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

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Abstract. Many Members of the 110th Congress continue to closely follow these BSE developments; hearings and legislative proposals on various aspects of the issue are possible. Among the policy questions have been whether expanded agency actions have provided further protections against BSE, whether they are scientifically sound, and what costs they may have imposed 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.

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CRS Report for Congress

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

Updated May 18, 2007

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**Prepared for Members and
Committees of Congress**

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

Summary

Through mid-May 2007, the United States had confirmed three cases of bovine spongiform encephalopathy (BSE, or “mad cow disease”): the first in December 2003 in a Canadian-born cow found in Washington state, the second in June 2005 in a cow in Texas, and the third in March 2006 in a cow in Alabama.

Shortly after the first case, 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 findings of BSE here 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. A final rule is pending.

Many Members of the 110th Congress continue to closely follow these BSE developments; hearings and legislative proposals on various aspects of the issue are possible. Among the policy questions have been whether expanded agency actions have provided further protections against BSE, whether they are scientifically sound, and what costs they may have imposed 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.

Contents

Introduction	1
Overview	1
U.S. Cases of BSE	4
Safeguards in Place Prior to December 2003	5
Additional Safeguards After December 2003	6
International Review Team Findings	7
Trade Restrictions	8
International BSE Standards	9
Canadian Beef and Cattle Imports	11
Japan and Korea Beef Trade Issues	14
Assessments of Import Safeguards	15
Harvard Risk Analysis	15
International Review Team	16
Government Accountability Office	17
Office of Inspector General	17
2003 Interagency Report	18
Congressional Role	19
The Livestock “Feed Ban”	20
Overview	20
The Feed Ban Prior to December 2003	21
Proposed Changes to the Feed Ban	22
Environmental and Economic Impacts of an SRM Ban in Feed	25
FDA Impact Analysis	26
Industry Comments	27
Earlier NRA/APPI Impact Analysis	28
NGFA Impact Analysis	28
Kansas State Impact Analysis	28
Enforcement of the Feed Ban	29
FDA Reports	29
GAO Evaluations	30
Feed Testing Program	30
The Feed Ban in Canada	31
Congressional Role	31
BSE Surveillance and Testing in Cattle	32
Overview	32
BSE Surveillance in the United States Prior to December 2003	33
Enhanced Surveillance Program	33
The “Downer” Ban and Impact on Surveillance	33
Initial Proposals for Expanded Surveillance	34
One-Time BSE Enhanced Surveillance Program	34
Ongoing Surveillance Plan	36
Critiques of the Enhanced Surveillance Program	36
“Inconclusive” Test Results	38
Confirmatory Testing Methods	38

Private BSE Testing: the Creekstone Decision	40
BSE Surveillance Costs	41
Congressional Role	42
BSE Prevention in Slaughter and Processing: the “Fourth Firewall”	43
Ban on “Downer” Cattle	44
Other New Slaughter and Processing Protections	45
Congressional Role	47
Related Issues and Options	48
Federal Spending on BSE	48
Animal Identification and Meat Traceability	49
Country of Origin Labeling	51
Beef Labeled “Organic”	52
Chronic Wasting Disease	52
Feline Spongiform Encephalopathy	55

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 in approximately two dozen countries. However, the majority of cases, approximately 183,000, have been in the United Kingdom (UK), where the disease was first detected in 1986. Most of the rest occurred elsewhere in Europe, although Japan and North America have reported multiple cases. 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. Almost 200 people have been diagnosed with vCJD since 1986, most of them in the UK. As of mid-May 2007, no persons had been reported to have contracted vCJD in the United States.¹

As of mid-May 2007, BSE had been reported in 14 cattle in North America. One animal, found in Canada in 1993, had been imported from the UK. The rest were born in North America and were detected in 2003 or afterward. They include 10 native-born cases in Canada, one case in the United States (U.S.) which was born in Canada, and two native-born U.S. cases. Because the first Canadian case in 1993 is not relevant to an understanding of recent North American BSE risk or control measures, it is often excluded from official case counts. While both native-born U.S.

¹ Three cases of vCJD diagnosed in the United States to date are felt to have been contracted in other countries. 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*, *E. coli*, *Listeria*, *Salmonella*, and *Yersinia*.

cases were born prior to the institution of feed controls (the “feed ban”) in 1997, at least six of the 11 Canadian-born animals (including the one discovered in the United States) were born after similar controls were implemented in Canada, also in 1997. This has raised concerns about the effectiveness of the feed ban in general, and the speed and thoroughness of its implementation, particularly in Canada. A list of North American BSE cases follows:

Canada:

- **December 1993**, Canada reported BSE in a cow imported from the UK in 1987, around the height of the outbreak there;
- **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;
- **January 2, 2005**, Canada confirmed BSE in an Alberta dairy cow born in October 1996;
- **January 11, 2005**, Canada confirmed BSE in an Alberta beef cow born in March 1998;
- **January 22, 2006**, Canada confirmed BSE in an approximately six-year-old crossbred cow born and raised in Alberta;
- **April 16, 2006**, Canada confirmed BSE in a six-year-old dairy cow in British Columbia;
- **July 4, 2006**, Canada confirmed BSE in a crossbred beef cow of at least 15 years of age in Manitoba;
- **July 13, 2006**, Canada confirmed BSE in a 50-month-old dairy cow from Alberta;
- **August 23, 2006**, Canada confirmed BSE in a “mature” (likely 8- to 10-year-old) crossbred beef cow from Alberta.
- **February 7, 2007**, Canada confirmed BSE in a “mature” bull from Alberta. Preliminary investigation suggested that the animal was born in 2000.
- **May 2, 2007**, Canada confirmed BSE in a mature (likely 66-month-old) dairy cow from British Columbia.

United States:

- **December 23, 2003**, USDA announced the first U.S. case of BSE, a Holstein dairy cow in Washington state that was born in Alberta, Canada in April 1997;

- **June 24, 2005**, USDA confirmed the second (first native-born) U.S. BSE case, a 12-year-old Brahma cross cow from a Texas ranch. This animal had been killed and tested in November 2004, when BSE was initially ruled out, but subsequent retesting of brain tissue in June 2005 confirmed BSE;
- **March 13, 2006**, USDA confirmed the third (second native-born) U.S. BSE case, a nonambulatory, red crossbred cow in Alabama that was more than 10 years old.

U.S. Beef Recall

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.” The agency stated that the tissues of highest infectivity are the brain, spinal cord, and distal ileum, and 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 and Third U.S. Cases: Material from the second and third U.S. cases did not enter the food or feed supply, according to USDA. The Texas 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. The Alabama cow was buried on the farm. So no beef recall was necessary in either case.

² USDA, “FSIS Update Of Recall Activities,” release, February 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.”

U.S. Cases of BSE

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 (see box), and also conducted an extensive epidemiological investigation into how the cow likely contracted BSE 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

Regarding the third U.S. case, in which no material entered the food or feed supply (the animal had been euthanized and buried on the farm), APHIS and Alabama State officials investigated 36 farms and five auction houses, and conducted DNA testing on herds that may have included relatives of the BSE case. However, they were unable to determine the cow’s herd of origin or to find any related animals of interest, except for the two most recent calves of the infected animal. One calf was still on the farm of the infected cow and being held by APHIS for observation; the other had died the year before.

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) is considered the most likely source of BSE infection. Of concern to some scientists, however, was that several of the Canadian BSE cases were born after 1997, when both the United States and Canada instituted similar but separate bans on the use of most mammalian proteins in cattle feed. This

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 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 Texas BSE Investigation — Final Epidemiology Report, August 2005*. For recent USDA information, see [http://www.aphis.usda.gov/newsroom/hot_issues/bse/index.shtml].

led some to question the effectiveness of such a feed ban in general, and/or the effectiveness of its implementation in Canada. (Both native-born U.S. cases were born before 1997.)

In June 2006, a USDA official reported that the two native-born U.S. cattle had “atypical” BSE, not the type seen in cattle in Europe or in the other North American cases.⁶ The implications of this finding, including whether atypical BSE could be spread by novel means, or whether existing controls are appropriate, are unclear at this time. The USDA official stated at the time that there were no plans to change existing controls, and the department was already in the process of ramping down its domestic BSE surveillance activity.

The North American BSE cases 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 have not constituted a “piecemeal” approach to addressing the BSE threat but rather an increasingly unified system of overlapping and complementary safeguards.

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 fully 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 and other countries 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

⁶ Bill Tomson, “Much Still Unknown About Two US BSE Cases,” *Dow Jones Newswires*, June 8, 2006.

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.⁷ 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*);
- 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).

⁷ Joshua Cohen et al., *Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States*, November 2001, revised October, 2003, Harvard Center for Risk Analysis, School of Public Health, at [http://www.aphis.usda.gov/lpa/issues/bse/bse_initiatives.html]. (Hereinafter cited as Cohen, Harvard study.) USDA-FSIS announced the public availability of the most recent (2005) version of the Harvard risk assessment in the July 12, 2006 *Federal Register* (pp. 39282-39283).

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.⁸ However, in the July 14, 2004 *Federal Register*, FDA published, jointly with USDA, a somewhat different approach, in 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). A final rule had not been issued as of mid-May 2007. Some have criticized FDA over both the pace and adequacy of these proposed changes. 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 had released its findings on February 4, 2004.⁹ The panel (the “International Review Team” or IRT, a subcommittee of a 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 the three-year examination of the U.S. BSE situation by the Harvard Center for Risk Analysis.

⁸ U.S. Department of Health and Human Services (HHS), “Expanded ‘Mad Cow’ Safeguards Announced to Strengthen Existing Firewalls Against BSE Transmission,” press release, January 26, 2004.

⁹ 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*, February 4, 2004, hereafter referred to as the USDA Subcommittee report or the IRT report.

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.¹⁰

The actions taken by USDA and FDA in response to the finding of BSE in North America were intended not only to reassure consumers and protect livestock health, but also to calm foreign markets, most of which had banned the entry of U.S. cattle and beef products after December 23, 2003. Beef exports continue to recover slowly, although Korea remained effectively closed at the end of 2006 and a number of major markets still restrict certain types of U.S. beef.¹¹ 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.

Worldwide, some 24 countries, including the United States, had reported one or more indigenous cases of BSE, and several others reported only imported cases, as of early 2007. The United Kingdom (UK), where BSE was first reported, has experienced 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.¹²

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).

¹⁰ USDA, *Report of the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases: Measures Relating to Bovine Spongiform Encephalopathy in the United States*, February 23, 2004, hereafter referred to as the USDA Advisory Committee report.

¹¹ For a discussion of economic issues and impacts on 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.

¹² 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].

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.)¹³

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.¹⁴

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.¹⁵ (Until 2005, 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) were banning most ruminant products from any country that reported even a single case of BSE. Many still do.

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

¹³ Sources for this section: various APHIS backgrounders and briefing materials, available at [http://www.aphis.usda.gov/newsroom/hot_issues/bse/index.shtml]. No establishments in countries with BSE have been permitted to ship beef to the United States, unless they have been determined by USDA to have adequate BSE safeguards.

¹⁴ 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].

¹⁵ 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).

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 country 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.

APHIS announced in March 2007 that the OIE Scientific Commission had approved the U.S. request to be classified as a Category 2 “controlled risk” country.¹⁶ The recommendation and the same risk designation for Canada were to go to the OIE General Assembly for final approval in late May 2007. 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. U.S. officials have stressed on several occasions that they expect other countries to recognize the OIE designation in opening their markets to more types of U.S. beef. (See “Japan and Korea Beef Trade Issues,” below.)

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 by practical developments between the United States and its trading partners. More specifically, Canada has been gaining continued 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

¹⁶ Statement of APHIS Administrator Ron DeHaven, March 9, 2007, accessed May 18, 2007, at [http://www.aphis.usda.gov/newsroom/content/2007/03/OIE_statement3-9-07.shtml].

been trying to rebuild foreign confidence in its own beef supply, and to convince other countries that U.S. safeguards are scientifically sound, equaling or exceeding the internationally-recognized standards (also see “Japan and Korea 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.¹⁷ 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 followed appropriate rulemaking procedures.¹⁸ 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

¹⁷ 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, November 4, 2003.

¹⁸ *Ranchers Cattlemen Action Legal Fund USA vs. USDA* (CV-04-51-BLG-RFC).

(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....”¹⁹

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.”²⁰

July 18, 2005, became the first day that live cattle began to cross the border from Canada since May 2003. Subsequently, from July 18 through the end of 2005, approximately 563,000 cattle were imported from Canada. Approximately 1 million head were imported through all of calendar year 2006.²¹

Restarting U.S.-Canadian beef and cattle trade has not been error-free. For example, in early August 2005, 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. USDA officials also found that more than a dozen of the Canadian cattle during the first month of imports were pregnant, also in violation of the rule. The incidents fueled criticism among some opponents that the border reopening was premature.

Despite such mistakes, and despite recent findings that a number of the Canadian cattle with BSE were born after that country instituted its cattle feeding restrictions in 1997, the U.S. Secretary of Agriculture and others have generally expressed confidence in the safety of Canadian beef and cattle. They have continued to assert that U.S. import safeguards, both generally and as applied to Canada, have been applied with scientific rigor and careful oversight.

¹⁹ *Ranchers Cattlemen Action Legal Fund USA vs. USDA* (CV-05-06-BLG-RFC).

²⁰ *Ranchers Cattlemen Action Legal Fund United Stockgrowers of America 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.

²¹ USDA, Foreign Agricultural Service and Agricultural Marketing Service (AMS) data. For new import data see the AMS website at [<http://www.ams.usda.gov/ismnpubs/canada.htm>]. Details on import requirements and procedures are posted on the USDA-APHIS website.

USDA-APHIS officials also had long been working on a proposed rule to permit older (i.e., over 30-month-old) cattle to enter from Canada as well. This rule in July 2006 had been at the White House Office of Management and Budget (OMB) for clearance, generally considered one of the final steps prior to publication in the *Federal Register*. However, the department reportedly withdrew the proposed rule from OMB to await more information from Canada about a BSE case announced earlier in July in an approximately four-year-old cow. Some critics outside of the department had asserted that because the cow was born long after the Canadian feed ban was instituted, the effectiveness of the ban and its enforcement should be scrutinized more closely before further relaxing import restrictions.²²

On January 4, 2007, APHIS announced the proposed rule to permit older cattle from Canada.²³ Under the proposal, the following would be added to the list of permitted imports:

- Any live cattle and other bovines for any use so long as they were born on or after March 1, 1999. This effectively would enable Canada to ship cattle over 30 months of age, including those, like breeding animals, which are not ready or nearly ready for immediate slaughter (as under the current final rule);
- Blood and blood products from bovines if collected under prescribed conditions;
- Casings and part of the small intestine derived from bovines.

APHIS officials observed that the proposed expansion does not cover deer, sheep, and goats. Also, although this proposal does not explicitly address the import eligibility of additional meat and meat products (as long as SRMs are removed). However, such products were to be permitted under the January 2005 final Canada rule, but their eligibility was postponed. If this January 2007 proposal is finalized, USDA also will allow the importation of these meat products as well, APHIS stated, adding that any such meats would be permitted — even those from animals born before March 1, 1999.

APHIS stated that it had chosen the March 1, 1999, cutoff for live cattle shipment because this was what it had determined to be the date of effective enforcement of the Canada feed rule. An agency official explained that its assessment allowed for six months beyond the formal implementation of the ban in August 1997, and also for an additional year “for the normal marketing period where you would expect feed to be cycled through in the cattle in that system.”²⁴

²² Various trade publication reports, including “USDA Withdraws Rule to Allow Imports of Older Canadian Cattle,” *Food Chemical News*, July 31, 2006; and “USDA Will Likely Delay OTM Rule,” *Cattle Buyers Weekly*, September 4, 2006.

²³ Unless noted, sources for the following section are materials and remarks provided by APHIS on January 4, 2007. The proposed rule was published at 72 *Federal Register* 1582-1619, January 9, 2007; public comments are due by March 12, 2007.

²⁴ Dr. John Clifford, USDA Chief Veterinary Officer, January 4, 2007, audioconference.

Some U.S. cattle groups, among others, have expressed discomfort about the proposal. Fueling their concern were Canada's announcements on February 7, 2007, of BSE in a "mature bull" in Alberta, and on May 2, 2007, of BSE in a likely 66-month-old dairy cow from British Columbia.²⁵ Some critics cited the cases as more evidence that Canada had not yet effectively implemented its BSE safeguards. U.S. and Canadian authorities acknowledged that three of the earlier Canadian BSE cases were found in cattle born after March 1, 1999, but have continued to argue that the entirety of Canadian and U.S. safeguards ensured that any additional risk would remain extremely low. Nonetheless, some analysts were speculating that the latest Canadian case might delay publication of a final rule.²⁶

An accompanying economic impact statement, also in the January 9, 2007 *Federal Register*, would result in higher imports of cull cattle from Canada, but declines in feeder cattle, fed cattle, and fed beef. Cull cattle primarily are used for processing beef, and so price declines in processing beef are anticipated, ranging from \$5 per 100 pounds in 2007 to \$3 in 2009.

Japan and Korea 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 had stated that the two countries would evaluate this interim system by July 2005 and modify it if appropriate. However, Japan, which reported 28 cases of BSE in its own cattle herd through mid-September 2006, moved much more slowly to open its market than U.S. interests had hoped for, not accepting any U.S. beef until December 2005. Then, on January 20, 2006, the Japanese again halted all U.S. beef imports after finding vertebral column bones (a prohibited material) in several boxes of veal shipped by a New York processor. Despite U.S. apologies and promises of stronger oversight measures, Japan did not reopen its market again until July 27, 2006. Japanese safety inspections of U.S.-certified beef plants were among a number of new concessions made by the United States.

²⁵ See, for example, R-CALF United Stockgrowers of America, "Latest Alberta BSE Case Leaves Little Doubt: Canada Has a Problem," February 9, 2007. A larger U.S. cattle group, the National Cattlemen's Beef Association, had earlier expressed some reservations about the proposed rule at their recent annual convention, urging USDA to require permanent identification of all live Canadian cattle imports through slaughter. Source: *Cattle Buyers Weekly*, February 12, 2007.

²⁶ *Cattle Buyers Weekly*, May 7, 2007.

Despite these concessions, the Japanese market has remained difficult to rebuild for a number of reasons. For example, Japan has continued to inspect 100% of the boxes of U.S. beef shipments. Announcing another possible step forward, Agriculture Secretary Johanns said in April 2007 that the Japanese had promised to ease the 100% testing after conducting another series of audits of U.S. processing plants. He also reminded the Japanese and other countries that he expected them to observe OIE's anticipated recognition of the United States as a "controlled risk" country. That presumably means Japan should begin accepting beef from animals from under 30 months of age, not just under 21 months old.²⁷ Meanwhile, Japanese consumers were substituting other proteins and other beef sources (notably, Australia and New Zealand) for U.S. beef, which had once accounted for 25% to 30% of beef consumed in Japan.

U.S. rules to permit the importation of Japanese beef are already in place. USDA published, in the December 14, 2005, *Federal Register*, a rule to permit the importation of whole cuts of boneless beef from Japan, under specified conditions. USDA said the rule was in accord with OIE guidelines and was based on a risk analysis indicating that such cuts could be safely imported.²⁸ Prior to imposition of a U.S. ban on Japanese beef imports due to animal disease (including BSE) outbreaks there, Japan exported an annual average of less than 9 tons of primarily specialty beef (Kobe and other Wagyu), according to department data. Some in Congress had expressed frustration that the United States appeared to be favoring Japanese beef producers at a time when authorities in Japan, where the BSE problem has been more pronounced, were blocking U.S. imports.

The United States has encountered even more difficulty in regaining the South Korean market, once the second-largest U.S. beef buyer. Although Korea ostensibly lifted its ban on certain U.S. beef products on September 11, 2006, extremely strict import inspection requirements and procedures have continued to effectively block most of them. The South Koreans were rejecting U.S. beef first because they found bone fragments, albeit very small ones that are typically acceptable in commercial trade, in boneless beef (bone-in has not yet been made eligible), and, later, for what they claimed were unacceptable levels of dioxin. In late April 2007, the Koreans reportedly passed a 6.4-ton beef shipment, raising expectations that additional clearances would soon follow.²⁹

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

²⁷ Statement of Agriculture Secretary Mike Johanns, April 23, 2007, accessed on May 18, 2007, on the USDA website. Also, "USDA gives on inspections and 'expects' science-based import requirements ahead," accessed April 4, 2007, at [http://agweb.com/].

²⁸ 70 *Federal Register* 48494 and 73905.

²⁹ "Korea's acceptance of Creekstone beef draws praise," *Food Chemical News*, May 7, 2007.

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.³⁰

International Review Team. 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.³¹

In another section of its report, the 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

³⁰ 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].

³¹ *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].

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.”³²

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 as inspection capacity that has not kept pace with the growth in imports, may allow BSE-infected products to enter the country.³³

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

³² *Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States*, p. 11.

³³ Government Accountability 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, January 2002; hereafter cited as GAO Mad Cow Disease report. At the time, the agency was called the General Accounting Office.

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.³⁴

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 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.³⁵ 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.³⁶

³⁴ 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>].

³⁵ *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, January 2003.

³⁶ *Ibid.*

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, with hearings held and several legislative proposals introduced (but not passed) in the 109th Congress. Attention to this issue is likely to persist in the 110th Congress, particularly with the release of the new Canada import proposal, and also if any lingering problems with Japan and South Korea are not soon resolved.

On March 3, 2005, the Senate had approved, 52-46, a resolution (S.J.Res. 4) to disapprove USDA's January 4, 2005 Canada import rule, but the measure did not advance in the House. The Administration opposed the resolution. Other pending bills addressing the Canada rule included 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. S. 294 would have prohibited 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." These bills also did not advance, but several COOL-related bills (H.R. 357; S. 404; S. 1308) have re-emerged in the 110th Congress.³⁷

The sluggish pace of the Japanese negotiations frustrated the beef industry and many Members of Congress, who believed opening the Japanese market would convince other importing nations, particularly in Asia, to follow suit. This frustration was evident in the Senate's passage on September 19, 2005, of a floor amendment which would have prohibited implementation of USDA's August 18, 2005 Japan rule unless Japan opened 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 lacked the amendment, which was deleted in conference on the final measure (P.L. 109-97).

Other proposals included a House resolution introduced earlier in 2005 (H.Res. 137) calling for economic sanctions against Japan if it did not permit U.S. beef; several bills (S. 3364; S. 3538; H.R. 5675) introduced in June 2006 that would have required trade sanctions against Japan if the market was not opened; and the pending Senate version of the FY2007 USDA appropriation (H.R. 5384), which included a committee-approved, nonbinding amendment recommending such sanctions if necessary. The final appropriation did not pass, and USDA and most other agencies operated since the start of the fiscal year through at least early 2007 under a continuing resolution.

A more comprehensive proposal, the "BSE and Other Prion Disease Prevention and Public Health Protection Act" (S. 2002), included a section prohibiting the importation of any human food, animal feed, or other article intended for human or

³⁷ For details, see "Country-of-Origin Labeling," later in this report.

animal use that contains animal-derived material but does not include information stating in English the common name of the animal. If the source animal is a ruminant, the item must also include text stating in English the country of origin and whether it contains any prohibited material (i.e., SRM). Also, no ruminant-derived imports could be imported from a country with BSE risk unless that country met OIE guidelines. This proposal also did not advance in the 109th Congress.

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.”³⁸ 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 noted that, relative to other countries, U.S. surveillance and import controls were stronger, but the feed ban was more permissive.³⁹ 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.

³⁸ 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.

³⁹ GAO, *Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts*, (GAO-02-183), January 2002.

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.⁴⁰

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 U.S. BSE case, the FDA in January 2004 announced imminent plans to expand feed ban restrictions. The agency published an advance notice of proposed rulemaking (ANPR) in 2004 and a proposed rule in 2005, each with provisions that varied from the other and from the 2004 announcement. The regulation had yet to be altered as of mid-May 2007. An analysis of these rulemaking proposals follows.

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 have 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.⁴¹

⁴⁰ Cohen, Harvard study, p. 111.

⁴¹ FDA, *Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk* (continued...)

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.⁴²

Proposed Changes to the Feed Ban

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.⁴³

On February 3, 2004, the IRT recommended additional steps, including more stringent animal feed restrictions than those just announced by FDA. The panel 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.”⁴⁴ 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.⁴⁵ The report stressed 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.

⁴¹ (...continued)

of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products, January 2002, at [<http://www.fda.gov/cber/gdlns/cjdvcjd.htm>].

⁴² FDA, “Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed,” *67 Federal Register* 67572, November 6, 2002.

⁴³ U.S. Department of Health and Human Services, “Expanded ‘Mad Cow’ Safeguards Announced To Strengthen Existing Firewalls Against BSE Transmission,” press release, January 26, 2004.

⁴⁴ USDA Subcommittee report, pp. 8-9.

⁴⁵ USDA Advisory Committee report, p. 2.

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.”⁴⁶ 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.

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.⁴⁷ 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.⁴⁸ 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 proposed rule to modify the feed ban on October 6, 2005.⁴⁹ Comments were accepted until December 20, 2005, after which they were to be evaluated prior to publication of a final rule. The proposal would ban, from all types of animal feeds (including pet food), the following materials that would be considered higher-risk (i.e., SRM):

⁴⁶ USDA/HHS, “Federal Measures to Mitigate BSE Risks: Considerations for Further Action,” *Federal Register*, July 14, 2004.

⁴⁷ 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.

⁴⁸ U.S. Senate Committee on Agriculture, Nutrition and Forestry, hearing on Mad Cow Disease, January 27, 2004, 108th Cong., 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.

⁴⁹ 70 *Federal Register* 58570-58601.

- 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 in Slaughter 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. Each of the remaining SRMs covered by the USDA-FSIS human food ban contain much smaller percentages of total infectivity, FDA said.⁵⁰

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.⁵¹

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.

⁵⁰ 70 *Federal Register* 58578.

⁵¹ 70 *Federal Register* 58576.

In its accompanying economic analysis, FDA stated that it had considered 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 to be prohibited in all feeds. It generally concluded that such additional measures are not necessary because the partial SRM ban being proposed would remove an estimated 90% of BSE infectivity. However, it again asked for further comments on these options.

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.”⁵² 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.⁵³ Members of the rendering industry expressed concerns about the cost of the proposed measures to their industry. These concerns are discussed further in a section on environmental and economic impacts.

Consumer advocacy groups argued that the proposal was too weak because, among other things, it didn’t prohibit SRMs from all animal feed, and because it continued to allow exemptions for bovine blood, poultry litter, and plate waste in cattle feed. For example, comments from Consumers Union argued, among other things, that the proposed list of SRMs was too narrow to adequately protect the feed supply, and is more narrow than the SRM definition used by FSIS to protect the supply of beef for human consumption.⁵⁴

As of mid-May 2007, FDA had not finalized any proposed changes to the feed ban. An FDA official was quoted in September 2006 as saying that the agency may have underestimated the impacts that the ban of SRM in all feeds could have on the rendering industry. He said that FDA continued to review the proposal, and that publication of a final rule would be pushed back to “later this year” or beyond.⁵⁵

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 in all feeds 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),

⁵² Hodges, Jim, American Meat Institute Foundation, October 6, 2005, letter in the *Atlanta Journal-Constitution*.

⁵³ McAdams, Jim, NCBA President, statement on October 4, 2005.

⁵⁴ Consumers Union, “Consumers Union’s Comments on FDA Docket Number 2002N-0273: Substances Prohibited from Use in Animal Food and Feed,” December 20, 2005, at [<http://www.fda.gov/ohrms/dockets/dockets/02n0273/02n-0273-EC248-Attach-1.pdf>].

⁵⁵ Tomson, Bill, “U.S. Feed Ban May Be Too Costly to Industry - FDA Official,” *Dow Jones Newswires*, September 12, 2006.

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.⁵⁶

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.⁵⁷ 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.

FDA Impact Analysis.⁵⁸ In its October 2005 proposed rule, 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

⁵⁶ 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, April 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.

⁵⁷ See FDA, *TSE Regulatory Options Cost Analysis*, June 1997, at [http://www.fda.gov/cvm/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.

⁵⁸ FDA's Analysis of Economic Impacts begins on page 58584 of 70 *Federal Register*. See, also, Eastern Research Group, "Economic Impacts of Proposed Regulatory Changes," and "Economic Impacts of Alternative Changes to the FDA Regulation," both viewed on July 25, 2005; studies commissioned by FDA, at [<http://www.fda.gov/cvm/bsefrdNotices.htm>].

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.⁵⁹

Industry Comments. The National Renderers Association (NRA), which commissioned its own economic analysis of the proposal, commented that by prohibiting most if not all cattle brains and spinal cords from all livestock feed markets, the rule would “have immediate and profound impacts on the livestock sector, particularly on the rendering industry and livestock producers.” The analysis, based in part on a survey of rendering plants, “conservatively” estimated the direct economic losses faced by the rendering industry and livestock producers at more than \$127.7 million annually, substantially higher than FDA's estimate. When slaughter plants' costs of handling and disposing of newly prohibited materials are added, the aggregate impact would exceed \$150 million annually, the NRA argued.

The NRA sponsored analysis concludes that FDA significantly underestimated the proportion of dead cattle and calves that are currently rendered in the United States; that the proposed rule severely reduces the number to be rendered; that reduced collections by renderers and higher fees would create more potential for environmental problems; and that livestock producers' disposal costs could increase by \$112 million per year. Reduced MBM and tallow sales from the loss of deadstock for rendering could exceed \$15.7 million yearly, or more than 15 times the level suggested by FDA, among other NRA assertions.⁶⁰

⁵⁹ 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.

⁶⁰ National Renderers Association, comments on FDA Docket No. 2002N-0273, Substances Prohibited From Use in Animal Food or Feed, December 20, 2005. The analysis, *Economic Impacts of Proposed Changes to Livestock Feed Recommendations*, was conducted for NRA by Informa Economics, an agribusiness consulting firm. Its report provides much more detail on how it arrived at its findings than is described here. NRA's comments are at [<http://www.fda.gov/ohrms/dockets/dockets/02n0273/02n-0273-c000461-01-vol139.pdf>]. The Informa economic analysis can be viewed on the NRA website at [http://www.renderers.org/economic_impact/index.htm].

Earlier NRA/APPI Impact Analysis. In its earlier (2004) ANPR, FDA also had sought information about the economic and environmental impacts of prohibiting SRM in all animal feeds. Joint comments on the earlier ANPR by 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.⁶¹

The NRA/APPI response also 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 states 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, in 2004 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.⁶²

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.⁶³ Banning animal consumption of all SRM

⁶¹ National Renderers Association and Animal Protein Producers Industry, Response to FDA Docket No. 2004N-0264, Federal Measures to Mitigate BSE Risks: Considerations for 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.

⁶² National Grain and Feed Association, Response to FDA Docket No. 2004N-0264, August 13, 2004.

⁶³ 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 (continued...)

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 be 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.)

Enforcement of the Feed Ban

FDA Reports. The FDA Center for Veterinary Medicine has since 2001 provided periodic updates of its feed ban enforcement activity on a public website.⁶⁴ Its January 12, 2007 update reported that it had received more than 50,000 inspection reports since the program began, on 19,492 renderers, feed mills, protein blenders, and related establishments. The agency noted that 5,905 of them (30%) handled materials prohibited for use in ruminant feeds.

Of this subset, FDA reported that the vast majority were within compliance. More specifically, the January 2007 update found that seven of the firms that handled prohibited material (0.1%) were classified as so-called “Official Action Indicated,” or OAI, meaning that significant problems were found that warranted regulatory sanctions. For example, one OAI might be that the manufacturer lacked the procedures to ensure that ruminant feed is not contaminated with nonruminant feed. Another 188 firms (3.2%) were classified as “Voluntary Action Indicated,” or VAI, meaning that problems were found but only advisory actions were warranted. A VAI example might be a minor recordkeeping lapse, FDA explained.

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%).

FDA had asserted on several past occasions that feed industry compliance with the ban has reached 99%.⁶⁵ FDA bases its compliance determinations mainly 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

⁶³ (...continued)

Agriculture), April 2005, at [http://www.agmanager.info/livestock/marketing/bulletins_2/industry/demand/EconomicImpactofBSEonUSBeefIndustry.pdf], and henceforth called the Kansas State University study.

⁶⁴ See the FDA website at [<http://www.fda.gov/cvm/2007updates.htm>].

⁶⁵ See, for example, FDA, “FDA Statement on Rendered Products Derived From BSE Cow in Washington State,” December 27, 2003, at [<http://www.fda.gov/bbs/topics/NEWS/2003/NEW01000.html>].

material. In its July 2004 ANPR, FDA requested information on potential test methods for detecting SRM in animal feed.⁶⁶

GAO Evaluations. GAO issued reports on FDA's oversight of the feed ban, in 2002 and 2005, in which it noted a number of problems with administrative procedures, inspection, and enforcement.⁶⁷ 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 at the time. Among other concerns, GAO also commented that FDA had not reinspected approximately 2,800 firms for several years and therefore did 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 alerted USDA and the states when it learns that cattle may have been given prohibited feed.

Feed Testing Program. FDA started a small, discreet feed testing program in 2003, which GAO evaluated in an October 11, 2005, report to several Senators.⁶⁸ The purpose of the program, according to GAO, was to collect and study samples of cattle and other animal feeds and ingredients to determine whether permitted cattle feed might contain FDA prohibited material. Because some cattle-derived products are permitted in feeds (blood, milk protein, plate waste), laboratory tests could not definitively determine violations — only potential violations, leading to follow-up reviews, it was noted.

⁶⁶ Such tests would determine only if prohibited materials were present in the feed, not whether infectious BSE prions were present. For information on a small FDA feed testing program begun in 2003, see the subsequent section of this report.

⁶⁷ GAO, *FDA's Management of the Feed Ban Has Been Improved, but Oversight Weaknesses Continue to Limit Program Effectiveness* (GAO-05-101), February 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), January 2002.

⁶⁸ *Mad Cow Disease: An Evaluation of a Small Feed Testing Program FDA Implemented in 2003 With Recommendations for Making the Program a Better Oversight Tool* (GAO-06-157R). Report for the Hon. Saxby Chambliss, Tom Harkin, Thad Cochran, and Richard J. Durbin, October 11, 2005.

GAO cited several weaknesses in the testing program, including no FDA requirement that districts document follow-up reviews or provide the basis for their final determinations on samples; extended periods to complete nearly half of the 989 samples studied by GAO, making it possible for feed to be consumed before results were in; and inadequate headquarters oversight of the program.

The Feed Ban in Canada

On June 26, 2006, the Canadian Food Inspection Agency announced a proposal to strengthen the country's feed ban, introduced in 1997, with new measures to become effective on July 12, 2007.⁶⁹ The expansion would prohibit SRMs in all animal feeds and in fertilizer. The Canadian ban is somewhat stronger than the FDA proposal of October 2005: the list of SRMs is somewhat more restrictive, and the prohibition against SRMs in fertilizer is not included in the FDA proposal. There may be trade and other concerns if the FDA's final feed rule is substantially different from the amended Canadian rule.

Congressional Role

If Congress more closely reviews the feed ban and its role in preventing the spread of BSE, issues for consideration might include the effects on the safety of the feed supply of banning "downer" animals from slaughter and thus channeling them to rendering, and whether current oversight of the feed ban has accommodated 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 that processes to ensure the safe disposal of animal remains are included in new regulations as they are implemented. Congress also could scrutinize the anticipated changes in feed ban restrictions proposed by FDA, particularly regarding 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, S. 73 would have statutorily defined "SRM," and explicitly made it illegal for any person to introduce into interstate or foreign commerce these and other prohibited materials, among other provisions. Also introduced was S. 2002, a more comprehensive BSE proposal that included a section similarly defining and restricting the introduction of "SRM" into commerce. Members of the 110th Congress could reintroduce these or additional measures, and

⁶⁹ Canadian Food Inspection Agency, "Bovine Spongiform Encephalopathy (BSE) in North America," Web page, at [<http://www.inspection.gc.ca/english/anim/heasan/disemala/bseesb/bseesbindexe.shtml>].

are likely to be interested in the substance of the anticipated final rule and its implementation.

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.⁷⁰ 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 proposed that surveillance should approximate programs in European countries, where every adult animal was 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

⁷⁰ 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., February 24, 2004 (Washington: GPO, 2004).

level of one in 1 million adult cattle. (USDA reported a total of approximately 97 million cattle in the United States as of January 1, 2006.)

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 and 2003, out of about 35 million cattle slaughtered each year.⁷¹ 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.⁷²

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.)

⁷¹ Early (May 2004) information on the APHIS BSE cattle surveillance program is available at [<http://www.aphis.usda.gov/lpa/issues/bse/bse-surveillance.html>].

⁷² 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.

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.⁷³

Initial Proposals for Expanded Surveillance. 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 first U.S. case (i.e., the Canadian-born cow found in Washington state). 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.⁷⁴

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.⁷⁵ 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

⁷³ See transcripts of U.S. House of Representatives Committee on Agriculture, Hearing on Mad Cow Disease Response, January 21, 2004, and U.S. Senate Committee on Agriculture Nutrition and Forestry, Hearing on Mad Cow Disease, January 27, 2004, 108th Cong., 2nd Sess.

⁷⁴ USDA, *Report of the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases: Measures Relating to Bovine Spongiform Encephalopathy in the United States*, February 23, 2004, at [<http://www.aphis.usda.gov/lpa/issues/bse/bse.html>].

⁷⁵ See USDA, "Veneman Announces Expanded BSE Surveillance Program," press release, March 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.

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 of the apparently healthy older cattle population, including animals that were born prior to institution of the feed ban. APHIS completed this testing of 21,216 clinically normal adult animals on November 21, 2005. All of these animals tested negative for BSE.

Enhanced surveillance of the high-risk population began on June 1, 2004, which has required a number of expansions of USDA activities.⁷⁶ USDA set sampling goals for each state, noting that these were estimates based on cattle population data.⁷⁷ The program has depended 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.⁷⁸

The approved rapid tests are for screening purposes. The policy has been 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.⁷⁹ USDA officials and representatives of the rendering industry later maintained that sufficient numbers of animals were being 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 had agreements with such plants that pay up to \$100 per carcass for storage until BSE test results are complete;

⁷⁶ 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].

⁷⁷ See APHIS, “Examples of Geographic Distributions of Sample Collections for the BSE Surveillance Plan,” at [http://www.aphis.usda.gov/lpa/issues/bse/bse_geo_dist_samples.html].

⁷⁸ 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, March 4, 2004.

⁷⁹ For example, see Andy Dworkin, “Testing Protocols for Mad Cow a Complex Process,” *The Oregonian*, July 7, 2004.

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.⁸⁰

After more than two years of enhanced surveillance through late August 2006, USDA reported that it had completed testing of about 788,000 animals.⁸¹ Four of these animals tested “inconclusive” on screening; two, which had been tested in the early weeks of the program, 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. The fourth also proved to be positive on subsequent testing. (A discussion of the reporting of inconclusive findings follows later.)

Ongoing Surveillance Plan. In April 2006, USDA made public its analysis of BSE surveillance data, covering not only the period (to date) of the enhanced surveillance program, but also earlier “routine” testing. The data covered a total of seven years. “The analysis concluded that the prevalence of BSE in the United States is less than one case per million adult cattle. The analysis further revealed that the most likely number of cases is between four and seven infected animals out of 42 million adult cattle,” USDA declared.⁸² USDA also said that the analysis was subjected to peer review and that a panel of outside experts had affirmed the conclusions.

The Secretary of Agriculture released this analysis in announcing that enhanced surveillance would soon be scaled back to an ongoing level of 40,000 tests per year. From September 2006 through April 2007, USDA tested a total of 23,818 cattle for BSE, with no positive results reported.⁸³

Critiques of the Enhanced Surveillance Program. The enhanced surveillance program garnered considerable criticism, at least in its early stages. 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.⁸⁴ The committee raised questions about 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

⁸⁰ Personal communications with National Renderers Association, July 11, 2005, and with APHIS veterinarians, July 13, 2005.

⁸¹ See APHIS BSE testing results at [http://www.aphis.usda.gov/lpa/issues/bse_testing/].

⁸² “USDA Announces New BSE Surveillance Program,” May 20, 2006 press release.

⁸³ Monthly test results and related information are at [http://www.aphis.usda.gov/newsroom/hot_issues/bse/surveillance/ongoing_surv_results.shtml].

⁸⁴ Letter from Reps. Tom Davis and Henry Waxman to Agriculture Secretary Veneman concerning “Mad Cow” Disease, February 17, 2004, and related committee documents.

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 concerns became the subject of investigation 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."⁸⁵

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.⁸⁶

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.⁸⁷

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

⁸⁵ 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.

⁸⁶ *Ibid.*

⁸⁷ 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.

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.⁸⁸ 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 generally recovered 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 was 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-

⁸⁸ A fuller statistical and descriptive picture of the surveillance conducted, such as the types of sites where samples were taken, their geographical locations, and clinical signs observed, is available in APHIS documents on the web, i.e., *Summary of Enhanced BSE Surveillance in the United States*, prepared by APHIS' Veterinary Services Centers for Epidemiology and Animal Health National Surveillance Unit, April 27, 2006 at [http://www.aphis.usda.gov/newsroom/hot_issues/bse/surveillance/bse_disease_surv.shtml].

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.⁸⁹

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.⁹⁰

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.⁹¹

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 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, 2005, 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.⁹²

⁸⁹ 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.

⁹⁰ Statement by Clifford, John, APHIS Deputy Administrator, November 23, 2004.

⁹¹ "Market Rebounds With a Vengeance," *Cattle Buyers Weekly*, November 29, 2004.

⁹² Transcript of media conference, USDA, June 24, 2005.

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.⁹³ 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 test 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.”⁹⁴

In the four instances of “inconclusives,” including the March 2006 test, 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 Western blot test, but negative on immunohistochemistry (IHC) — a case that Japan reported to OIE as “atypical BSE.”⁹⁵ 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.⁹⁶ 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

⁹³ *Ibid.*

⁹⁴ Transcript of media conference, June 24, 2005. The APHIS website also had posted a series of factsheets explaining in more detail the confirmatory testing methods and how they were applied in the 2005 case. In the March 2006 case, both types (the Western blot and IHC) confirmed the presence of the BSE agent.

⁹⁵ For more information, see OIE, Disease Information, “Bovine spongiform encephalopathy in Japan: atypical case,” Vol. 16, No. 41, October 10 2003, at [http://www.oie.int/eng/en_index.htm].

⁹⁶ “Second US cow tests positive for BSE,” *NewScientist.com News Service*, June 28, 2004.

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 LLC (“Creekstone”), 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.”⁹⁷

Creekstone sued USDA in March 2006. The Federal District Court for the District of Columbia ruled on March 29, 2007, that the department lacks the authority to prohibit private BSE testing. The ruling is on hold pending an appeal, but takes effect on June 1, 2007, if USDA does not appeal the decision.

The Creekstone matter has prompted a range of reactions. Critics of USDA’s actions, 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.⁹⁸ 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.

BSE Surveillance Costs

The cost of BSE surveillance and the infrastructure to support it 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.⁹⁹ 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.¹⁰⁰

⁹⁷ USDA, “Statement by Bill Hawks, Undersecretary for Marketing and Regulatory Programs Regarding a Request by Creekstone for Private BSE Testing,” press release, April 9, 2004. A legal analysis of USDA’s Creekstone decision is available in CRS Report RL32414, *The Private Testing of Mad Cow Disease: Legal Issues*, by Stephen R. Vina.

⁹⁸ For information on these programs, see the website of USDA’s Agricultural Marketing Service at [<http://www.ams.usda.gov/>].

⁹⁹ Dennis Normile, “First U.S. Case of Mad Cow Sharpens Debate Over Testing,” *Science*, vol. 303, pp. 156-157, January 9, 2004.

¹⁰⁰ Kansas State University study. The study observes that the cost of testing, regardless of (continued...)

An APHIS spokesperson said in 2004 that, considering overhead costs, tests could run from \$25 to \$50 per animal. However, the USDA's enhanced surveillance program involved a variety of activities beyond the conduct of tests, including outreach to farmers and renderers (to identify all animals that should be tested), transportation of carcasses to sites where sample collection (including removal of the head) can be performed, sample transport and storage (including refrigeration), record-keeping, and the costs of investigating inconclusive and positive results, including indemnity payments. As a result, per-head cost comparisons can be difficult unless one knows the precise scope of activities that have been included, and whether the activities are limited to testing or encompass the broader requirements of a comprehensive surveillance program.

To fund the enhanced surveillance program, USDA in March 2004 transferred an initial \$70 million from its Commodity Credit Corporation (CCC). By the time enhanced surveillance had ended, a total of \$152.4 million in CCC funds had been used for the program. This amount was in addition to allocations for BSE surveillance coming out of annual congressional appropriations, which rose from \$2 million in FY2001 to \$17 million annually in each of FY2005-FY2007 (projected; this is an expected cost of testing 40,000 animals per year).¹⁰¹ Responding to questions at an April 2006 briefing on the program, the APHIS administrator estimated that the weekly cost of testing between 5,000 and 7,000 animals was approximately \$1 million.¹⁰²

Congressional Role

The 108th and 109th Congresses closely followed the enhanced BSE surveillance effort as it was getting under way in 2004, when concerns were raised about its basic design and initial operation. Many Members expressed interest in the impact of testing on cattle prices, particularly whenever USDA reported anything other than a negative finding of BSE, as occurred on four occasions during the two years of enhanced surveillance. 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 was later confirmed to be positive (see above).

The 109th Congress did not hold hearings or introduce many bills on these issues, although a section of S. 2002 did propose a relatively extensive prion disease surveillance program that would have included compensation to industry for animals

¹⁰⁰ (...continued)

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.

¹⁰¹ House Appropriations Committee, *Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2007*, Part 3 of hearings. Also, undated, unpublished APHIS fact sheet on BSE test funding obtained in December 2006.

¹⁰² Transcript of Telenews Conference on the Enhanced BSE Surveillance Program with Agriculture Secretary Mike Johanns and APHIS Administrator Dr. Ron DeHaven, April 28, 2006.

tested, and called for a task force on prion diseases to provide recommendations to Congress on all surveillance and research programs.

Questions about surveillance and testing also have arisen during lawmakers' consideration of annual funding for APHIS. In the 109th Congress, during House floor consideration of the pending FY2007 USDA appropriation bill (H.R. 5384), Representative Kucinich offered but later withdrew an amendment aimed at maintaining BSE testing at the enhanced surveillance level. During its markup on May 9, 2006, the House Appropriations Committee defeated, on a voice vote, an amendment by Representative Tiahrt that would have barred USDA from enforcing its restriction on the private testing of cattle for BSE. Similar proposals could arise in the 110th Congress, particularly if one or more additional positive BSE cases is found in the United States.

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.¹⁰³ 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.

The Secretary of Agriculture 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 these newer FSIS measures involve changes in meat inspection and human food safety protections, interventions that had been regarded by USDA and FSIS 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

¹⁰³ USDA, FSIS, *FSIS Current Thinking on Measures That Could Be Implemented to Minimize Human Exposure to Materials that Could Potentially Contain the BSE Agent*, January 15, 2002, at [http://www.fsis.usda.gov/OA/topics/BSE_thinking.htm].

specific animals or measures of BSE prevalence nationwide, represent the strongest actions to protect public health since the first U.S. finding of BSE.

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.¹⁰⁴ 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 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.¹⁰⁵ USDA’s statistical agency then 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 2004.¹⁰⁶

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.

¹⁰⁴ “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.

¹⁰⁵ 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.

¹⁰⁶ USDA, National Agricultural Statistics Service, *Non-Ambulatory Cattle and Calves*, released May 5, 2005.

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. 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.¹⁰⁷

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.¹⁰⁸

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.

¹⁰⁷ USDA, FSIS, *Preliminary Analysis of Interim Final Rules and an Interpretative Rule to Prevent the BSE Agent from Entering the U.S. Food Supply*, 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>].

¹⁰⁸ “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.

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 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.¹⁰⁹ 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.¹¹⁰

The USDA expert panel (IRT) had commented on February 4, 2004, that until a more aggressive BSE surveillance was 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.¹¹¹ 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 the following:

- 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?

¹⁰⁹ For further information on FSIS AMR standards and testing, see the agency's AMR Web page at [http://www.fsis.usda.gov/Fact_Sheets/Advanced_Meat_Recovery/index.asp].

¹¹⁰ GAO Mad Cow Disease report, p. 38.

¹¹¹ 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.¹¹²

Congressional Role

Although BSE's potential impact on food safety and public health has been of interest to many Members of Congress, the trade-related, animal disease, and economic aspects of the disease have attracted as much attention. Still, a few proposed measures in the 109th Congress would have directly or indirectly affected FSIS's oversight of BSE safeguards in meat plants. For example, as noted earlier, S. 73 focused primarily on keeping higher-risk cattle parts out of animal feeds, but one section of the bill explicitly would have made it illegal for any person to introduce into interstate or foreign commerce these and other prohibited materials, among other provisions.

Other measures 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 have prohibited nonambulatory livestock from being used for human food. The House-passed bill lacked such a ban, and the amendment was deleted during the House-Senate conference. When the Senate adopted the provision, there was discussion of its potential to protect against BSE. However, the amendment would have applied not only to cattle, but also to any sheep, swine, goats, horses, mules or other equines "that are unable to stand or walk

¹¹² 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.

unassisted” at the point of antemortem inspection. (Senator Akaka also again introduced the Downed Animal Protection Act as S. 1779; the House companion bill by Representative Ackerman was 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.”

These or other proposals aimed at addressing the food safety and animal welfare aspects of the BSE issue could re-emerge in the 110th Congress. Senator Akaka and Representative Ackerman in January 2007 introduced bills (S. 394; H.R. 661) to ban downed animals in human food and to require that they be humanely euthanized immediately. Among the possible venues for debating them are the House and Senate Agriculture Committees, which plan to draft new omnibus legislation to replace expiring provisions of the 2002 farm bill (P.L. 107-171), and the House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, whose new chairwoman has expressed a strong desire to review a variety of food safety problems and the effectiveness of existing federal programs.

Related Issues and Options

Federal Spending on BSE

Federal dollars devoted to BSE-related activities have risen significantly in recent years, from less than \$6 million in appropriated funds in FY2001 to an estimated \$90 million in FY2006, and a requested \$98 million in FY2007. These figures do not include transfers of an additional \$157.4 million from the CCC account (which the Secretary is permitted to do under standing authority). Most of these CCC funds were used to pay for the enhanced surveillance program.

More specifically, USDA’s BSE spending (exclusive of the CCC money) has increased from less than \$500,000 in FY2000 to \$60 million in FY2006 and a requested \$68 million in FY2007. Within these totals, \$7 million has been budgeted for research by USDA’s Agricultural Research Service (which wants an increase to \$15 million for FY2007), \$17 million for APHIS ongoing surveillance, and \$3 million for FSIS meat safety activities. APHIS also includes another \$33 million annually within this total to continue the establishment of a national animal ID system, but this program is intended to support efforts to address any animal disease, not just BSE.

FDA spending for BSE-related work has risen from less than \$4 million in FY2001 (the first year for which figures are available) to nearly \$30 million in each of FY2005-FY2007 (estimated). Within this total, \$16 million annually is for federal

feed inspections, more than \$3 million for state feed inspections, and about \$10 million for a variety of regulatory, educational, and research activities.¹¹³

The Administration's final FY2007 budget for USDA and for FDA was not cleared by the 109th Congress, so programs for these (and most other federal) agencies and activities have been funded under a series of continuing resolutions, including the fourth and final one, H.J.Res. 20 (P.L. 110-5). The 110th Congress in spring 2007 was beginning to consider the FY2008 USDA and FDA appropriations requests. Although the Administration's requests for BSE-related appropriations generally have not been highly contentious, efforts to constrain the federal budget deficit, along with the observations of some that BSE is a diminished threat to U.S. cattle and people, could be factors in future spending decisions.

Animal Identification and Meat Traceability

Following the first U.S. report of a cow with BSE in late December 2003, the Secretary of Agriculture promised to take the lead in implementing an animal ID program capable of identifying all animals of interest within 48 hours of a disease discovery (BSE or other). Many animal producers support establishment of a nationwide identification (ID) system capable of quickly tracking animals from birth to slaughter. Many of them already keep records on the identities of each of their animals, primarily for herd management and marketing purposes.

Still, 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, 2004.¹¹⁴

However, despite years of effort on an animal ID program for disease purposes, many contentious issues remain unresolved. For example, should it be mandatory

¹¹³ Sources for these figures include unpublished figures from the budget offices of USDA and FDA, as well as hearings to support the agencies' FY2006 and FY2007 budget requests before the House Appropriations Committee.

¹¹⁴ 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*, February 4, 2004, 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.”

or voluntary? What types of information should be collected, on what animal species — and who should hold it, government or private entities? How much will it cost, and who should pay?

USDA has committed through FY2006 about \$85 million to a program, with another \$33 million sought for FY2007; all states now have systems for registering animal premises. In April 2006, USDA had published a new implementation plan envisioning an “incremental” series of implementation steps leading to full producer participation by 2009. By November 2006, USDA had further revised its thinking on how to achieve implementation. It unveiled a draft “user guide,” which stated that it was “the most current plan for the NAIS and replaces all previously published program documents, including the 2005 Draft Strategic Plan and Draft Program Standards and the 2006 Implementation Strategies.”¹¹⁵ The document seeks to reassure producers that USDA will not require them to participate in the program, and that it is bound by law to protect individuals’ private and confidential business information. The draft user guide describes three successively greater steps toward full participation, if a producer chooses to do so, which include premises registration, animal identification, and selection of an animal tracking database to report animal movements (actually a series of privately or state-administered databases rather than a central USDA system).

Some industry groups and lawmakers have criticized USDA for moving too slowly and/or not providing a clearer path toward a universal ID program. Others believe that USDA’s progress to date simply reflects the deep divisions among producers and other interests over the many unresolved questions. Meanwhile, a vocal number of livestock producers, many of them smaller-scale, are opposing any effort to establish broader programs, fearing they will be costly and intrusive.

The 108th and 109th Congresses were asked to address animal ID issues. The House Agriculture Committee held hearings in 2005 on the feasibility of establishing a privately held system. A provision in the House-passed USDA appropriation for FY2007 (H.R. 5384) would have conditioned the use of the next \$33 million in spending for animal ID on publication in the *Federal Register* of a “complete and detailed plan” for the program, “including, but not limited to, proposed legislative changes, cost estimates, and means of program evaluation.” However, a House floor amendment to prohibit all ID program funding was defeated by a wide margin. The Senate committee-reported version of H.R. 5384 requested a GAO review of USDA’s efforts.

Other bills in the 109th Congress included 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. A provision of S. 2002 would have required USDA to establish a ruminant ID program.

¹¹⁵ APHIS is accepting comments on the draft user guide until January 22, 2007; it is posted at its NAIS website: [<http://animalid.aphis.usda.gov/nais/index.shtml>].

Continuing differences over animal ID have propelled the issue into the 110th Congress. Many observers expect that these differences could be resolved in a part of the next omnibus farm bill, which the House and Senate Agriculture Committees hope to complete in 2007. As of mid-May, two animal ID bills had been introduced: H.R. 1018, to prohibit USDA from implementing a mandatory program; and H.R. 2301, to establish a producer-governed program.¹¹⁶

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.

Past Congresses delayed the implementation deadline several times. 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). The FY2006 appropriation for USDA (H.R. 2744; P.L. 109-97) postpones COOL for an additional two years, until September 30, 2008.

Meanwhile, debate over the pros and cons of COOL continues into the 110th Congress, where some Members still oppose the delay, and have expressed their intention to require implementation sooner.¹¹⁷ 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.

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

¹¹⁶ See CRS Report RL32012, *Animal Identification and Meat Traceability*, by Geoffrey S. Becker.

¹¹⁷ For example, Representative Rehberg introduced the first such bill (H.R. 357), to require COOL by September 30, 2007.

from Canada. Hoping to satisfy Japanese (and Korean) demands, the department unveiled in August 2003 a “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 it has been widely viewed as a minimum prerequisite for gaining access to the Japanese and other foreign markets.

Bills offered earlier in the 109th Congress (H.R. 384/S. 108) the Canada rule (see “Trade Restrictions”) unless mandatory COOL were implemented. Other bills would have made 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 have prohibited use of funds to implement COOL for meats. On the other hand, S. 1331 would have accelerated implementation for mandatory COOL to January 30, 2006.

Although this bill did not pass, new proposals have been offered in the 110th Congress to accelerate implementation to September 30, 2007: H.R. 357, by Representative Rehberg, and S. 404, by Senator Thomas.¹¹⁸ Another bill, S. 1308, would prohibit USDA from allowing the importation of additional types of Canadian cattle until the implementation of country of origin labeling requirements.

Beef Labeled “Organic”

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.”¹¹⁹ Numerous news reports have implied 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

¹¹⁸ See CRS Report 97-508, *Country-of-Origin Labeling for Foods*, by Geoffrey S. Becker.

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

under experimental conditions suggested that CWD may be transmissible through contaminated environments long after infectious animals were no longer present.¹²⁰

Since 1997, CWD has been detected in captive cervid herds in nine states: Colorado, Kansas, Minnesota, Montana, Nebraska, New York, Oklahoma, South Dakota, and Wisconsin. As of early December 2006, there were five known positive captive herds in the United States: four elk herds in Colorado, and one deer herd in Wisconsin. Federal and state policy is to depopulate (destroy) these herds (see below). CWD has been detected in wild cervids in 11 states: Colorado, Illinois, Kansas, Nebraska, New Mexico, New York, South Dakota, Utah, West Virginia, Wisconsin, and Wyoming.¹²¹ 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.¹²²

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.

¹²⁰ M.W. Miller, *et al.*, “Environmental Sources of Prion Transmission in Mule Deer,” *Emerging Infectious Diseases*, June 2004.

¹²¹ Maps of U.S. CWD distribution are prepared by USDA, APHIS and are available at [<http://www.aphis.usda.gov/vs/naahps/cwd/cwd-distribution.html>].

¹²² Found at USDA APHIS, “Questions and Answers About Chronic Wasting Disease,” September 2002, at [http://www.aphis.usda.gov/lpa/pubs/fsheet_faq_notice/faq_ahcwg.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/>].

CWD has been experimentally transmitted by artificial means to mice, ferrets, mink, goats, squirrel monkeys, and calves.¹²³

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 recommends against the use of rendered deer and elk material considered high-risk in any animal feeds.¹²⁴

Activities related to CWD control are also conducted by USDA's Agricultural Research Service (ARS) and Cooperative State Research, Education and Extension Service (CSREES)¹²⁵ and several agencies in the Department of the Interior (DOI). In recognition that CWD was 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."¹²⁶ 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.

APHIS, whose regulations govern cooperative programs to control animal diseases, had published a final rule in the July 21, 2006, *Federal Register* to establish a captive herd certification program for CWD, and rules on interstate movement of cervids.¹²⁷ The rule was to take effect on October 19, 2006, but APHIS subsequently announced an indefinite delay in the effective date and an extension of the comment period through January 3, 2007. The agency had received petitions raising concerns about the rule, such as whether federal interstate movement regulations should preempt state requirements for importation, and the scientific basis underlying federal interstate movement requirements.¹²⁸ A revised rule had not been published as of mid-May 2007.

¹²³ *Ibid.*

¹²⁴ FDA, *Guidance for Industry #158: Use of Material from Deer and Elk in Animal Feed*, September 15, 2003, at [<http://www.fda.gov/cvm/Documents/guide158.pdf>].

¹²⁵ See ARS research website to search for CWD studies at [<http://www.ars.usda.gov/main/main.htm>].

¹²⁶ USDA/ DOI, *Plan for Assisting States, Federal Agencies, and Tribes in Managing Chronic Wasting Disease in Wild and Captive Cervids*, June 26, 2002.

¹²⁷ 71 *Federal Register* 41682.

¹²⁸ Chronic Wasting Disease Alliance, "CWD Update," September 13, 2006, at [<http://www.cwd-info.org/>].

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.

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.¹²⁹

¹²⁹ Cornell Feline Health Center, “Mad Cow Disease and Cats,” at [<http://www.vet.cornell.edu/fhc/news/madcow.htm>].