declining there since then.⁹

As the UK was coping with a then-rising number of BSE discoveries, USDA's Animal and Plant Health Inspection Service (APHIS), the lead agency for controlling animal diseases, began to impose a series of import restrictions here. During 1989, APHIS first began to ban (by not issuing import permits) the importation of live ruminants (i.e., cattle, sheep, goats, deer, elk, buffalo) and most ruminant products from the UK and other countries where BSE has been diagnosed. On December 6, 1991, APHIS published formal rules banning the importation of ruminants, ruminant meats and related products from BSE countries (these rules essentially superseded the policy of not issuing import permits).

On December 12, 1997, as BSE cases were emerging in other parts of Europe, APHIS instituted a ban on importing ruminants and most ruminant products from all of Europe. On December 7, 2000, USDA began to prohibit imports of all rendered animal protein products, regardless of species, from Europe out of concern that feed of nonruminant origin was potentially cross-contaminated with the BSE agent. (These prohibitions on imports are distinct from the FDA's domestic feed controls, described later in this report.)¹⁰

International BSE Standards

The Organization of International Epizootics (OIE), the international animal disease control organization, has recommended that disease risk assessments be carried out to promote consistent, science-based practices and transparency in international trade. OIE provides guidance and standards for countries managing BSE within their borders, and BSE-free countries wanting to maintain their status.

These BSE guidelines are formally published within the OIE Terrestrial Animal Health Code. As for other animal diseases, the OIE standards for BSE are considered to be scientifically-based guidelines and recommendations, not hard and fast rules for trade. Veterinary authorities in individual countries are free to interpret and implement these guidelines to help prevent the introduction of foreign diseases into their domestic herds and flocks.¹¹

⁹ The UK banned the feeding of meat and bone meal (MBM) to ruminants as of July 18, 1989, and imposed a total ban on feeding of MBM to any farm animals in 1996. The OIE provides regularly updated information on countries with BSE at [http://www.oie.int/eng/info/en_esb.htm].

¹⁰ Sources for this section: various APHIS backgrounders and briefing materials, available at [<http://www.aphis.usda.gov/lpa/issues/bse/bse.html>]. Under FSIS's foreign inspection program, no establishments in countries with BSE have been permitted to ship beef to the United States.

¹¹ OIE standards are at [http://www.oie.int/eng/normes/en_norm.htm]. See also OIE, [http://www.oie.int/eng/info/en_statesb_2003.htm#evaluation].

The OIE-recommended trade conditions for such countries become increasingly restrictive as a country's BSE risk status increases. Under the OIE code, trade in some ruminant products, even from a highest-risk country, theoretically could occur so long as the exporting country followed the recommended safeguards.¹² (Until recently the OIE Code described five BSE risk categories for exporting countries, ranging from BSE free to high BSE risk; there are now three categories. See below). In practice, however, most countries — including, until August 2003, the United States — have banned most ruminant products from virtually all countries reporting even a single case of BSE.

In August 2003, the United States had announced that it, Canada, and Mexico were entering into discussions at the OIE to develop new guidance for resuming trade with countries that have reported BSE, under certain conditions. The basis for the proposal, according to U.S. officials, was that conditions for trade should be based not simply on the number of “mad cow” cases a country has reported. Rather, trade conditions should better reflect the adequacy of a country's safeguards in addressing whatever level of risk is found through a scientifically valid risk assessment. In other words, countries with strong safeguards should not be penalized because rigorous testing has found an acceptably low number of BSE cases, whereas another exporting with inadequate protections may simply not be testing for and/or reporting the disease. On May 26, 2005, the OIE agreed to new BSE trade guidelines. Included is a simplified hierarchy of risk:

- Category 1 countries are those with negligible risk, and thus subject to the least restrictive conditions for exporting ruminants and ruminant products;
- Category 2 are those countries with controlled risk; and
- Category 3 are those where the risks are unknown.

In another guideline change, OIE decided that trade in boneless muscle beef from cattle under 30 months of age should be considered to be safe, regardless of their exporting country's BSE risk profile, so long as that country has appropriate controls in place. For example, one control would be an acceptable method for determining these animals' ages and for segregating them from older animals.

The United States and Canada most likely fall within category 2, several analysts have observed. Again, as under the prior OIE guidelines for BSE, the newly modified guidelines leave it up to the exporting countries to convince importing country authorities that their beef and cattle are safe. The importing country, in turn, might or might not accept these demonstrations of safety — and might not necessarily agree to observe the OIE guidelines.

¹² OIE authorities have explained that importing countries should evaluate the source country's risk mitigation measures as a whole, not as separate items on a checklist. See for example, Declaration of David Wilson, head of the OIE International Trade Department, February 17, 2005, in the case *Ranchers Cattlemen Action Legal Fund USA vs. USDA* (CV-05-06-BLG-RFC).

If a bilateral trade disagreement over a country's BSE safeguards were to reach an international dispute panel, presumably that panel would look to the OIE guidelines for direction in resolving it. However, a dispute resolution process (such as under the Uruguay Round agreements administered by the World Trade Organization) can be lengthy and not always settled to the satisfaction of either party.

The U.S.-supported approach to BSE and trade has been put to the test recently by practical developments between the United States and its trading partners. More specifically, Canada has been seeking expansion of its permitted ruminant exports to the United States. Although the Administration and many in Congress agree with Canada, several U.S. producer groups and their allies do not (see "Canadian Beef and Cattle Imports," below). At the same time, the United States has been trying to regain access to the Japanese, Korean, and other important export markets, which have been closed since the United States found its first case of BSE in December 2003. This is despite U.S. efforts to convince them that U.S. safeguards are scientifically sound, and that they equal or exceed the internationally-recognized standards (see "Japan Beef Trade Issues" later in this section).

Canadian Beef and Cattle Imports

When Canada announced its first indigenous case of BSE on May 20, 2003, the United States immediately banned imports of live ruminants, including live cattle, and ruminant products, including beef and veal, from Canada. On August 8, 2003, the Secretary of Agriculture announced that the United States would begin to use a system of permits to import selected ruminant products from Canada, including boneless beef from cattle under 30 months of age at slaughter. This announcement was not published in the *Federal Register* as a formal notice or rule.

USDA did publish, in the November 4, 2003, *Federal Register*, proposed changes to its BSE rules that would allow the importation of certain live ruminants and ruminant products from proposed "minimal risk" regions, including Canada.¹³ The proposed rules most notably would permit imports of cattle for slaughter before 30 months of age, among other younger ruminants and various products from these animals.

However, APHIS already had been gradually expanding the types and/or definitions of eligible Canadian products, by posting these changes on its website but not widely announcing the changes or publishing them as formal rules. These actions were challenged in a lawsuit by a group of U.S. cattlemen, Ranchers Cattlemen Action Legal Fund, United Stockgrowers of America (R-CALF USA).

On April 26, 2004, a federal judge in Montana issued a temporary restraining order barring USDA from allowing imports of any beef or veal, beyond the types that the Department had announced as eligible on August 8, 2003. The judge cited concerns about the safety of animal and human health, and said that USDA had not

¹³ U.S. Dept. of Agriculture, "Exportation and importation of animals and animal products: Bovine spongiform encephalopathy; minimal risk regions and importation of commodities," 68 *Federal Register* 62386, Nov. 4, 2003.

followed appropriate rulemaking procedures.¹⁴ USDA subsequently reached a May 5, 2004, agreement with plaintiffs that it would no longer allow products beyond those listed in August 2003 (see above). Any additional Canadian products (including bone-in beef or live cattle) would not be permitted until after issuance of the final rule that was first proposed on November 4, 2003, USDA promised.

The final version of the November 4, 2003, proposal was then published in the January 4, 2005, *Federal Register*, to take effect March 7, 2005. Specifically, the rule creates a new category of “minimal risk” BSE regions — those in which BSE-infected animals have been diagnosed, but where sufficient regulatory measures have been in place to ensure that the introduction of BSE into the United States is unlikely. The rule further classifies Canada in this category. The U.S. cattle group (R-CALF USA) again sued. The same federal judge on March 2, 2005, issued a preliminary injunction halting implementation of the final rule. The judge stated in part that R-CALF had “demonstrated the numerous procedural and substantive shortcomings of the USDA’s decision to allow importation of Canadian cattle and beef. The serious irreparable harm that will occur when Canadian cattle and meat enter the U.S. and co-mingle with the U.S. meat supply justifies issuance of a preliminary injunction”¹⁵

The Administration appealed. On July 14, 2005, a three-judge panel of the U.S. Court of Appeals for the Ninth Circuit stayed the district judge’s preliminary injunction. In its opinion, the three-judge appeals panel rejected each of the major grounds for the district court’s findings. Among the appeals court’s conclusions were that “... based on the low incidence of BSE in the Canadian herd, the numerous safeguards against BSE in this country, the lack of any Canadian cattle under 30 months of age found with BSE, and the lack of any case of vCJD attributable to Canadian beef, any increased risk to human and animal health created by the Final Rule is negligible.”¹⁶

Subsequently, July 18, 2005, became the first day that live cattle began to cross the border from Canada since May 2003. From July 18 through October 1, 2005, approximately 190,000 cattle had been imported from Canada.¹⁷ In early August, a U.S. packer recalled more than 1,800 pounds of beef after authorities discovered that a 31-month-old Canadian heifer had been imported and processed into meat. The animal, which was one month older than the 30-month cutoff in the rule, had been certified as part of a 35-head shipment by veterinarians accredited by Canadian food safety authorities. In addition, USDA officials have found that more than a dozen of the Canadian cattle during the first month of imports were pregnant, also in violation

¹⁴ *Ranchers Cattlemen Action Legal Fund USA vs. USDA* (CV-04-51-BLG-RFC).

¹⁵ *Ranchers Cattlemen Action Legal Fund USA vs. USDA* (CV-05-06-BLG-RFC).

¹⁶ *Ranchers Cattlemen Action Legal Fund USA vs. USDA*, (No. 05-35264, DC No. CV05-006RFC), July 25, 2005. U.S. Court of Appeals for the Ninth Circuit. On September 9, 2005 R-CALF petitioned for a rehearing before the full appellate court.

¹⁷ Details on import requirements and procedures are posted on the USDA-APHIS website at [<http://www.aphis.usda.gov/lpa/issues/bse/bse.html>]. For the latest import data see the Agricultural Marketing Service website at [<http://www.ams.usda.gov/lsmnpubs/canada.html>].

of the rule. The incidents fueled criticism among some opponents that the border reopening was premature.

Japan Beef Trade Issues

On October 23, 2004, U.S. and Japanese negotiators announced that they had made progress in negotiations to resume two-way beef trade. According to a joint statement, the United States would certify that only beef from cattle of 20 months or younger are shipped. (Roughly 70% of the 35 million U.S. cattle each year are believed by USDA to be 20 months of age or younger, but verifiable age records may only be available for anywhere from 10% to 25% of cattle, according to various estimates.) The United States also agreed to, among other things, an expanded SRM definition, to cover cattle of *all ages*. USDA's current SRM list is somewhat different and generally covers only cattle over 30 months of age.

The announcement stated that the two countries would evaluate this interim system by July 2005 and modify it if appropriate. However, Japan, which has reported 20 cases of BSE in its own cattle herd as of mid-October 2005 had not yet accomplished what it maintains are all the necessary regulatory changes. Although Japan said that as of August 1, 2005, it had eased its testing rules so that only cattle over 20 months of age must be tested, additional policy changes to actually allow imports of U.S. beef are not yet final. These changes have involved many steps and a number of different agencies, including review by Japan's independent Food Safety Commission. Press reports have been conflicting as to how soon the market might reopen. For example, the Commission again deferred a final decision at a September 26, 2005 meeting, with members stating that they wanted more time to evaluate U.S. safety measures. Then, by mid-October 2005, Reuters and several other news sources reported there were signs that the Commission's concerns about the adequacy of U.S. safeguards had been eased. Still, most observers do not expect any U.S. beef to enter Japan before the end of the year at the earliest.

Meanwhile, U.S. rules to permit the importation of Japanese beef are advancing. USDA published, in the August 18, 2005, *Federal Register*, a proposed rule that would permit the importation of whole cuts of boneless beef from Japan, under specified conditions. USDA said the proposal is in accord with OIE guidelines and is based on a risk analysis indicating that such cuts could be safely imported. Some expressed frustration that the United States appeared to be acceding to the Japanese request without a coinciding move by Japan, where the BSE problem has been more pronounced.

Assessments of Import Safeguards

Harvard Risk Analysis. After discovery of the first Canadian BSE case in May 2003, but before the first U.S. case in December 2003, USDA officials had asked the Harvard Center for Risk Analysis to reassess its earlier analysis (completed in 2001) of the potential for an outbreak and spread of BSE in the United States. The reassessment concluded in part that "the possible introduction of BSE into the United States from Canada cannot be dismissed," but that the likelihood is very low, and U.S. protective measures by now would have contained any possible spread.

However, the reassessment also noted that a group of cattle imported into Canada from the United Kingdom in 1993 included one that was found to have BSE:

If additional animals in this group harbored the disease and were slaughtered and rendered, infectivity may have been introduced into the Canadian and U.S. cattle feed supplies before the 1997 feed ban was implemented in both countries.... If additional animals were infected, they may have been exported to the U.S. as well.... [It] appears that any related introduction of BSE into the U.S. from Canada would have been due to the import of either infected animals or contaminated feed. Imports are a plausible source of introduction of BSE into the U.S. from Canada because the American and Canadian beef industries are closely linked. During the last five years, the U.S. has on average imported over 1.2 million cattle and 185,000 tons of feed annually from Canada.¹⁸

In its February 4, 2004, report, the international panel of BSE experts which examined the first U.S. BSE case and the government's response (the "International Review Team," or IRT) observed:

... the number of cattle actually infected on the farm of origin in Canada was probably small. Indeed the index case identified in the USA may be the only infected animal from the Canadian herd of origin that survived to adulthood. However, it is probable that other infected animals have been imported from Canada and possibly also from Europe. These animals have not been detected and therefore infective material has likely been rendered, fed to cattle, and amplified within the cattle population, so that cattle in the USA have also been indigenously infected. Therefore, animals that have not been identified from the birth cohort of the index case do not represent significant additional risk for further propagation of BSE within the USA.¹⁹

Government Accountability Office. A January 2002 report by the Government Accountability Office (GAO) stated that federal actions had not ensured that all BSE-infected animals or products are excluded from the United States. GAO observed that:

[T]he United States had imported about 125 million pounds of beef (0.35% of total imported) and about 1,000 cattle (0.003% 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

¹⁸ Joshua Cohen and George M. Gray, *Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the United States from Canada*, pp. 1-2 (undated 2003 report). Harvard Center for Risk Analysis, School of Public Health. [http://www.aphis.usda.gov/lpa/issues/bse/harvard_10-3/text_wrefs.pdf].

¹⁹ *Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States*, p. 3. The expert panel, formally a subcommittee of the Secretary of Agriculture's Foreign Animal and Poultry Disease Advisory Committee, included two Swiss experts and one each from the United Kingdom, New Zealand, and the United States, the latter Dr. Will Hueston, a veterinarian who is Director of the Center for Animal Health & Food Safety at the University of Minnesota and a former FSIS official. The report can be viewed at [http://www.aphis.usda.gov/lpa/issues/bse/US_BSE_Report.pdf].

as inspection capacity that has not kept pace with the growth in imports, may allow BSE-infected products to enter the country.²⁰

GAO recommended that the Secretaries of Health and Human Services (HHS) and of Agriculture develop a coordinated strategy to strengthen import inspections, in consultation with the Commissioner of Customs. Although the GAO has since re-examined the Administration's recent record on the animal feed rules, it has not done so with regard to U.S. import protections.

Office of Inspector General. USDA's Office of Inspector General (OIG) in February 2005 published a critical report on the Department's actions on opening the border to cattle and beef products from Canada. The OIG concluded that USDA's actions were sometimes arbitrary and undocumented; policy decisions were poorly communicated to the public and between APHIS and FSIS; and controls over the regulatory process were inadequate. Explaining that APHIS used a permitting system (as opposed to formal rulemaking) for reopening the border to some Canadian products, OIG found that between August 2003 and April 2004:

APHIS issued 1,155 permits for the importation of ruminant products from Canada without ensuring that the agency had an appropriate system of internal controls to manage the process. The APHIS permit system was originally designed to allow for the import of research quantities (generally small amounts) of material into the United States. According to APHIS officials, this permit system handled approximately 400 permit requests annually. The procedures that APHIS had developed for handling permit requests for small amounts of product were not adequate to deal with the high volume of requests for large quantities of commercial use beef. The agency did not implement or finalize standard operating procedures for processing the large volume of permits. For example, APHIS did not establish controls to ensure that risk mitigation measures were consistently applied. We found that 8 of the 83 permits issued for bovine liver did not include the risk mitigation measure that the livers be from animals slaughtered after August 8, 2003. We also found that APHIS did not implement requirements to perform onsite monitoring of permit holders, Canadian facilities, or inspection personnel at U.S. ports of entry. As a result, there was reduced assurance that Canadian beef entering the United States was low-risk. Some product with questionable eligibility, as described above, entered U.S. commerce.²¹

The OIG recommended that APHIS institute procedures for communicating changes in policy to all interested parties, e.g., importers and the public, and for monitoring the consistency between agency practice and publicly stated policy. OIG also recommended, among other things, that APHIS strengthen its controls and procedures for issuing and monitoring permits for commercial quantities of products; that FSIS implement its own controls for communicating changes in the eligibility of imported products; and that FSIS implement an edit check in its import

²⁰ General Accounting Office, *Mad Cow Disease: Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts* (GAO-02-183), p. 3, Jan. 2002. (Hereafter cited as GAO Mad Cow Disease report.).

²¹ USDA, OIG, *Animal and Plant Health Inspection Service Oversight of the Importation of Beef Products from Canada*, at [<http://www.usda.gov/oig/webdocs/33601-01-HY.pdf>].

information system to identify ineligible product presented for entry into the United States. USDA agreed with and promised to implement most of the report's findings.

2003 Interagency Report. A January 2003 federal interagency report on animal disease prevention had also recommended that USDA and HHS update risk assessments, import regulations, and guidance on enforcing regulations at ports of entry.²² More specifically, it was noted that agencies need to develop guidance and plans at ports of entry to fully implement the recently enacted Animal Health Protection Act (7 U.S.C. 8301 *et seq.*). Further, the report recommended revisions to the Virus-Serum-Toxin Act to help APHIS enforce import rules on animal biologics products. The interagency report also concluded that the FDA needs additional authority to strengthen its BSE capabilities at ports of entry. The report said FDA has been considering a number of additional protective measures for FDA-regulated products, including: directing importers to use only designated ports for entry of products that might contain bovine materials; requiring certain importers to be certified in order to import such products into the United States; destroying detained products so that they cannot be re-imported at another time or port; requiring country-of-origin documentation of all imports containing mammalian or mammalian sourced ingredients; and prohibiting imports containing bovine materials from any BSE country.²³

International Review Team. In a section of its report entitled "Lessons Learned," the international panel (IRT) commended the United States for following a science-based approach to policy formulation. It further noted that the North American BSE cases "demonstrate again that exporting countries feel significant national social and financial impacts when importing countries fail to comply with international rules regarding trade." Therefore, the United States "should demonstrate leadership" by following international standards and by encouraging "the discontinuation of irrational trade barriers when countries identify their first case of BSE." At the same time, the panel concluded, the United States should "continue to act responsibly when considering export of potentially contaminated materials such as live cattle, MBM [meat and bone meal] and feed. Risk materials must be destroyed or safely utilized to protect human health, animal health, and the environment in the USA and worldwide."²⁴

Congressional Role

USDA and FDA so far have not recommended any statutory changes in import safeguards. However, Congress has demonstrated interest in trade-related aspects of the BSE situation, and several legislative proposals have emerged. In the 109th Congress, the Senate Agriculture Committee received testimony on February 3, 2005,

²² *Animal Disease Risk Assessment, Prevention, and Control Act of 2001 (PL 107-9) Final Report*, pp. 44-45, prepared by the P.L. 107-9 Federal Interagency Working Group, Jan. 2003.

²³ *Ibid.*

²⁴ *Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States*, p. 11.

from Agriculture Secretary Johanns on the impacts of BSE on U.S. cattle and beef imports and exports. The House Agriculture Committee held a hearing on March 1, 2005, on USDA's rulemaking to admit more Canadian beef and live cattle. The matter also was a major topic at Secretary Johanns' confirmation hearing and at USDA's FY2006 appropriations hearings.

On March 3, 2005, the Senate approved, 52-46, a resolution 1 (S.J.Res. 4) to disapprove USDA's January 4, 2005, Canada import rule. However, House and Presidential approval have not been anticipated. Other pending bills addressing the Canada rule include H.R. 187, to prohibit the rule "unless United States access to major markets for United States exports of cattle and beef products is equivalent or better than the access status accorded such exports as of January 1, 2003"; and H.R. 384/S. 108, to prohibit the Canada rule unless mandatory retail country of origin labeling (COOL), is implemented. The current statutorily set deadline for COOL for fresh meats is September 30, 2006. S. 294 would prohibit imports (from a minimal risk region like Canada) of meat, meat byproducts, and meat food products from bovines over 30 months old unless the Secretary reports to Congress that the region "is in full compliance with a ruminant feed ban and other [BSE] safeguards."

The sluggish pace of the Japanese negotiations has frustrated the beef industry and many Members of Congress, who believe opening the Japanese market will convince other Asian nations, including Korea, to follow suit. This frustration was evident in the Senate's passage on September 19, 2005, of a floor amendment which would prohibit implementation of USDA's August 18th Japan rule unless Japan opens its market to U.S. beef. The amendment was attached by a 72-26 vote to H.R. 2744, the FY2006 appropriation for the Department and related agencies. The House-passed version of H.R. 2744 lacks the amendment, so the provision awaits House-Senate conference. Pending in the House is a resolution introduced earlier in 2005 (H.Res. 137) which calls for economic sanctions against Japan if it does not permit U.S. beef.

The Livestock "Feed Ban"

Overview

Feed is thought to be the most common and perhaps only route of infection for BSE in cattle. The emergence of BSE in the UK is generally thought to have resulted from the feeding of rendered by-products of infected animals, including highly infectious brain tissue, to other cattle as a protein supplement. The cause of the first cases of BSE is unknown; theories include spontaneous emergence of a single case, or the anomalous transmission of the sheep scrapie agent to cattle. It is thought that the long incubation period and possibly changes in rendering and feeding practices led to amplification of the agent in the feed supply and spread of the disease for years before it was recognized in 1986.

In 1988, the UK banned the practice of feeding ruminant by-products back to ruminants. When the purported causal link between BSE and the human disease, variant Creutzfeld-Jakob disease (vCJD), was announced by the UK in 1996, the

United States added similar controls over cattle feed, to prevent spread of the disease should it emerge. The FDA Center for Veterinary Medicine (CVM), responsible for the safety of animal feeds, began prohibiting the use of most mammalian protein in feeds for ruminants in August 1997, a restriction commonly called the “feed ban.”²⁵ FDA registers and inspects renderers, feed mills, pet food manufacturers, animal feed distributors and others to ensure compliance.

In a 2002 report on the feed ban, the GAO (then called the General Accounting Office) noted that relative to other countries, U.S. surveillance and import controls were stronger, but the feed ban was more permissive.²⁶ The Harvard study concluded that the feed ban was the dominant protective firewall, and would protect against spread of BSE even if the other firewalls failed. Conversely, the study also showed that failure of the feed ban led to the greatest increase in number of BSE cases. Many also noted that certain continuing, permissible practices may nonetheless result in the feeding of rendered ruminant materials to cattle. One such potential breach is the feeding of rendered cattle to poultry and the subsequent incorporation of poultry waste (called “litter”), which may contain spilled feed, into livestock feeds.

Though in 2002 GAO limited its recommendations to improved enforcement of the existing feed ban, others suggested that the regulation itself be changed to enhance protection. The Harvard study found that if BSE were present in the United States, the greatest source of potential feed contamination would be from cattle that died on the farm and were rendered. By-products from these animals could legally be fed to non-ruminants, and the Harvard study found that if one such rendered cow were BSE-positive, the resulting release of infectivity into the feed supply could lead to new bovine cases from a single subsequent breach in the feed ban.²⁷

Many, including the GAO and the Harvard study, have noted that there are opportunities for noncompliance at many points in the feed chain, and that some may be difficult to detect, such as intermittent commingling of feeds on farms that feed cattle along with poultry and other livestock. Some experts argued that if high-risk materials were prohibited in *all* animal feeds, that cross-contamination, breaches at feeding, and the concurrent regulatory oversight of these activities would become irrelevant. Livestock industry representatives have expressed concern about potential lost income if certain beef by-products were to lose their commercial value. Yet others have voiced concern about potential environmental and other impacts of converting these by-products from their useful functions and instead designating them as waste.

Following the first domestic BSE case, the FDA in January 2004 announced imminent plans to expand feed ban restrictions. The regulation has yet to be altered

²⁵ 21 CFR Part 589.2000, published in the *Federal Register* on June 5, 1997. Canada adopted a similar but not identical ban at the same time.

²⁶ GAO, *Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts*, (GAO-02-183), January 2002.

²⁷ Cohen, Harvard study, p. 111.

as of October 2005, although FDA did publish, on October 6, 2005, its proposed rule to ban some higher-risk cattle parts from all types of animal feed.

The Feed Ban Prior to December 2003

The feed ban imposed in 1997 did not prohibit the inclusion of potential bovine risk materials such as brain and spinal cord in all animal feeds, but only those feeds intended for ruminants. FDA required that feeds containing ruminant material be labeled with a prohibition against feeding to ruminants, and that firms and farms effectively separate prohibited and non-prohibited feeds in production, shipping and feeding. The ban exempted certain bovine by-products, such as blood, milk, gelatin and restaurant plate waste, on the premise that the exempted materials posed a minimal risk of transmission.

Some also questioned the feed ban exemptions, including the practice of using rendered bovine blood in milk substitutes for calves. Based on concerns that the agent linked to the human form of BSE, vCJD, could be present in blood, another center at FDA had recommended that persons having resided in the UK be barred from blood donation in the United States, to eliminate the potential for transmission from blood donors infected in the UK and not yet showing symptoms.²⁸

In 2002, FDA published an advance notice of proposed rule-making (ANPR), stating that it was considering revising its feed regulation and seeking comments on five relevant topics: excluding from feed the brain and spinal cord from rendered animal products; use of poultry litter in cattle feed; use of pet food in ruminant feed; preventing cross-contamination; and elimination of the plate waste exemption.²⁹

The Feed Ban After the First U.S. BSE Case

On January 26, 2004, after the first U.S. BSE case was found, FDA announced the imminent publication of a new interim final rule with four provisions to further strengthen the feed ban. The provisions were to be the elimination of the exemptions for 1) blood and 2) plate waste, 3) a prohibition on feeding poultry litter to cattle, and 4) expanded measures to prevent cross-contamination of ruminant feeds with non-ruminant feeds in mills and storage facilities.³⁰

On February 3, 2004, the IRT recommended additional steps, including more stringent animal feed restrictions than those just announced by FDA. The panel

²⁸ FDA, *Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products*, Jan. 2002, at [<http://www.fda.gov/cber/gdlns/cjdvcjd.htm>].

²⁹ FDA, “Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed,” 67 *Federal Register* 67572, Nov. 6, 2002.

³⁰ U.S. Department of Health and Human Services, “Expanded ‘Mad Cow’ Safeguards Announced To Strengthen Existing Firewalls Against BSE Transmission,” press release, Jan. 26, 2004.

expanded both the proposed list of products that should be banned from ruminant feed, and also from the feed stream in general, recommending “that the current feed ban be extended to exclude all mammalian and poultry protein from all ruminant feeds,” and that “all (specified risk material, or SRM) must be excluded from all animal feed, including pet food.”³¹ The panel defined SRM more stringently than had the USDA in December 2003 in its food safety provisions, recommending the removal of high-risk tissues from all cattle older than 12 months, rather than 30 months, keeping these SRM out of both the food and feed supplies.

In the subsequent report of the full advisory committee, released on February 24, 2004, concerns were expressed about inconsistencies between the IRT recommendations and findings from the Harvard study. The Committee noted that “A major discrepancy exists with the Subcommittee’s conclusions that BSE continues to circulate, or even amplify, ... when compared with the Harvard risk assessment,” and stated that this issue of risk must be resolved before the Committee could complete its recommendations.³² The report explains the importance of establishing a robust nationwide surveillance system as a means to better understand the extent of BSE circulation. The Committee endorsed some elements of the IRT’s proposed feed ban expansions, but was silent on others.

Instead of implementing the measures it had announced in January 2004, FDA, on July 14, 2004, published an ANPR seeking information and comment about its “(tentative conclusion) that it should propose removing SRM from all animal feed to adequately control the risks associated with cross-contamination throughout feed manufacture and distribution and with intentional or unintentional misfeeding on the farm.”³³ Since this measure would eliminate the need for protections against cross-contamination or a ban on feeding of poultry litter, FDA said, those proposals would not be finalized at that time but would be reassessed in light of a possible expanded SRM ban. But the previously announced bans on feeding bovine blood and plate waste were also not finalized. FDA instead posed a number of questions to gather information and relevant scientific evidence, as well as economic, environmental and other consequences of a variety of proposals, including an SRM ban in feed.

Consumer groups and some Members of Congress criticized the FDA for its failure to move more quickly on proposed feed ban modifications. They said that decisions regarding the exemptions for blood and plate waste would not depend on a decision on SRM prohibitions, and that the blood and plate waste exemptions should therefore be promptly removed. The blood exemption has been the subject of considerable discussion. Blood is used to make formula (“milk replacer”) for newborn calves, which some experts feel may be especially susceptible to infection from small doses of the BSE agent.

³¹ USDA Subcommittee report, pp. 8-9.

³² USDA Advisory Committee report, p. 2.

³³ USDA/ HHS, “Federal Measures to Mitigate BSE Risks: Considerations for Further Action,” *Federal Register*, July 14, 2004.

The OIE continues to state, as it always has, that bovine blood and blood products in feed do not present a risk for BSE transmission.³⁴ But in its rationale for proposing a blood ban in January 2004, FDA noted recent concerns about human transmission of vCJD by blood transfusion, which suggested that infectious prions could be present in blood, while also noting that transfusion would likely pose a greater risk from minute exposures than would feeding.³⁵ In its July 2004 ANPR, the agency requested comment on the evidence of a transmission risk from blood in feed.

The FDA next published a proposal to modify the feed rule on October 6, 2005.³⁶ Comments are being accepted until December 20, 2005, after which the comments are to be evaluated and, presumably, the rule can be published in final form. The proposal would ban, from all types of animal feeds (including pet food), the following materials that would be considered higher risk (that is, SRM):

- brains and spinal cords of cattle 30 months of age and older;
- brains and spinal cords of any cattle, regardless of age, if they were not inspected and passed for human consumption;
- the entire carcass of any cattle not so inspected and passed if their brains and spinal cords have not been removed;
- tallow derived from the above higher-risk materials if it contains more than 0.15% insoluble impurities;
- mechanically separated beef derived from such higher-risk materials.

The FDA proposed rule thus defines SRM more narrowly for animal feeds than USDA-FSIS defines it for human food (see a more complete discussion of the FSIS rule in the section of this report entitled “BSE Prevention and Processing: The ‘Fourth Firewall’”). For example, the FDA proposal appears to permit skull, eyes, trigeminal ganglia, spinal cord, vertebral columns, and dorsal root ganglia of cattle 30 months of age and older, and the tonsils and part of the small intestine (distal ileum) of cattle of all ages. The October 6 proposed rule also would not ban — even from ruminant feed — blood and blood products, plate waste, and poultry litter.

Explaining its proposal, FDA stated that banning the brain and spinal cords of cattle 30 months and older would remove 90% of BSE infectivity without creating an undue burden on the rendering and meat industries. It based the 90% claim on a report by a European Union scientific panel which found that approximately 64% of the infectivity in an animal with BSE is in the brain, and 26% is in the spinal cord.

³⁴ OIE Terrestrial Animal Health Code 2005, Chapter 2.3.13, Bovine Spongiform Encephalopathy, at [http://www.oie.int/eng/normes/mcode/en_chapitre_2.3.13.htm]. OIE notes the caveat that blood and blood products pose no known risk as long as cattle are slaughtered with a method that does not result in spreading of brain matter into the blood.

³⁵ U.S. Senate Committee on Agriculture, Nutrition and Forestry, hearing on Mad Cow Disease, Jan. 27, 2004, 108th Congress, 2nd sess., comments of Lester Crawford, then Deputy Commissioner of FDA. See also CRS Report RL32269, *Transmissible Spongiform Encephalopathies (TSEs), Including “Mad Cow Disease”: Public Health and Scientific Issues*, by Sarah A. Lister and Judith A. Johnson.

³⁶ 70 *Federal Register* pp. 58570-58601.

Each of the remaining SRMs covered by the USDA-FSIS human food ban contain much smaller percentages of total infectivity, FDA said.³⁷

Even though the existing feed rule provides “strong control measures” and compliance “is high by renderers, protein blenders and feed mills,” FDA acknowledged that concerns about cross-contamination remain:

For example, without fully dedicated equipment, it may not be possible to verify that there is zero carryover of feed or feed ingredients in equipment, even where a firm’s cleanout procedures have been judged to be adequate. In addition, resource constraints limit FDA’s ability to assure full compliance by all segments of the industry that are subject to the current BSE feed regulation. For example, resources are not available to the FDA and its state counterparts to fully verify compliance on over 1 million farms where cattle are being fed.³⁸

The agency also noted concerns not only about unintentional but also intentional misfeeding of non-ruminant feed to ruminants on the farm. Financial incentives may exist to do so whenever inexpensive sources of prohibited protein are locally available, FDA concluded, adding that it believes the proposed rule would protect cattle by removing the highest risk materials even from non-ruminant feed.

In its accompanying economic analysis, FDA stated that it did consider the following options: requiring the use of dedicated facilities or equipment to keep ruminant feed separate from non-ruminant feed; bans on poultry litter, blood products and/or plate waste in ruminant feeds; and a larger list of SRM unacceptable in all feeds. It generally concluded that such additional measures are not necessary because the partial SRM ban being proposed removes so much (i.e., an estimated 90%) of BSE infectivity. However, it again asked for further comments on these options.

Stakeholder Response. Initial reactions to the proposed rule were mixed. The American Meat Institute (AMI), representing the major meat packing companies, described the approach, in part, as “the appropriate science-based policy.”³⁹ The National Cattlemen’s Beef Association (NCBA) declared that the proposals would “further enhance stringent BSE safeguards already in place and diligently enforced in the United States for the past two decades.” But NCBA said it would be analyzing the rule to ensure that it is science-based.⁴⁰

Public Citizen, a consumer advocacy organization, argued that the proposal would leave “gaping holes” in the animal feed ban by continuing to allow the use of cattle blood, poultry litter, and plate waste in cattle feed. The rule also would still allow the use of rendered cattle remains, including some nervous system tissues, in feed for hogs and poultry. Because their remains, in turn, “can be put back into cattle

³⁷ 70 *Federal Register* p. 58578.

³⁸ 70 *Federal Register* p. 58576.

³⁹ Hodges, Jim, American Meat Institute Foundation, October 6, 2005, letter in the *Atlanta Journal-Constitution*.

⁴⁰ McAdams, Jim, NCBA President, October 4, 2005, statement, accessed on the Internet at [<http://hill.beef.org/newview.asp?DocumentID=16518>].

feed, the pathways for the disease to spread will still exist.” The group also contended that the rule is less restrictive than the “complete ban on SRMs in animal feed” under development in Canada.⁴¹

Environmental and Economic Impacts of an SRM Ban in Feed

The feed ban instituted in 1997 permits rendering of ruminant by-products as long as they are not re-fed to ruminants. Proposals to ban the use of SRM imply that alternate disposal routes for these products will be needed. Proper rendering practices kill most important human and animal disease organisms (including the Foot and Mouth disease virus, Salmonella, and the anthrax organism), and can reduce BSE infectivity, while complying with existing clean air and clean water regulations. Some assert that a broader SRM ban in animal feeds could lead to disposal of these products in ways that are unsafe, with adverse health, economic and environmental impacts. Some studies have concluded that there may not at this time be safe, legal, widely-available alternatives if certain cattle and their by-products cannot enter either the slaughter-and-food system, or the rendering-and-feed system. Alternative carcass disposal options, such as burial or burning on the farm, or disposal in a landfill, may be prohibited by state or federal law, or be unavailable.⁴²

SRM removal from cattle at slaughter is already underway for all cattle over 30 months of age, in accordance with FSIS food safety measures introduced in December 2003. FDA’s proposal to ban SRM from all animal feed would alter where these by-products could go, but would not substantially alter slaughter practices. In contrast, cattle that are dead or condemned at slaughter had gone to rendering in their entirety. Careful removal of SRM from these animals would require entirely new carcass-handling arrangements at rendering, with attendant economic consequences. Economic analyses often were outdated, did not use comparable assumptions, or did not address FDA’s current proposals.⁴³ Nonetheless, impacts appeared to be substantial, with ripple effects through the rendering industry, beef and live cattle markets, and markets for alternative livestock feed ingredients such as soybeans.

⁴¹ Hauter, Wenonah, Director, Public Citizen’s Food Program, “New Animal Feed Rules Still Leave Consumers at Risk for Mad Cow Disease,” October 4, 2005 statement, accessed on the Internet at [<http://www.citizen.org/pressroom/release.cfm?ID=2058>].

⁴² See Jean E. Sander et. al., “Selected Methods of Animal Carcass Disposal,” *Journal of the American Veterinary Medical Association*, vol. 220, no. 7, pp. 1003-1005, Apr. 1, 2002, and Sparks Companies Inc., *The Rendering Industry: Economic Impact of Future Feeding Regulations*, June 2001. Several comments in response to FDA’s ANPR noted that the packing and rendering industries are exploring alternative uses for SRM such as biomass-based energy.

⁴³ See FDA, *TSE Regulatory Options Cost Analysis*, June 1997, at [http://www.fda.gov/cvm/index/bse/tse_options.htm], and Sparks Companies, Inc., *The Rendering Industry: Economic Impact of Future Feeding Regulations*, June 2001. For a description of the industry and its role in livestock production also see CRS Report RS21771, *Animal Rendering: Economics and Policy*, by Geoffrey S. Becker.

In its ANPR, FDA had sought information about the economic and environmental impacts of prohibiting SRM in all animal feeds. There have been several recent efforts to better describe and/or quantify these environmental and economic impacts. Some of these observations were reflected in comments submitted in 2004 in response to FDA's feed rule ANPR, and are described in more detail later in this section of the report.

FDA Impact Analysis.⁴⁴ FDA calculated the total costs of the proposed changes to rendering and slaughtering firms at between \$14.4 million and \$23.8 million per year over seven years. These figures include the costs of needed capital investments in slaughter and rendering facilities, plus their labor and recordkeeping expenses, lost value of cattle parts no longer eligible for feed, feed substitution costs, and disposal costs.

Disposal costs account for the single largest expense for slaughterers and renderers, estimated at \$7.7 million to nearly \$10 million per year. This expense is based on the need to dispose of from 64.3 million to 83.1 million pounds of cattle parts no longer eligible for animal feed use. In addition, cattle producers will incur additional costs of from \$1.02 million to \$2.53 million per year for disposing of from 26,000 to 64,000 cattle carcasses that could no longer be rendered, according to FDA's economic analysis.

Several analysts argue that under the proposed rule, enough potential remaining BSE infectivity (i.e. 90%) would be removed from the feed supply, leaving a much lower cost burden to industry than a broader SRM ban, which would bring only minimally greater risk reduction, and at far higher cost. For example, as the economic analysis estimates, banning all SRM plus all dead and downed cattle carcasses would have cost the industry an estimated \$195 million to \$240 million. Such a broader ban also would have had major environmental implications, because quantities of all SRM, dead and downer animals could total 2.1 billion pounds or more, and much of this would have to be incinerated, placed in landfills, or otherwise disposed of.⁴⁵

NRA/APPI Impact Analysis. Joint comments on the earlier ANPR by the National Renderers Association (NRA) and the Animal Protein Producers Industry (APPI) cited an August 2004 study commissioned by NRA. The study estimated that 1.423 billion pounds of raw material (i.e., cattle parts) generated annually by livestock slaughter facilities would be affected by a broader SRM ban, at a loss in annual sales value to the industry of \$91.6 million. Adding a disposal cost of \$74.7 million per year, the total economic loss to the industry would be \$166.3 million annually.⁴⁶

⁴⁴ FDA's Analysis of Economic Impacts begins on page 58584 of 70 *Federal Register*.

⁴⁵ This volume estimate is from FDA's *Environmental Assessment for Amendments to 21 CFR 589, Substances Prohibited From Use in Animal Food or Feed Proposed Rule*, September 26, 2005, page 29.

⁴⁶ National Renderers Association and Animal Protein Producers Industry, Response to FDA Docket No. 2004N-0264, Federal Measures to Mitigate BSE Risks: Considerations for (continued...)

The NRA/APPI response claims that extensive SRM restrictions could discourage pickup of dead animals by renderers. Their study also found that the rendering industry now processes many dead or condemned animals before they can be slaughtered for food. It estimated the lost value of this material (1.133 billion pounds annually) at another \$100.8 million per year. The NRA/APPI comment agrees that limited disposal options as a result of the rule would create a major environmental impact.

NGFA Impact Analysis. The National Grain and Feed Association (NGFA), representing grain, feed, processing, and other grain-related companies including commercial feed mills, has cited one estimate of the per-head cost of removing and disposing all SRM at \$10.70 per animal. This includes removal and segregation of SRM at the packing plant, lost value of rendered product, and disposal costs.⁴⁷

Kansas State Impact Analysis. A 2005 study by Kansas State University estimated that after implementation of the 1997 (current) feed ban, the average price of ruminant meat and bone meal (MBM) was discounted by \$15.78 per ton relative to porcine MBM, which did not change from January 1998 to December 2003. (As an example, a 1,275 pound steer, live weight, which yields 108 pounds of MBM, would be discounted 86 cents per head.) After discovery of the first U.S. cow with BSE in December 2003, during the first half of 2004, the discount reached \$58.56 per ton, or \$3.17 per steer, the study reported.⁴⁸ Banning animal consumption of all SRM would represent a further revenue loss of \$1.63 for an animal under 30 months of age and \$5.11 for animals over 30 months, the study calculated. Disposal costs would add an additional 53 cents per younger animal and \$1.66 per older animal — for a total combined cost of \$2.16 per head for fed slaughter cattle, and \$6.77 per head for older animals. For dead and downer animals, the total cost of such a rule would be \$76.50 per head, of which \$57.75 is lost MBM revenue, and \$18.75 is disposal costs. (The latter figure may be overestimated, according to the study.)

⁴⁶ (...continued)

Further Action, August 13, 2004. The study, *An Economic and Environmental Assessment of Eliminating Specified Risk Materials and Cattle Mortalities from Existing Markets*, August 2004, is on the FDA docket website as an attachment to the NRA/APPI comment.

⁴⁷ National Grain and Feed Association, Response to FDA Docket No. 2004N-0264, August 13, 2004.

⁴⁸ The Kansas study also examined per-steer costs associated with a number of other feed policy options: an end only to the exemption in the current feed ban for blood meal; an expanded definition of SRM to cover younger as well as over 30-month-old cattle; a ban on feeding any animal protein to ruminants; a ban on feeding ruminant protein to any farmed animals; and a ban on feeding any animal protein to any farmed animals. Coffey, Brian, *et al.*, Kansas State University Agricultural Experiment Station and Cooperative Extension Service, *The Economic Impact of BSE on the U.S. Beef Industry: Product Value Losses, Regulatory Costs, and Consumer Reactions*, (prepared for the Kansas Department of Agriculture), April 2005, at [http://www.agmanager.info/livestock/marketing/bulletins_2/industry/demand/EconomicImpactofBSEonUSBeefIndustry.pdf], and henceforth called the Kansas State University study.

Enforcement of the Feed Ban

The FDA Center for Veterinary Medicine has since 2001 provided periodic updates of its feed ban enforcement activity on a public website.⁴⁹ On June 20, 2005, the agency reported that it had identified and conducted initial inspections on 15,676 renderers, feed mills, protein blenders and related establishments. The agency noted that 4,093 of them (26%) handled materials prohibited for use in ruminant feeds. Of this subset, FDA reported that the vast majority were within compliance.

FDA has asserted on several occasions that feed industry compliance with the ban has reached 99%.⁵⁰ FDA bases its compliance determinations on inspection of facilities, practices, and records. At this time there is no certified test that can be used on actual ruminant feed to determine if it contains prohibited material. In its July 2004 ANPR, FDA requested information on potential test methods for detecting SRM in animal feed.⁵¹

The Government Accountability Office (GAO) has twice evaluated FDA's oversight of the feed ban, in 2002 and 2005, and reported a number of problems with administrative procedures, inspection, and enforcement.⁵² In its February 2005 report, GAO commented that FDA's 99% reported compliance rate may be misleading because the rate was based on inspections of only about 570 firms. GAO added that FDA does not include all serious violations in its calculations because it reclassifies firms as being in compliance once they correct violations, no matter how long a problem existed. For this and other reasons GAO said that FDA did not have sufficient information to calculate a compliance rate and recommended instead that the agency report enforcement information in its complete context.

Also in its 2005 report, GAO concluded that FDA had made improvements in its management of the feed ban since the 2002 GAO report, but that "various program weaknesses continue to undermine the nation's firewall against BSE." One of the weaknesses cited was the lack of a uniform approach to identify all the additional feed manufacturers, on-farm mixers, and other feed industry businesses beyond the approximately 14,800 firms the agency had identified. Among other concerns, GAO also commented that FDA had not reinspected approximately 2,800 firms for several years and therefore does not know whether they use prohibited materials in their feed, that the agency had not required a warning label on feed for export that is not intended for cattle and other ruminants, and that it had not always

⁴⁹ See FDA, "BSE — CVM Updates" page at [http://www.fda.gov/cvm/bse_updates.htm].

⁵⁰ See, for example, FDA, "FDA Statement on Rendered Products Derived From BSE Cow in Washington State," Dec. 27, 2003, at [<http://www.fda.gov/bbs/topics/NEWS/2003/NEW01000.html>].

⁵¹ Such tests would determine only if prohibited materials were present in the feed, not whether infectious BSE prions were present. No such prion test for feed exists.

⁵² GAO, *FDA's Management of the Feed Ban Has Been Improved, but Oversight Weaknesses Continue to Limit Program Effectiveness* (GAO-05-101), Feb. 2005. See also GAO, *Mad Cow Disease: Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts*, (GAO-02-183), Jan. 2002.

alerted USDA and the states when it learns that cattle may have been given prohibited feed.

The preamble to the October 6, 2005, proposed feed rule provides additional insights into compliance with the present ban. FDA stated that during FY2004 and the first half of FY2005, federal and state inspections had identified 41 instances of cross-contamination or commingling problems in firms that handle feeds containing prohibited mammalian protein. That number represented 0.4% of inspections. During the same period these inspectors found 165 instances of mislabeling (1.7%) and 604 instances of improper recordkeeping (6.3%).

Congressional Role

If Congress reviews the feed ban and its role in preventing the spread of BSE, issues that it might consider could include: the effects on the safety of the feed supply of banning “downer” animals from slaughter and thus channeling them to rendering; whether current oversight of the feed ban can accommodate this shift; the effect of changing market conditions that may result from the “downer” ban on the safety of both food and feed in the United States; and, processes to ensure the safe disposal of animal remains as new regulations are implemented. Congress may also be interested in any changes in feed ban restrictions proposed by FDA, their economic implications, their likely impact in strengthening BSE prevention, and the agency’s strategies for enforcement.

In its July 2004 ANPR, FDA requested comment on the matter of whether its authorities under the Federal Food, Drug and Cosmetic Act and the Public Health Service Act provide a legal basis to support an SRM ban. The concern is that SRM themselves are not harmful unless they were to contain a BSE or other TSE agent. Since there is not a test to identify the presence of harmful TSE agents in feed, the agency’s authority to prosecute a violation of an SRM ban may not be clear. In the 109th Congress, pending S. 73 would statutorily define “SRM,” and explicitly make it illegal for any person to introduce into interstate or foreign commerce these and other prohibited materials, among other provisions.

BSE Surveillance and Testing in Cattle

Overview

The goals of BSE surveillance are to determine the prevalence of disease in a country, and to ensure timely detection and response to cases. Surveillance is not synonymous with testing. Depending on the disease of interest, surveillance may or may not involve laboratory tests. For BSE, which is clinically similar to other neurologic diseases, surveillance requires testing, so the two activities are closely intertwined.

BSE testing is constrained by the unique nature of the disease, and this drives the design of surveillance programs. Because it evokes no immune or inflammatory response, BSE cannot be diagnosed from blood, urine, or other noninvasive samples.

And, because abnormal prions are found in abundance only in the brain and spinal cord, an animal must die or be killed to be tested. Also, research to date suggests that existing tests cannot detect the disease in an animal any time sooner than two to three months before an animal begins to exhibit clinical signs of infection.

Representatives of the USDA and some in industry have repeatedly stressed that BSE testing serves to support the surveillance program, and is not directly intended as food safety testing. Dr. Elsa Murano, then the USDA Under Secretary for Food Safety, testified in 2004 that the consistent removal of certain high-risk tissues from cattle at slaughter (described in greater detail in a subsequent section of this report) is the relevant food safety protection.⁵³ For this reason, USDA argues that a BSE surveillance program does not have to test every animal slaughtered for food, but can instead use targeted sampling to determine overall prevalence.

After the first report of BSE in a U.S. cow in December 2003, the U.S. BSE surveillance program came under fire from critics who argued that the program did not test sufficient numbers of animals or was not properly targeting high-risk animals, thereby failing to give a true picture of BSE risk in the United States. The International Review Team, in particular, commented in its report that uncertainty about domestic BSE prevalence hampered decisions about the scope of other safeguards such as the feed ban.

Some observers propose that surveillance should approximate programs in European countries, where every adult animal is being tested, or Japan, which has claimed to test every animal slaughtered. USDA has argued that it already tested many more animals than are recommended by the OIE, and that because the program targeted animals with suspicious signs, it could detect BSE if it were present at a level of one in 1 million adult cattle. (USDA reported a total of nearly 96 million cattle in the United States as of January 1, 2005.)

A complicating factor was that Japan — the top foreign customer — had demanded that all cattle be tested for BSE as a precondition for again accepting U.S. beef. Some individual firms in 2004 sought, unsuccessfully, to offer such testing in order to regain access to Japanese markets, even though most U.S. government and industry officials have asserted that such testing would be unscientific, expensive, and a bad trade precedent. (Private testing issues are discussed later in this report.)

BSE Surveillance in the United States Prior to December 2003

In 1990 APHIS began surveillance for BSE in cattle, in response to the British livestock outbreak. The program grew steadily in scope, from a few thousand animals tested annually in the mid-1990s to about 20,000 animals each year in 2002

⁵³ Testimony of Elsa Murano, Under Secretary for Food Safety, USDA, before the U.S. Congress, Senate Committee on Appropriations, *Bovine Spongiform Encephalopathy (BSE)*, hearing, 108th Cong., 2nd sess., Feb. 24, 2004 (Washington: GPO, 2004).

and 2003, out of about 35 million cattle slaughtered each year.⁵⁴ The Washington state cow was the first BSE-positive animal detected by the program.

Three high-risk groups of cattle were targeted for surveillance: animals that die on the farm, animals exhibiting neurologic signs, and a sample of “downers,” animals presenting non-ambulatory at slaughter. While the former two groups are considered high-yield populations for screening, they provided limited numbers for surveillance. Most of the samples came from downer animals. Although animals can be non-ambulatory for reasons other than neurologic disease, the sheer numbers of downed animals available and concentrated at slaughterhouses, once reported by USDA to be about 200,000 animals per year, offered a ready sample for targeted surveillance.⁵⁵

Enhanced Surveillance Program

Following the finding of BSE in December, 2003, USDA began revising its surveillance program. Among other factors, advisory committee recommendations and negotiations with trading partners affected proposals to expand BSE surveillance.

The “Downer” Ban and Impact on Surveillance. Following the first finding of a cow with BSE, USDA announced, on December 30, 2003, a ban on downer cattle in the human food supply. Some Members of Congress and industry representatives had previously expressed concern that a downer ban, by removing economic incentives that brought animals into the testing program, could force this high-yield population “under the radar” and compromise BSE surveillance. (The rationale for the ban and its potential merits are discussed in a subsequent section on slaughter and processing practices, the “Fourth Firewall” of food safety protections.)

In House and Senate hearings following this first BSE discovery, USDA officials were asked how they were finding and testing downed cattle, since they were no longer being brought to slaughter plants. Officials did not provide concrete information about downer animals tested since the ban, but acknowledged the importance of finding and testing these animals at new points of concentration such as rendering plants.⁵⁶

Initial Proposals for Expanded BSE Testing. After the discovery of BSE in Canada in May 2003, but before the finding in the United States in December 2003, USDA had planned to nearly double surveillance to 38,000 animals tested per year. Initially this was modified only slightly after the discovery of the domestic case

⁵⁴ Additional information on the APHIS BSE cattle surveillance program is available at [<http://www.aphis.usda.gov/lpa/issues/bse/bse-surveillance.html>].

⁵⁵ USDA (at 9 CFR §309.2(b) defines nonambulatory or “downer” cattle as those “that cannot rise from a recumbent position or that cannot walk,” More recent USDA surveys also have estimated that there may be as many as 450,000 or more nonambulatory cattle and calves on U.S. farms and ranches. See “Ban on ‘Downer’ Cattle” later in this report.

⁵⁶ See transcripts of U.S. House of Representatives Committee on Agriculture, Hearing on Mad Cow Disease Response, Jan. 21, 2004, and U.S. Senate Committee on Agriculture Nutrition and Forestry, Hearing on Mad Cow Disease, Jan. 27, 2004, 108th Congr., 2nd Sess.

of BSE. The Administration's FY2005 budget for APHIS proposed the testing of 40,000 animals.

On February 4, 2004, the International Review Team recommended that USDA continue to focus its surveillance on high-risk animals, but that *all* such animals over 30 months of age be tested, along with a sample of healthy animals over 30 months of age. The subcommittee report did not state how many animals this proposal might encompass, but a USDA official at the time estimated it at 600,000 per year. In its subsequent report to the Secretary, the full advisory committee also urged expanded surveillance but fell short of recommending that all animals of any subgroups must be tested, saying only that USDA should focus its efforts on high risk animals — cattle showing symptoms of central nervous system disease, non-ambulatory cattle, and cattle that die on farms.⁵⁷

One-Time BSE “Enhanced Surveillance Program”. On March 15, 2004, USDA announced a one-time expansion of its BSE surveillance activities. The Department said it would test as many cattle as possible in the high-risk population, animals with signs of a central nervous system disorder, animals that are nonambulatory, or animals that are dead for reasons that are unknown.⁵⁸ Enhanced surveillance was to occur over a 12 to 18 month period and was expected to test between 200,000 and 300,000 animals. USDA did not set a fixed target for the number of tests. Instead, it stated its intention to test all animals in the high risk groups (estimated to total 446,000 on an annual basis), and noted that finding and testing as many of them as possible would increase the certainty that the program would identify BSE if it was present in the United States. Officials stated that if 268,500 high-risk animals were to be sampled, APHIS could detect BSE at the rate of 1 positive in 10 million adult cattle with a 99 percent confidence level.

In addition, USDA announced plans to test a sample (about 20,000) of the apparently healthy older cattle population, including animals that were born prior to institution of the feed ban.

Enhanced surveillance of the high-risk population began on June 1, 2004, and has required a number of expansions of USDA activities.⁵⁹ USDA set sampling goals for each state, noting that these were estimates based on cattle population data.⁶⁰ The

⁵⁷ USDA, *Report of the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases: Measures Relating to Bovine Spongiform Encephalopathy in the United States*, Feb. 23, 2004, at [<http://www.aphis.usda.gov/lpa/issues/bse/bse.html>].

⁵⁸ See USDA, “Veneman Announces Expanded BSE Surveillance Program,” press release, Mar. 15, 2004, and “Transcript of Technical Briefing with Bill Hawks, Under Secretary for Marketing and Regulatory Services, Dr. Elsa Murano, Under Secretary for Food Safety, Dr. Ron DeHaven, Administrator, Animal Plant Health Inspection Service, Dr. Barbara Masters, Acting Administrator, Food Safety Inspection Service,” May 21, 2004

⁵⁹ See APHIS, “Bovine Spongiform Encephalopathy (BSE) Surveillance Plan,” March 15, 2004, at [http://www.aphis.usda.gov/lpa/issues/bse/BSE_Surveil_Plan03-15-04.pdf].

⁶⁰ See APHIS, “Examples of Geographic Distributions of Sample Collections for the BSE Surveillance Plan,” at [<http://www.aphis.usda.gov/lpa/issues/bse/>]
(continued...)

program depends on the use of APHIS-approved “rapid tests” for screening at geographically dispersed laboratories, so negative results can be obtained in 12-72 hours, minimizing the burden for holding carcasses pending negative test results. FSIS veterinarians, whose daily presence is already required for ante- and post-mortem inspections at slaughter plants, have collected brain samples from animals sampled at slaughter, freeing APHIS staff to collect samples at farms, rendering plants, and other points of concentration of high-risk animals.⁶¹

The approved rapid tests are for screening purposes. The policy is to follow up any screening test that reacts as positive for BSE — which USDA has termed an “inconclusive” result — with confirmatory testing at USDA’s National Veterinary Services Laboratory (NVSL) in Ames, Iowa. The OIE recognizes either the immunohistochemistry (IHC) test, or a version of the *Western blot* test, for confirmatory purposes. However, until recently (see below), most official USDA and cattle industry statements referred only to the IHC test as being the “gold standard” confirmatory test.

News reports in 2004, noting the slow pace of the program in its first month, had mentioned initial delays in setting up the national laboratory network, and educating farmers, veterinarians, animal haulers and renderers about the new program and how to submit animals for testing.⁶² USDA officials and representatives of the rendering industry now maintain that sufficient numbers of animals have been obtained through voluntary incentives, particularly at facilities that render and process animals into non-human food uses (e.g., so called “4D” plants which collect dead, dying, disabled, and diseased animals). USDA has agreements with such plants that pay up to \$100 per carcass for storage until BSE test results are complete; up to \$40 per sample to cover collection of the brain stem, data processing, and submission of samples; and up to \$10 per sample for removal and presentation of the head at facilities where a trained collector is not available immediately.⁶³

After 71 weeks through October 9, 2005, USDA reported that it had completed testing of more than 491,000 animals.⁶⁴ Three of these animals tested “inconclusive” on screening; two were subsequently determined to be negative on the IHC test. The third was determined to be negative in an initial round of confirmatory testing but later was found to be positive for BSE, becoming the first native-born U.S. case. (Discussion of the reporting of inconclusive findings follows in subsequent sections.)

⁶⁰ (...continued)

bse_geo_dist_samples.html].

⁶¹ In March 2004, USDA finalized a rule clarifying its authority to enter such establishments and conduct sampling in furtherance of its animal disease control efforts. USDA, APHIS, “Blood and Tissue Collection at Slaughtering and Rendering Establishments,” 69 *Federal Register* 10137, Mar. 4, 2004.

⁶² For example, see Andy Dworkin, *Testing Protocols for Mad Cow a Complex Process*, The Oregonian, July 7, 2004.

⁶³ Personal communications with National Renderers Association, July 11, 2005, and with APHIS veterinarians, July 13, 2005.

⁶⁴ See APHIS BSE testing results at [http://www.aphis.usda.gov/lpa/issues/bse_testing/].

As of mid-October 2005, it was unclear when USDA would terminate this special surveillance program, although some observers have speculated it could end at the close of calendar 2005. The Department already has exceeded both the number of animals that some observers had once predicted would be tested and its own estimate of the high-risk population. The single BSE-positive animal from this testing was found in November 2004 but not announced until June 2005 (see below for details). Some analysts have speculated that it would be politically awkward for officials to call an end to the program so soon after this case. Also, USDA did not announce the start of testing of the 20,000 healthy cattle until late August 2005; this segment of the program was supposed to get under way in the fall of 2005.

Surveillance Program Criticisms. USDA's surveillance program has garnered considerable criticism. On February 17, 2004, the House Committee on Government Reform held a hearing to question USDA officials and others, following the Committee's month-long investigation into the circumstances surrounding testing of the Washington state cow (December 2003). The Committee Chairman and Ranking Member released a letter to the Secretary of Agriculture the same day, in which they questioned whether the cow was in fact non-ambulatory when it was selected for testing.⁶⁵ The committee raised questions relevant to the design of an improved surveillance program. If in fact the animal were not a downer but rather an apparently healthy cow with BSE, had the surveillance program been targeted effectively, and could Congress be confident that the disease is very rare in the United States?

On April 27, 2004, a cow showing signs of a central nervous system disease at a Texas slaughter plant was condemned for human food use by FSIS, and the FSIS veterinarian on site recommended that it be tested for BSE. However, a higher-level APHIS official determined that it should not be tested, so the animal's carcass was sent to a rendering plant for processing into inedible byproducts. This led some critics to charge that the Department had "covered up" a possible case of BSE.

Such testing concerns became subjects of investigations by USDA's Inspector General (IG). She presented her preliminary findings at a joint hearing held July 14, 2004, by the House Government Reform and Agriculture Committees. The IG told the committees that in the case of the Washington state cow, her office had "...found no instances where USDA personnel knowingly conveyed false or misleading information, or engaged in intentional misconduct." The investigation, however, "...did reveal procedural errors and inconsistent descriptions that gave rise to some of the public concerns that the identification of the BSE-positive cow may have been mishandled."⁶⁶

⁶⁵ Letter from Reps. Tom Davis and Henry Waxman to Agriculture Secretary Veneman concerning "Mad Cow" Disease, Feb. 17, 2004, and related documents, available at [<http://reform.house.gov/GovReform/News/DocumentSingle.aspx?DocumentID=2497>].

⁶⁶ Testimony of Phyllis K. Fong, USDA Inspector General, "A Review of the USDA's Expanded BSE Cattle Surveillance Program," joint hearing of the House Committee on Government Reform and the House Committee on Agriculture, July 14, 2004.

The IG testified that her office also found “no substantive evidence” that USDA officials provided any “false information or engaged in intentional misconduct” in the Texas case. However, the IG cited inconsistencies in officials’ understanding of BSE sampling and carcass handling procedures. As a result, FSIS and APHIS on May 5, 2004, had announced a new joint policy to clarify these procedures and responsibilities, she observed.⁶⁷

The IG also presented the preliminary results of an audit of the Department’s expanded surveillance plan, finding a number of inconsistencies. For example, the IG stated that surveillance findings may be unreliable because the plan: is not truly random since participation is voluntary; assumes that BSE is confined only to the high-risk cattle population while other studies show that healthy-looking animals could have BSE; does not include a process for obtaining animals that die on farms; cannot obtain a statistically appropriate geographical representation of the cattle population; and does not allow APHIS to find and test enough cattle in the high-risk population. The final OIG report, issued in late August 2004, generally paralleled the preliminary findings.⁶⁸

The Secretary of Agriculture and other USDA officials at the July 2004 hearing defended the surveillance program, noting among other things that the OIG observations were based on the plan before it was implemented and that many of the report’s recommendations had already been addressed. APHIS was receiving a representative mix of samples from all locations, reaching deeply into the higher-risk cattle population, and the statistical basis for the sampling was sound, officials asserted. They added that adjustments had been made as the result of ongoing assessments of the program. The OIG has continued to assess the testing program. It was at the IG’s insistence that APHIS researchers re-tested tissue from a cow that first was determined to be negative, and then ultimately positive for BSE (see below).

“Inconclusive” Test Results. In June 2004, shortly after the enhanced surveillance program was begun, USDA announced two inconclusive findings for BSE which were later determined to be negative. The finding announced on June 25, 2004, was confirmed negative on June 30. The finding announced on June 29, 2004, was confirmed negative on July 2. USDA reported each inconclusive finding but did not provide information on the location or any other details about the animals. According to policy instituted in December 2003, the carcasses of the two affected animals were held pending test results, and were later destroyed.

Cattle market prices fell in response to news of the inconclusive findings, but rebounded to varying degrees once the conclusive negative results were announced. USDA was criticized both for releasing too much and too little information, though some industry groups said the policy to release partial information struck the right balance. During the wait for final results, USDA officials repeated the assertion that rumors generated by withholding information while an inconclusive test were

⁶⁷ *Ibid.*

⁶⁸ USDA, Office of Inspector General Audit Report, *Animal and Plant Health Inspection Service and Food Safety and Inspection Service Bovine (BSE) Surveillance Program — Phase I*, Report No. 50601-9-KC, August 2004.

pending would be just as damaging to markets as would the release of preliminary findings. They also reiterated that given the extent of the enhanced surveillance problem, some false positive screening tests were to be expected and, possibly, additional true cases of BSE could surface as well.

APHIS's policy had been to announce an inconclusive result if an initial screening test were positive. APHIS changed this policy after the controversy and market uncertainties which followed the first two inconclusive announcements. On August 4, 2004, the agency stated that it would announce a result as inconclusive (i.e., testing positive in the screen but not yet confirmed in follow-up testing) only if a second screening test on the sample were also positive.

Confirmatory Testing Methods. With this newer policy in place, APHIS announced another inconclusive finding on November 18, 2004. As with the previous two announcements, the agency did not provide details on the animal's age or location, although some unconfirmed press reports speculated that it was a 12-year-old cow in Texas. Cattle market prices again fell steeply, as did stock prices for such chains as McDonald's Corporation and Wendy's International.⁶⁹

Five days later, on November 23, APHIS reported that confirmatory testing at its Ames NVSL facility had found the sample to be negative for BSE. Ames had run the

immunohistochemistry (IHC) test, an internationally-recognized gold standard test.... Because the November 18 screening test results were reactive in both the first and second screens, NVSL scientists made the recommendation to run the IHC test a second time.... Negative results make us confident that the animal in question is indeed negative for BSE.⁷⁰

Following this announcement, live cattle prices rebounded dramatically, enabling cattle producers to more than recoup their earlier losses at the expense of buyers (i.e., meat packers) who paid the higher prices, thus incurring their own operating losses.⁷¹

When its November 2004 IHC test came back negative for BSE, USDA did not run the other OIE-recognized confirmatory test, the Western blot, or send tissue to the World Reference Laboratory in Weybridge, England, to evaluate the sample. By contrast, USDA did run the Western blot test and consult with Weybridge to confirm the BSE-positive result in December 2003.

In the spring of 2005, USDA's IG asked APHIS to retest the samples from the three 2004 "inconclusives," because of its concerns about the original testing. For example, the November 2004 sample should not have been frozen; and there were paperwork reporting problems, it was reported. This OIG-requested retesting in early

⁶⁹ See for example "New mad cow case possible," *The Kansas City Star*; and "Mad cow test news again hits producers; As future prices fall, officials industry promote safety of U.S. beef," *The Fort Worth Star Telegram*, both November 19, 2004.

⁷⁰ Statement by Clifford, John, APHIS Deputy Administrator, November 23, 2004.

⁷¹ "Market Rebounds With a Vengeance," *Cattle Buyers Weekly*, November 29, 2004.

June 2005 was done by USDA scientists (reportedly without the direct knowledge of the Secretary of Agriculture) using the Western blot method. When this test showed the presence of BSE in the November 2004 sample, the Secretary of Agriculture made the result public on June 10, calling it a “weak positive.” USDA officials delivered a sample from the animal to Weybridge for further testing and also began their own additional testing.

The Weybridge lab conducted a series of analyses on the sample. All but one detected BSE, including another IHC test. The Secretary of Agriculture explained that the positive IHC test by Weybridge used a different procedure than the one used in November 2004 by USDA at Ames. A Weybridge scientist, Dr. Danny Matthews, confirmed that “there are no two laboratories around the world that are using identical IHC methods and not a single test that you can take off the shelf,” so that tests may not perform comparably.⁷²

USDA officials also revealed on June 24, 2005, that a USDA laboratory had actually found possible BSE in the animal when it applied an “experimental” version of the IHC test back in November 2004. However, they asserted that the laboratory had not reported this result because the test method had not been validated for regulatory use.⁷³ This information, and the positive BSE confirmation by Weybridge, provoked strong criticism by consumer groups and several Members of Congress. They expressed renewed skepticism about the adequacy of USDA’s testing methods and procedures; about department officials’ efforts to communicate all relevant information about BSE in the United States; and about earlier assurances that the IHC was “the gold standard.”

Secretary Johanns, who replaced Ann Veneman as Secretary earlier in 2005, promised on June 24, 2005, that henceforth the Department would conduct two types of confirmatory tests — the IHC and the Western blot — if any screening tests were to yield an “inconclusive” result. If either confirmatory test is positive, a positive result will be reported, he announced. But Secretary Johanns also defended USDA’s surveillance program, stating, “Science is ever evolving. It is not static. And as we learn more we apply the knowledge.” USDA is carefully reviewing its testing to ensure that it is “in line with the very latest science,” he said, adding, “perhaps the most important thing to remember is that we’ve only needed this test three times since our enhanced surveillance began.”⁷⁴

In all three instances of “inconclusives,” the so-called Bio-Rad ELISA test was used as the screening test. Bio-Rad Laboratories has previously said that its test detected a case of BSE in a 23-month old bull in Japan, shown to be positive on a

⁷² Transcript of media conference, June 24, 2005, at [<http://www.usda.gov/wps/portal/usdahome>]. For an explanation of the two OIE-approved tests, see the June 2005 APHIS factsheet at [http://www.aphis.usda.gov/lpa/pubs/fsheet_faq_notice/faq_BSE_confirmtests.pdf].

⁷³ *Ibid.*

⁷⁴ Transcript of media conference, June 24, 2005. The APHIS website also has posted a series of factsheets explaining in more detail the confirmatory testing methods and how they were applied in this case.

Western blot test, but negative on immunohistochemistry (IHC) — a case that Japan reported to OIE as “atypical BSE.”⁷⁵ It also has been reported that the Bio-Rad screening test has been found to be “false positive” (i.e., positive in the screening test but negative upon confirmatory testing) at a rate of about one in a thousand times.⁷⁶ The variety of testing schemes for BSE and seemingly conflicting statements about their accuracy illustrates that laboratory science itself, and international consensus on it, continue to evolve.

Private BSE Testing: The Creekstone Decision

On January 13, 2004, APHIS requested permit and license applications for rapid BSE tests to be used to support the surveillance program. Subsequently, APHIS approved five commercial test kits for use, and has certified 12 laboratories to conduct these tests, all existing university or state-government based animal diagnostic labs that are working under contract to USDA. This arrangement effectively restricts BSE testing to USDA and its contract labs.

Early in 2004, Creekstone Farms Premium Beef, a private specialty producer of Black Angus beef, applied to USDA to conduct BSE testing (using a USDA-approved test) on every animal it slaughtered, in hopes of reclaiming Japanese customers lost following the discovery of BSE. Denying Creekstone’s request, USDA stated that approved BSE tests had only been licensed for animal health surveillance purposes and “the test as proposed by Creekstone would have implied a consumer safety aspect that is not scientifically warranted.”⁷⁷ The Creekstone decision prompted a range of reactions. Critics, including consumer advocates, decried the decision as free-market interference and a lost opportunity for additional BSE testing at private expense. They also noted that other USDA programs permit label claims for marketing rather than food safety purposes, including the “organic” label and a number of certified beef and quality system assessment programs.⁷⁸ Government officials and many in industry countered that especially because BSE is a foreign animal disease, there must be strong federal oversight of control measures, and that allowing private-sector testing of low-risk animals would undermine negotiations with Japan and other countries aimed at re-opening the entire U.S. beef market to trade.⁷⁹

⁷⁵ For more information, see OIE, Disease Information, “Bovine spongiform encephalopathy in Japan: atypical case,” Vol. 16, No. 41, Oct. 10 2003, at [<http://www.oie.int>] and the Bio-Rad Laboratories website, [<http://www.bio-rad.com>].

⁷⁶ “Second US cow tests positive for BSE,” *NewScientist.com News Service*, June 28, 2004.

⁷⁷ USDA, “Statement by Bill Hawks, Undersecretary for Marketing and Regulatory Programs Regarding a Request by Creekstone for Private BSE Testing,” press release, Apr. 9, 2004.

⁷⁸ For information on these programs, see the website of USDA’s Agricultural Marketing Service at [<http://www.ams.usda.gov/>].

⁷⁹ A legal analysis of the Creekstone decision is available in CRS Report RL32414, *The Private Testing of Mad Cow Disease: Legal Issues*, by Stephen R. Vina.

BSE Testing Costs

The cost of BSE tests and the infrastructure to support a testing program have been topics of discussion since BSE was first announced in the United States. The cost of individual rapid BSE test kits has been reported to range from \$7 to \$25 per animal.⁸⁰ An APHIS spokesperson said in 2004 that considering overhead costs, tests could run \$25 to \$50 per animal.

A more recent study published by Kansas State University indicates that the variable cost of testing is approximately \$15 to \$20 per head. This figure includes the cost of the test itself (\$12 to \$15), plus the cost of labor (\$3 to \$5), but not the investment needed to establish a testing facility at a plant.⁸¹

To fund the enhanced surveillance program, USDA said that it transferred \$80.4 million during FY2004 from the Commodity Credit Corporation (CCC) to APHIS to support testing. On a fiscal year basis, \$32 million of this was spent in FY2004, and \$48 million was budgeted for FY2005. When annually appropriated funds are added to the CCC transfer, the total BSE regulatory, surveillance, and testing budget was \$44 million in FY2004 and \$69 million in FY2005.

If one assumed that 500,000 cattle will have been tested by the end of the special program, and based on a simple mathematical calculation, this total would translate into approximately \$161 per head. However, analysts point out that this has been a far more extensive and complex program than is the case with routine testing of a smaller number of samples. For example, as noted, USDA has agreements with rendering firms to cover such costs as collecting and submitting samples, and storing carcasses until test results are known.

Using the Kansas State per-head figures, testing 20,000 cattle annually (the amount tested by USDA in 2003) would cost a total of \$300,000 to \$400,000 per year. The Kansas State study observes that the cost of testing, regardless of the actual dollar figure, will be offset by any economic benefits if one assumes that such testing would reopen more foreign markets (e.g., Japan, Korea) to U.S. beef.

The House-passed and Senate committee-approved appropriation for BSE testing for FY2006 is approximately \$17 million. (These would be funds used to resume ongoing testing, after the expected end of the enhanced surveillance program, probably later in 2005.)

Congressional Role

Congress closely followed the special BSE surveillance effort as it was getting under way in 2004, when concerns were raised about its basic design and initial operation. Many Members continue to express keen interest in the impact of testing

⁸⁰ Dennis Normile, "First U.S. Case of Mad Cow Sharpens Debate Over Testing," *Science*, vol. 303, pp. 156-157, Jan. 9, 2004.

⁸¹ Kansas State University study.

on cattle prices, particularly whenever USDA has reported anything other than a negative finding of BSE, as has occurred on three occasions over a 13-month period. There was renewed congressional interest in testing when USDA, at OIG's insistence, in June 2005 retested tissues from a cow which initially had been declared negative for BSE, but were later confirmed to be positive (see above). Despite the recent controversies, however, the current 109th Congress has not yet held a hearing or received proposed legislation on these issues. Lawmakers' major role in surveillance so far has been in considering and approving funding for some APHIS testing activities through the annual USDA appropriation.

BSE Prevention in Slaughter and Processing: The "Fourth Firewall"

USDA (FSIS) is responsible for the safety of meat produced in facilities under federal inspection. In addition, under Memoranda of Understanding with FSIS, many states have programs to inspect meat for in-state sale only. State-regulated safety measures, including all BSE prevention measures, must be equivalent to those in federally-inspected plants. Therefore, all food safety measures announced by USDA to control BSE apply to state meat inspection facilities as well as federal facilities.

FSIS earlier had been considering a number of policy options for protecting the human food supply from possible contamination by BSE agents. These measures were summarized in a January 15, 2002, "current thinking" paper.⁸² A number of these possible options related to designating various types of cattle parts as "Specified Risk Materials" (SRM, thereby making them unfit for human consumption), or to restricting the use of certain mechanical systems for recovering meat from vertebral columns (notably so-called advance meat recovery systems, or AMR). The agency announced a number of steps to ensure the safety and proper labeling of AMR products, but major new regulatory actions did not come until after the discovery of the first U.S. BSE cow.

USDA announced these new preventive measures on December 30, 2003. The "three firewalls" had been in place, but they primarily were intended to prevent the emergence of BSE or its spread in cattle. Most of the new measures involved changes in meat inspection and human food safety protections, interventions that had been regarded by USDA to be unnecessary before BSE was known to be present in the United States. Officials and an advisory panel have subsequently noted that these measures, which remove all designated high-risk material from the food supply, regardless of test findings on specific animals or measures of BSE prevalence nationwide, represent the strongest actions to protect public health since the first U.S. finding of BSE.

⁸² USDA, FSIS, *FSIS Current Thinking on Measures That Could Be Implemented to Minimize Human Exposure to Materials that Could Potentially Contain the BSE Agent*, Jan 15, 2002, at [http://www.fsis.usda.gov/OA/topics/BSE_thinking.htm].

Ban on “Downer” Cattle

The most sweeping USDA action in response to BSE was the immediate ban on the use of non-ambulatory or so-called “downer” cattle in the food supply. USDA/FSIS took this regulatory action as part of the series of rule changes it announced on December 30, 2003. This action was published on January 12, 2004, as an interim final rule.⁸³ Under the rule, meat inspectors must condemn all nonambulatory cattle presented for inspection for human food, regardless of the reason for their condition. “Downers” are defined as non-ambulatory or disabled animals that are unable to rise from a recumbent position (i.e., to stand) or are unable to walk. The action was based on the concern that animals could become non-ambulatory as a result of BSE.

Proponents of this ban have argued that downer animals pose numerous food safety hazards, not limited to BSE but including microbial hazards such as Salmonella; they have noted that some prominent fast-food chains already ban the use of these animals for the meat they accept. Opponents of the ban have expressed concern about the integrity of BSE surveillance if these animals are no longer brought to slaughter, and have questioned the scientific basis of the ban, in light of its economic impacts. (As noted earlier, USDA says it has taken steps to ensure that many downed animals can continue to be tested, even if they are diverted from slaughter for human food.)

USDA has estimated that up to 200,000 “downer” cattle were slaughtered in the United States annually, and accounted for less than 1% of roughly 35 million animals slaughtered. Within this total, 25% or perhaps higher were ultimately condemned by meat inspectors as unfit for human consumption.⁸⁴ USDA’s statistical agency has since collected two years of on-farm national data; it estimates there were approximately 465,000 nonambulatory cattle and calves at U.S. beef and dairy operations in 2003, and 450,000 in 2004.⁸⁵

Some within the cattle industry have argued that the downer ban should distinguish between animals that cannot walk because of BSE or another potentially dangerous disease, and those that are simply lame (and, presumably, safe for use as food). Opponents have argued that a cow might have become lame because it was suffering from a nervous condition like BSE, and that making an accurate diagnosis would be difficult under the conditions which exist at slaughter.

Nonambulatory disabled cattle generally can be separated into those that display central nervous system (CNS) disorders (of which BSE is one of several possible types) and those that do not but simply appear to be lame, USDA has observed.

⁸³ “Prohibition on the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disable Cattle,” 69 *Federal Register* 1861.

⁸⁴ USDA, FSIS, *Preliminary Analysis of Interim Final Rules and an Interpretative Rule to Prevent the BSE Agent from Entering the U.S. Food Supply*, April 7, 2004.

⁸⁵ USDA, National Agricultural Statistics Service, *Non-Ambulatory Cattle and Calves*, released May 5, 2005.

However, the Department concluded, no data are available to determine the level of disease infectivity among non-ambulatory disabled cattle without CNS symptoms. So, officials decided it would be prudent to prohibit all “downers” from the food supply.⁸⁶

Prior to the emergence of the North American BSE cases, downer cattle were linked with the issue of humane slaughter. Widespread media reports in the 1990s made claims that nonambulatory cattle were suffering in transport to and after arrival at slaughter plants. Some in Congress believed that a ban on their inspection (effectively reducing any higher value as human food) would serve to improve their treatment.

Other New Slaughter and Processing Protections

Additional measures announced on December 30, 2003, include a policy to hold meat from any animals tested for BSE until the test results are known; a ban on air-injection stunning, which is suspected to spread brain matter through the bloodstream and into meat; a ban on mechanically-separated meat, in which bones may be crushed to produce meat paste; and several provisions to keep certain high-risk materials out of the food supply, or out of Advanced Meat Recovery (AMR) systems, depending on the age of the animal. (AMR, as distinct from mechanically-separated meat, uses pressure to remove edible tissues from bone without crushing it. The resulting product can be labeled “meat,” and is typically incorporated into products such as hot dogs and sausages.) USDA published in the January 12, 2004, *Federal Register* three interim final rules and one notice to codify these actions, effective immediately.⁸⁷

One of these rules redefines so-called “Specified Risk Materials,” (SRM), those parts of a carcass where prions are believed to concentrate, and that are deemed inedible and cannot be inspected and passed as human food. The rule designates as SRM, among other tissues, brain and spinal cord in cattle older than 30 months, but continues to permit such materials from younger animals (under 30 months) to be inspected and passed as human food.

Another of the rules prohibits the inclusion of certain parts in AMR meat. USDA has prohibited central nervous system tissue (brain, spinal cord and some

⁸⁶ USDA, FSIS, *Preliminary Analysis of Interim Final Rules and an Interpretative Rule to Prevent the BSE Agent from Entering the U.S. Food Supply*, undated document released in 2004, at [http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/03-025N/BSE_Analysis.pdf]. See also, USDA APHIS, *USDA BSE Surveillance Plan: Background on Assumptions and Statistical Inferences*, March 15, 2004, at [<http://www.aphis.usda.gov/lpa/issues/bse/BSEOIG.pdf>].

⁸⁷ “Prohibition on the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disable Cattle,” 69 *Federal Register* 1861; “Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems,” 69 *Federal Register* 1874-1885, “Prohibition on the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter,” 69 *Federal Register* 1885-1891, and “Bovine Spongiform Encephalopathy Surveillance Program,” 69 *Federal Register* 1892.

other nerve tissues) from AMR meat in the past based on quality standards, not for food safety, but has found in tests of AMR meat that about one-third of it did contain prohibited material.⁸⁸ The GAO has asserted that, irrespective of USDA's determinations of the safety of AMR meat, the public should be able to identify foods that may contain nervous system tissue. GAO recommended that USDA continue evaluating the safety of AMR meat, improve enforcement to keep prohibited nervous system tissue out, and consider labeling and other education efforts to advise consumers when they purchase products that may contain this tissue.⁸⁹

The USDA expert panel (IRT) had commented on February 4, 2004, that until a more aggressive BSE surveillance were in place, the SRM definition for parts excluded from food should be expanded, to exclude high-risk tissues from any animal older than 12 months of age (as they had also recommended for the feed ban). However, the report also included a seemingly contradictory statement that until a better understanding of BSE prevalence were established, the 30 month cut-off was "a reasonable temporary compromise." The full advisory committee reported that the USDA action to ban SRM from animals over 30 months removed the highest-risk tissues from the food supply and was in accordance with international standards. The Harvard risk assessment concluded that SRM removal would reduce potential human exposure by 95%.

FDA published in the July 14, 2004, *Federal Register*, an interim final rule to prohibit, in the food, drugs, and cosmetics that it regulates, the same materials (i.e., SRM) banned in FSIS-regulated products.⁹⁰ In the same issue, FDA and FSIS issued a joint advance notice of proposed rulemaking (ANPR) seeking public comments on additional measures under consideration to mitigate BSE risks. Among the questions specific to FSIS authorities were:

- What data or scientific information is available to evaluate an IRT recommendation that the entire intestine from cattle of all ages be removed, not only the distal ileum as currently required, to prevent potentially infective material from entering the human and animal food chains?
- What measures are needed to prevent cross contamination between cattle carcasses?
- In establishments that mainly slaughter cattle 30 months of age and older, are additional sanitation requirements necessary to prevent edible portions of carcasses from being contaminated with SRM?

⁸⁸ For further information on FSIS AMR standards and testing, see USDA, "Advanced Meat Recovery (AMR)" Web page at [<http://www.fsis.usda.gov/OA/topics/amr.htm>].

⁸⁹ GAO Mad Cow Disease report, p. 38.

⁹⁰ 69 *Federal Register* 42256-42274.

- With regard to determining the equivalence of imports, should FSIS exempt countries with low or no BSE risk from its SRM rule, and if so, under what conditions?

FSIS and FDA each published an interim rule in the September 7, 2005, *Federal Register* altering their separate rules on SRM in meat products, foods and cosmetics. Both agencies had earlier designated the distal ileum of all cattle, regardless of age, as SRM, but required companies to remove the entire small intestine, even though the distal ileum was the only portion where BSE infectivity has been confirmed. The September 7 interim rules permit companies, beginning on October 7, 2005, to remove the distal ileum (defined to be at least 80 inches) and to utilize the rest of the small intestine in food or cosmetics. These actions were in response to industry comments that technology exists to effectively remove the distal ileum.⁹¹

Congressional Role

Although BSE's potential impact on food safety and public health has been of interest to many Members of Congress, testimony at most of the recent hearings, and most BSE-related bills, have addressed the trade-related, animal disease, and economic aspects of the disease. But a few proposed measures could directly or indirectly affect FSIS's oversight of BSE safeguards in meat plants. For example, as noted earlier, pending S. 73 focuses primarily on keeping higher-risk cattle parts out of animal feeds, but one section of the bill explicitly makes it illegal for any person to introduce into interstate or foreign commerce these and other prohibited materials, among other provisions.

Other measures have focused on the "downer" issue. During action on the FY2004 agriculture appropriations bill (H.R. 2673) in the 108th Congress, for example, lawmakers debated amendments that reflected the content of companion bills in the House and Senate (the Downed Animal Protection Act; H.R. 2519/S. 1298). These would have amended the 2002 farm act to require that downed animals at stockyards, market agencies, livestock dealer facilities, and slaughter facilities be euthanized immediately and barred from federal inspection. The Senate adopted the downed animal provision in its version of the funding bill, but it was dropped in conference on the final measure, incorporated into the FY2004 Consolidated Omnibus Appropriations (P.L. 108-199).

In the 109th Congress, during floor consideration of the FY2006 USDA appropriation (H.R. 2744) on September 20, 2005, the Senate adopted by voice vote an amendment by Senator Akaka that would prohibit nonambulatory livestock (also called "downers") from being used for human food. The House-passed bill lacks such a ban, so the matter faces House-Senate conference. When the Senate adopted the provision, there was discussion of its potential to protect against BSE. However, the amendment would apply not only to cattle, but also to any sheep, swine, goats, horses, mules or other equines "that are unable to stand or walk unassisted" at the

⁹¹ 70 *Federal Register* 53043-53050 (FSIS) and 70 *Federal Register* 53063-53069 (FDA). The FDA interim rule also clarifies that milk and milk products, hide and hide-derived products, and tallow derivatives are not prohibited cattle materials.

point of antemortem inspection. (Senator Akaka also again introduced the Downed Animal Protection Act as S. 1779; the House companion bill by Representative Ackerman is H.R. 3931.)

One bill (H.R. 4121) in the 108th Congress would have amended the Federal Meat Inspection Act to define “non-ambulatory” as “any cattle that, at the time of examination and inspection ... is unable to rise from a recumbent position or unable to walk for any reason, including metabolic conditions or central nervous system disorders, unless the reason for such inability is fatigue, stress, obdurator nerve paralysis, obesity, or one or more broken or fractured appendages, severed tendons or ligaments, or dislocated joints.” Other meat safety-related proposals conceivably might emerge during the course of the 109th Congress, particularly if more BSE cases are found in North America and/or Members perceive the need to strengthen any FSIS regulations.

Related Issues and Options

Federal Spending on BSE

The Administration’s FY2006 budget, released in early 2005, requested a total of \$66 million for USDA’s BSE-related activities, including \$33 million to continue work on an animal identification (ID) program (see next section), \$21 million for BSE testing/surveillance, and \$12 million for research. Total USDA spending for BSE in FY2005 is estimated at \$123 million, of which \$69 million was for BSE testing (and most of that for the enhanced surveillance program), \$49 million to launch the animal ID effort, and \$3 million for research. Much of the FY2005 funding was through transfers from USDA’s Commodity Credit Corporation (CCC) account rather than through direct appropriation by Congress. USDA’s BSE spending in FY2004 was an estimated \$51 million.

Additional BSE amounts are spent through FDA and other agencies. The FDA request for FY2006 is for a total of nearly \$30 million, which both the House-passed and Senate-passed USDA-FDA appropriation measure (H.R. 2744) include. The House and Senate committee reports (H.Rept. 109-102 and S.Rept. 109-92, respectively) to accompany the bill state that this funding will be used primarily to enforce the 1997 feed ban, including yearly inspections of renderers and feed mills processing products containing prohibited materials; extension of more oversight to other segments of the industry subject to the rule; validation of test methods for detecting bovine-derived proteins in animal feed; and research activities. Conference committee action on the measure was pending on October 12, 2005.

Animal Identification and Meat Traceability

Among the steps announced on December 30, 2003, by the Secretary of Agriculture was to “begin immediate implementation” of a national animal identification (ID) system. Many producers already keep records on the identities of each of their animals, primarily for herd management and marketing purposes.

Though animals often may be identified individually as part of an animal disease program, no nationwide comprehensive U.S. animal ID system is in place.

Some observers have suggested that such a system, for example, would have enabled USDA to find more of the cows imported from Canada with the December 2003 BSE cow. APHIS officials acknowledged that they had concluded their investigation of the U.S. outbreak after positively identifying only 28 of the 80 cattle that were imported with the BSE cow. “The limitations of the cattle identification system necessitated a more extensive tracing exercise than would otherwise have been necessary in order to identify the cattle to be culled in accordance with international standards, thus enabling the identification of some animals only by process of elimination,” the international panel of experts reported on February 4, 2004.⁹²

More recently, the Center for Science in the Public Interest (CSPI), a consumer advocacy group, charged that lack of a cattle ID program initially had made it difficult for USDA to find the herd of origin of what has become the first U.S.-born cow to test positive for BSE (i.e., the November 2004 Texas cow). CSPI was among those calling for faster implementation of an ID program.⁹³

Interestingly, while the BSE issue has stimulated much of the current interest in animal ID, it historically has been regarded as a tool for tracking mainly contagious diseases — which BSE is not.

While most cattle and beef industry leaders appear to be supportive of an animal ID program (most major industry groups are represented on the task force), some also assert that animal ID should be viewed primarily as a potential tool in animal health and food safety assurance programs — not as another BSE preventive measure itself. Industry leaders also have pointed to a number of other policy issues that remain unresolved, including how much such an animal ID program will cost; how much government might contribute toward this cost; several questions regarding privacy of industry data and legal liability; and whether animal ID could or should be used for purposes besides animal disease management (also see Country of Origin Labeling, below). A growing number of animal industry leaders appears to recognize that a national system will have mandatory aspects to it.

For several years prior to the Secretary’s announcement, a government-industry task force had been working to develop the framework for an ID system, aimed at helping authorities to determine more rapidly the origin of an animal disease outbreak and to contain it quickly. With the discovery of BSE, USDA attempted to take the lead in development of a national program. On April 27, 2004, the Secretary

⁹² USDA, *The Secretary’s Foreign Animal and Poultry Disease Advisory Committee’s Subcommittee Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States*, Feb. 4, 2004, at [<http://www.aphis.usda.gov/lpa/issues/bse/bse.html>], p. 2. Earlier, the international team examining Canada’s BSE investigation also had observed that the lack of a mandatory ID system prior to Canada’s adoption of one in 2001, contributed to the need for “the extensive culling of animals.”

⁹³ *Reuters*, “Beef-loving U.S. shrugs at finding second mad cow,” June 26, 2005.

announced what she called “the framework for implementation” of the national ID plan.

On August 5, 2004, USDA said it was providing nearly \$12 million for cooperative agreements with states and tribal governments, to register premises (i.e., sites with animals), collect data, and test ID technologies. On June 21, 2005, USDA announced that it was accepting applications to disburse another \$14.3 million to continue premises registration efforts. APHIS now projects that all states will have the capability to register individual premises (but not yet animals) by this year, and that individual animal numbers will also become available this year. But a national system may not be fully in place and/or mandatory until 2009.⁹⁴

Some argue that USDA, which has embarked on an all-farm species approach, is progressing too slowly. The National Cattlemen’s Beef Association (NCBA), for example, announced its intention to establish a privately operated system for cattle and other species, that it has said could be fully operational for cattle by October 2006. Apparently responding to such producer concerns about the pace of implementation and the need for private sector leadership, Secretary Johanns on August 30, 2005, announced four “guiding principles” for a national ID system:

- It must be able to allow tracking of animals from point of origin to processing within 48 hours without unnecessary burden to producers and other stakeholders;
- Its architecture must be developed without unduly increasing the size and role of government;
- It must be flexible enough to utilize existing technologies and incorporate new identification technologies as they are developed;
- Animal movement data should be maintained in a private system that can be readily accessed when necessary by state and federal animal health authorities.

Focusing on the last point, Secretary Johanns stated: “We are eager to work closely with industry as they develop and maintain databases that contain animal movement information. After hearing the confidentiality concerns of producers, we envision a system that allows these databases to feed a single, privately held animal-tracking repository that we can access.”⁹⁵

Not everyone endorsed this approach. R-CALF United Stockgrowers of America, representing some cattle producers, issued an August 31, 2005, statement noting its disappointment with the decision, and asserting that protecting U.S. animal health has national security and public accountability dimensions that should not be ceded to the private sector.

⁹⁴ For updates on USDA’s animal ID activities, including information on its strategic plan for an ID program, see [<http://animalid.aphis.usda.gov/nais/index.shtml>].

⁹⁵ “Johanns Announces Key Component of Animal I.D. System.” August 30, 2005, press release.

Conceptually, animal ID follows cattle from place of birth to the point of slaughter. That is one segment of overall meat traceability, which extends further, generally through the marketing chain to the final consumer. Some policymakers have urged the adoption of this broader approach. For example, companion bills offered in 2003 (S. 1202 and H.R. 3546) would have required USDA to establish a traceability system for all stages of production, processing, and distribution of both meat and poultry and their products, essentially from the birth of source animals to the ultimate consumer. Other bills in the 108th Congress that would have required some type of animal ID system included H.R. 3961; H.R. 3714; S. 2008; H.R. 3787; S. 2070, and H.R. 3822.⁹⁶

In the 109th Congress, several animal identification bills had been introduced as of mid-September 2005, including H.R. 1254, the National Farm Animal Identification and Records Act, H.R. 1256, to limit animal ID information disclosure, and H.R. 3170, creating a private Livestock Identification Board to oversee the program. The House Agriculture Committee held two hearings in September 2005 on the feasibility of establishing a privately-held system.

Country of Origin Labeling

U.S. law requires most imports, including many food items, to bear labels informing the “ultimate purchaser” of their country of origin. Various raw agricultural products have been exempt. The 2002 farm bill (P.L. 107-171) required many retailers to provide, starting September 30, 2004, country-of-origin labeling (COOL) on fresh fruits and vegetables, and unprocessed red meats, fish, and peanuts. The conference report on the omnibus FY2004 appropriation, which included USDA funding (H.Rept. 108-401; P.L. 108-199) delayed the effective date for mandatory COOL for two years, until September 30, 2006 (except for fish; that portion is now in effect).

However, debate over the pros and cons of COOL has continued into the 109th Congress, where some Members continue to oppose the two-year delay, and others are working to make COOL a voluntary, not mandatory program for industry. Among the reasons that COOL is needed, according to supporters, is that consumers have a right to know where their food is from, particularly in light of recent animal health and food safety concerns such as the two BSE cases in Canadian-born cows. COOL critics have countered that it is a thinly-disguised trade barrier intended to increase the costs of imports, and that it undermines U.S. efforts to reform world agricultural trade; moreover, they argue that, as designed, the mandatory program for industry will be extremely expensive to maintain, and might hold them legally accountable for inadvertent or minor mistakes in records.

Prior to enactment of mandatory COOL in 2002, industry leaders were seeking from USDA a voluntary program for labeling beef of U.S. origin. Although such labeling already is permitted so long as existing FSIS conditions are satisfied, presumably a newer, more specific origin program would have been more attractive to the industry.

⁹⁶ See CRS Report RL32012, *Animal Identification and Meat Traceability*, by Geoffrey S. Becker.

Separately, after the May 2003 Canadian BSE discovery, Japanese officials said they would require proof, effective September 30, 2003, that beef shipped from the United States was of U.S. origin. Japan's aim was to ensure that no products came from Canada. Hoping to satisfy Japanese (and Korean) demands, the Department unveiled in August 2003 a new "Beef Export Verification" (BEV) program as a voluntary, user-fee funded service. Exporters desiring to sell beef to Japan (or any other country that may request similar documentation) were to apply for BEV certification from USDA after satisfying a list of requirements so that the agency could verify that their beef is from cattle slaughtered in the United States. As noted, BEV is considered voluntary, even though at the time it was widely viewed as a minimum prerequisite for gaining access to the Japanese and perhaps other foreign markets. After the December 23, 2003, announcement of a U.S. BSE cow, Japan was among the first countries to halt imports of U.S. beef, clouding the future of BEV.

Bills offered earlier in 2005 (H.R. 384/S. 108) would prohibit the Canada rule (see "Trade Restrictions") unless mandatory COOL is implemented. Other pending bills would make COOL voluntary for meats (H.R. 2068; S. 1333), and for meats and other commodities (S. 1300). The House-passed USDA appropriation for FY2006 (H.R. 2744) would prohibit use of funds to implement COOL for meats. On the other hand, S. 1331 would accelerate implementation for mandatory COOL to January 30, 2006. (See CRS Report 97-508, *Country-of-Origin Labeling for Foods*, by Geoffrey S. Becker.)

Beef Labeled "Organic"

A USDA program, the National Organic Program (NOP), prohibits the feeding of "mammalian or poultry slaughter by-products to mammals or poultry," if they are to be labeled "organic."⁹⁷ Numerous news reports have suggested a safety benefit from beef grown using organic or other alternative practices, now that there have been domestic BSE cases. The NOP was developed to assure that labeling claims reflect defined and verifiable production and handling practices. USDA endorses no claims that organically produced food is safer or more nutritious than conventionally produced food.

Chronic Wasting Disease

Chronic Wasting Disease (CWD), a TSE, is a fatal neurological disease of farmed and wild deer and elk in North America. CWD is generally similar to BSE, and is thought to be caused by a similar type of infectious prion protein. CWD differs from BSE in a number of significant ways, however, including the types of tissues involved and the fact that it is contagious among animals in a herd. A study under experimental conditions suggested that CWD may be transmissible through contaminated environments long after infectious animals were no longer present.⁹⁸

⁹⁷ 7 CFR 205.237, National Organic Program. For further information, see [<http://www.ams.usda.gov/nop/NOP/NOPhome.html>].

⁹⁸ M.W. Miller, *et al.*, "Environmental Sources of Prion Transmission in Mule Deer," *Emerging Infectious Diseases*, June 2004, at [<http://www.cdc.gov/ncidod/EID/vol10no6/04-0010.htm>].

Since 1997, CWD has been detected in 39 captive cervid herds in nine states: Colorado, Kansas, Minnesota, Montana, Nebraska, New York, Oklahoma, South Dakota, and Wisconsin. As of June 1, 2005, there were six known positive captive herds in the United States: 4 elk herds in Colorado, and two deer herds in Wisconsin. Federal and state policy is to depopulate (destroy) these herds (see below). CWD has been detected in wild cervids in nine states: Colorado, Illinois, Nebraska, New Mexico, New York, South Dakota, Utah, Wisconsin, and Wyoming.⁹⁹ (It has also been found in Canada and the Republic of Korea.)

The Centers for Disease Control and Prevention (CDC) says regarding the potential for CWD transmission to humans:

It is generally prudent to avoid consuming food derived from any animal with evidence of a TSE (a “transmissible spongiform encephalopathy,” or prion disease such as BSE and CWD). To date, there is no evidence that CWD has been transmitted or can be transmitted to humans under natural conditions. However, there is not yet strong evidence that such transmissions could not occur. To further assess the possibility that the CWD agent might occasionally cause disease in humans, additional epidemiologic and laboratory studies could be helpful. Such studies include molecular characterization and strain typing of the agents causing CWD in deer and elk and CJD (the human form of prion disease) in potentially exposed patients. Ongoing national surveillance for CJD and other neurological cases will remain important for continuing to assess the risk, if any, of CWD transmission to humans.¹⁰⁰

With regard to the potential for CWD transmission to cattle, possibly causing BSE or a related disease that could pose a food safety hazard, USDA says:

During the approximately two decades of monitoring, researchers have not found any evidence that CWD can be transmitted to domestic cattle under natural conditions. Ongoing experiments involving oral exposure and contact exposure on heavily CWD contaminated sites have not resulted in infection of cattle. These experiments, however, require additional time before they are completed. CWD has been experimentally transmitted by artificial means to mice, ferrets, mink, goats, squirrel monkeys, and calves.¹⁰¹

FDA prohibits the feeding of rendered deer and elk to ruminants. In addition, FDA prohibits the use of known-CWD positive animals in any animal feeds, and

⁹⁹ West Virginia state officials announced on September 2, 2005, that a road-killed deer had tested positive for CWD. A map on CWD in North America by the U.S. Geological Survey is at [http://www.nwhc.usgs.gov/research/chronic_wasting/chronic_wasting_map.html].

¹⁰⁰ Found at USDA APHIS, “Questions and Answers About Chronic Wasting Disease,” Sept. 2002, at [http://www.aphis.usda.gov/lpa/pubs/fsheet_faq_notice/faq_ahcwd.html]. In addition, see E.D. Belay, et. al., “Chronic Wasting Disease and Potential Transmission to Humans,” *Emerging Infectious Diseases*, June 2004, at [<http://www.cdc.gov/ncidod/EID/vol10no6/03-1082.htm>].

¹⁰¹ *Ibid.*

recommends against the use of rendered deer and elk material considered high-risk in any animal feeds.¹⁰²

Activities related to CWD control are also conducted by USDA's Agricultural Research Service (ARS) and Cooperative State Research, Education and Extension Service (CSREES)¹⁰³ and several agencies in the Department of the Interior (DOI). In recognition that CWD is being found in more areas, and that resource limitations and program inconsistencies exist among the states, a national CWD Task Force was formed in 2002 "to ensure that federal and state agencies cooperate in the development and implementation of an effective national CWD program."¹⁰⁴ This task force, initiated between USDA, DOI, and state wildlife and agriculture agencies, produced the strategic plan (see footnote) which, among other things, states that the primary federal role will be to provide coordination and assistance with research, surveillance, disease management, diagnostic testing, technology, communications, information, education, and funding for state CWD programs. The task force has working groups with action plans organized around most of these topics, though there have been concerns about delays in its implementation.

According to the most recent CWD task force's progress report, total federal spending for CWD approximates \$25 million annually, of which about \$20 million are USDA funds. The most recently published report estimates state spending to be roughly \$15-20 million per year.¹⁰⁵ Several bills addressing research, surveillance, or control of CWD were introduced in the 108th Congress, including H.R. 2057; H.R. 2430; H.R. 2431; H.R. 2636; H.R. 3714, and S. 1036; S. 1366 and S. 2007. A hearing on CWD was held by the Senate Environment and Public Works Committee, Fisheries, Wildlife and Water Subcommittee on April 5, 2004. CWD interest in the 109th Congress appears to be centered around the funding levels in the pending annual appropriation measures, including USDA's, H.R. 2744.

Feline Spongiform Encephalopathy

Feline Spongiform Encephalopathy (FSE) was first identified in domestic cats in Britain in 1990, and is believed to result from eating BSE-affected beef. (When brain tissue from cats with FSE was inoculated into mice, the pattern of incubation periods and lesions in the mice was indistinguishable from that produced by BSE.) There have been more than 100 cases of FSE in Europe, mostly in the UK. No cases have been reported in the United States.

¹⁰² FDA, *Guidance for Industry #158: Use of Material from Deer and Elk in Animal Feed*, Sept. 15, 2003, at [<http://www.fda.gov/cvm/guidance/published.htm>].

¹⁰³ See ARS research website to search for CWD studies at [<http://www.ars.usda.gov/Research/Research.htm>] and CSREES CWD website at [http://www.csrees.usda.gov/nea/animals/in_focus/health_if_wasting.html].

¹⁰⁴ PUSDA/ DOI, *Plan for Assisting States, Federal Agencies, and Tribes in Managing Chronic Wasting Disease in Wild and Captive Cervids*, June 26, 2002, at [<http://www.aphis.usda.gov/lpa/issues/cwd/cwd62602.html#intro>].

¹⁰⁵ *Progress Report on the Plan for Assisting States, Federal Agencies and Tribes in Managing Chronic Wasting Disease in Wild and Captive Herds* (October 2002-September 2003), May 2004.

The FDA feed ban both prior to and since the announcement of enhanced safeguards in January, 2004, permits beef by-products in U.S. commercial cat food, which is technically regulated as “feed.” Since the finding of BSE in the United States, some have expressed concern about the welfare of cats, and others about the risks faced by people who consume cat food.

The Cornell Feline Health Center comments that “the risk of BSE-contaminated pet food is very small indeed,” for the following reasons: none of the rendered by-products from U.S. BSE-positive cows were released into manufacturing channels for pet food; imports of rendered products prohibited from cattle feed but intended for pet food must originate from countries free of BSE; and, imported pet foods may not contain mammalian-derived material.¹⁰⁶

¹⁰⁶ Cornell Feline Health Center, “Mad Cow Disease and Cats,” accessed Aug. 1, 2005, at [<http://www.vet.cornell.edu/fhc/resources/madcow.htm>].