

# CRS Issue Brief for Congress

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## **Mad Cow Disease: Agricultural Issues for Congress**

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Geoffrey S. Becker  
Resources, Science, and Industry Division

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## Mad Cow Disease: Agricultural Issues for Congress

### SUMMARY

In December 2003 a Holstein dairy cow in Washington State tested positive for BSE (bovine spongiform encephalopathy, or mad cow disease), the first case discovered in the United States and the second native case in North America. (Canada confirmed a third and then a fourth case in early January 2005.)

All four North American cows were born in Canada, the first three before both countries banned, in 1997, the practice of feeding most ruminant material back to ruminants, including cattle. The fourth (third Canadian) case was in a cow born in March 1998. In all four cases, BSE-contaminated feed is considered the most likely cause of infection.

Lower-risk Canadian beef has been permitted into the United States since August 2003. As the two new BSE cases were emerging, USDA published a final rule, on January 4, 2005, to also allow younger live cattle and additional Canadian ruminant products to enter, effective March 7, 2005. However, a federal judge on March 2, 2005, issued a preliminary injunction blocking the rule.

In Congress, the Senate passed a joint resolution (S.J.Res. 4) on March 3 to overturn the rule. However, the resolution must pass the House (where similar H.J.Res. 23 is pending) and be signed by the President, which most observers believe is unlikely. Several other BSE-related measures have been introduced recently, such as a House resolution (H.Res. 137) urging economic sanctions against Japan if it does not begin to accept U.S. beef. Others include H.R. 187, H.R. 384, H.R. 1254, H.R. 1256, S. 73, S. 108, and S. 294. The agriculture committees have held hearings on BSE and trade.

Meanwhile, USDA's Office of Inspector

General in February 2005 issued an audit report that is highly critical of USDA's oversight of Canadian beef imports.

Elsewhere, recently released assessments by both USDA and the Canadian Food Inspection Agency have generally affirmed the effectiveness of Canadian feed controls — despite the discovery of a Canadian cow with BSE born after a ban was implemented on feeding prohibited cattle parts back to cattle.

Most countries banned U.S. beef after the December 2003 U.S. case. Several have partially reopened. Japan and Korea, the number one and three U.S. markets, respectively, remain closed. USDA said that total global exports in 2004 likely reached only 17% of their 2003 level of about 2.5 billion pounds. However, strong domestic demand and tight cattle supplies kept U.S. cattle prices relatively high in 2004.

USDA and other experts contend that the risk to human health from one or a few U.S. BSE cases is minimal. Nonetheless, USDA has intensified efforts to improve BSE safeguards, including banning downer (nonambulatory) cattle from human food; keeping from the food supply additional higher-risk animal parts; accelerating work on a national animal identification system for disease purposes; and increasing funds for BSE-related activities.

The Food and Drug Administration (FDA) is still weighing possible rules to tighten its feed controls. Further action is pending.

From June 2004 to mid-March 2005, nearly 285,000 mostly higher-risk U.S. cattle had been tested for BSE under a special, expanded surveillance program, all negative.

## MOST RECENT DEVELOPMENTS

On March 17, the Administration filed an appeal of a federal judge's March 2 order delaying implementation of USDA's January 4 final rule to permit imports of younger live cattle from Canada. Meat packers are joining USDA in seeking to overturn the lower court's ruling. Still, the live cattle imports are not likely for many weeks if not months, observers believe.

USDA's Office of Inspector General in February had issued an audit report that is highly critical of the department's oversight of Canadian beef imports, including its conduct in reopening the border. Elsewhere, recently released assessments by both USDA and the Canadian Food Inspection Agency have generally affirmed the effectiveness of Canadian feed controls — notwithstanding the discovery of a Canadian cow with BSE born after a ban was implemented on feeding prohibited cattle parts back to cattle.

Meanwhile, USDA reported that as of March 23, nearly 285,000 cattle had been specially tested since June 2004, and no results have been positive for BSE. A USDA official recently told Congress that the program likely would be ended in May or June, when the special testing program reaches a total of approximately 300,000 higher-risk cattle. Also in Congress, the Senate on March 3 passed a joint resolution that would overturn USDA's January 4 rule. However, to become effective, the resolution would have to pass the House and be signed by the President, which most observers believe is unlikely.

## BACKGROUND AND ANALYSIS

### Introduction

Bovine spongiform encephalopathy (BSE), widely known as mad cow disease, is a degenerative, fatal disease affecting the nervous system in cattle. Worldwide, BSE has been found in 187,000 animals, 183,000 of them in Great Britain, where it was first detected in 1986. (Most of the rest occurred elsewhere in Europe.) Reported cases of BSE have been declining since their peak in 1992 in Great Britain.

The predominant theory among scientists is that a “proteinaceous infectious particle” or “prion,” for which no treatment or preventive vaccine exists, causes BSE, which they believe is transmitted to other cattle through feed containing BSE-infected protein by-products. BSE cannot be detected until symptoms (e.g., neurological abnormalities; inability to stand or walk) appear, nor can it be confirmed until brain tissue is tested. Estimates of average incubation for BSE symptoms in cattle range from two to eight years.

Until December 2003, tests had not found BSE in a U.S. herd. Nonetheless, scientific uncertainty about its cause and transmission had spurred U.S. precautionary actions in recent years aimed at confirming BSE's continued absence and preventing imports of livestock or animal products that could carry it. Other BSE-like animal diseases, collectively called transmissible spongiform encephalopathies (TSEs), have long been present here. They include scrapie in sheep and chronic wasting disease (CWD) in deer and elk.

A rare but fatal human disease, Creutzfeldt-Jakob disease (CJD), also is known to occur in the United States, where it normally strikes about one in one million people yearly. Following the British BSE outbreak, a new-variant CJD (vCJD) was identified and is believed to be transmitted to humans mainly through consumption of cattle products contaminated with the BSE agent. About 160 people have been diagnosed with vCJD since 1986, most of them in Great Britain.<sup>1</sup>

## U.S. Case

USDA announced on December 23, 2003, that brain samples taken from a Holstein dairy cow in Washington State had tested positive for BSE, the first such U.S. case. While emphasizing that the risks to food safety and human health were minimal, U.S. officials initiated standing BSE response plans including an extensive investigation that eventually led to the precautionary killing of about 700 cattle and the testing for BSE of 250 of them. No other cases were found during this investigation, led by USDA's animal health agency, the Animal and Plant Health Inspection Service (APHIS).

**Meat Recall.** USDA's Food Safety and Inspection Service (FSIS), which inspects most meat and poultry for human food, determined that the brain, spinal cord, and part of the lower intestine of the BSE cow — tissues most likely to be infective — had been removed at slaughter. It also announced “out of an abundance of caution” a voluntary recall of 10,410 pounds of raw beef from 20 animals slaughtered on the same day as the BSE cow at a Moses Lake, Washington, facility. Officials, who in early February 2004 expanded the recall to 38,000 pounds, said some meat likely was consumed, but they attempted to reassure consumers that the meat posed “zero risk” to human health.

**Cow's Origin and Movements.** Officials traced the BSE cow to its birthplace in an Alberta, Canada herd in April 1997. It is believed to have entered the United States with 80 other dairy cattle from the same Alberta herd in September 2001; the cow reached a 4,000-head dairy herd in Mabton, Washington, in October 2001. The cow likely was infected in Canada by eating contaminated feed before a 1997 ban on feeding most mammalian proteins to cattle became effective, according to APHIS. U.S. authorities eventually located 28 of the 80 animals at eight different facilities, mostly in Washington. None of those found tested positive for BSE. Critics assert that if a U.S. animal identification (ID) system were in place, USDA could have accounted for the disposition of most if not all 80 animals, and possibly their products. Others counter that the likelihood of the others also being infected has always been quite low.

## BSE Safeguards Before the U.S. Case

U.S. and beef industry officials had long contended that three so-called firewalls would keep BSE from threatening domestic cattle and public health. These “firewalls” have been:

**Import Restrictions.** APHIS has an import ban on live ruminants (cows, sheep, goats) from countries with known BSE cases (started in 1989); an import ban on ruminant

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<sup>1</sup> Except where noted, sources primarily are USDA daily briefings and backgrounders on BSE, which are available through the USDA website at [<http://www.usda.gov>].

meat and meat products from BSE countries (since 1991); and a prohibition on importing ruminants and most ruminant products from all of Europe (since 1997). In late 2000, USDA prohibited 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. Under the FSIS foreign inspection program, no establishments in countries where BSE has been found can ship beef to the United States. The exception now is Canada, which USDA contends has a science-based approach to BSE safety.<sup>2</sup>

**Targeted Domestic Surveillance.** Among other duties, meat inspectors examine every animal entering slaughter plants for human consumption. FSIS indicates it has not permitted cattle showing suspicious neurological symptoms to be slaughtered for human consumption. It has sent brain samples from such animals to an APHIS laboratory in Ames, Iowa, as part of what USDA called a “targeted surveillance approach designed to test the highest risk animals, including some but not all downer (nonambulatory) animals, those that die on the farm, older ones, and animals exhibiting signs of neurological distress.”<sup>3</sup>

The program had grown steadily from a few thousand animals tested annually in the mid-1990s to about 20,000 cattle in each of FY2002 and FY2003, out of about 35 million slaughtered each year. Critics argued that this surveillance was inadequate to detect BSE. Some proposed that testing should approximate levels in Europe, where policy calls for testing all cattle over 30 months old, or in Japan, which claims to test all cattle for slaughter. USDA argued that its program was testing many more animals than recommended by the World Organization for Animal Health (or OIE, its French acronym) and that because surveillance is targeted to test higher-risk animals, it could effectively detect BSE if it is present in the bovine population at a level of one in one million adult animals. USDA had intended to test 40,000 cattle in FY2004, but in June 2004 it began a greatly expanded program (see “Expanded Surveillance” later in this report).

**Domestic Cattle “Feed Ban”.** The Food and Drug Administration (FDA), which regulates animal feed ingredients, banned most mammalian proteins from cattle feed on August 4, 1997.<sup>4</sup> Exceptions have existed for blood and blood products; gelatin; inspected, processed, and cooked meat products for human consumption (such as restaurant plate waste); milk products; and products containing pork and equine proteins only. Most mammalian proteins can still be fed to other animals such as pigs, poultry, and pets. To ensure compliance, FDA enforcement includes education as well as inspections of the estimated 264 renderers (firms that prepare animal parts not destined for human food), and of all known feed mills (as many as 9,240 or more, according to the agency). FDA promised

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<sup>2</sup> The United States, Canada, and Mexico are working through the World Organization for Animal Health (or OIE, the French acronym) on new guidance for resuming trade with countries that have reported BSE. See *The OIE standards on BSE: a guide for understanding and proper implementation*, January 2004, at [[http://www.oie.int/eng/press/en\\_040109.htm](http://www.oie.int/eng/press/en_040109.htm)].

<sup>3</sup> USDA backgrounder on BSE, July 10, 2003. For more details, see CRS Issue Brief IB10082, *Meat and Poultry Inspection Issues*.

<sup>4</sup> See *CVM and Ruminant Feed (BSE) Inspections*, at [<http://www.fda.gov/cvm/index/bse/RuminantFeedInspections.htm>]. For background on the rendering industry, also see CRS Report RS21771, *Animal Rendering: Economics and Policy*.

in January 2004 that it would strengthen its feed controls, but no changes had been formally proposed as of early March 2005.

## Assessments of Previous U.S. BSE Safeguards

**Government Accountability Office (GAO).** A February 2002 GAO study (*Mad Cow Disease: An Improvement in the Animal Feed Ban*; GAO-02-183) reported that 364 out of 10,576 firms inspected by FDA were still out of compliance. The GAO report also stated that FDA was using flawed data to track compliance, and had no clear enforcement strategy for firms that were not obeying the ban. The report criticized USDA's failure to test the brains of cattle that die on farms (which subsequently resulted in a change in the testing program), and questioned the adequacy of the inspection procedures for imported meats.

A subsequent GAO report, published in February 2005, concluded that FDA had made improvements in its management of the feed ban, but that program weaknesses continue to limit its effectiveness, placing U.S. cattle at risk of spreading BSE. Among the weaknesses cited by GAO are that FDA has no uniform approach for identifying all the additional feed manufacturers, on-farm mixers, and other feed industry businesses beyond the approximately 14,800 firms it has inspected so far; that it has not reinspected approximately 2,800 of the firms it has inspected and does not know whether they use prohibited materials (i.e., cattle parts that might harbor the BSE agent) in their feed; that FDA has not required a warning label on feed for export even though it is not intended for cattle and other ruminants; and that it has not always alerted USDA and the states when it learns that cattle may have been given prohibited feed.

In July 2003 and January 2004, FDA reported that feed industry compliance with the ban had reached 99%. However, that may be misleading, because the compliance rate was last based on inspections of only about 570 firms, GAO reported. The GAO report added that FDA does not include all serious violations in the calculations because it reclassifies firms as being in compliance once they correct violations, no matter how long a problem existed, among other problems with the data.

**Harvard.** A USDA-funded study issued in November 2001 by the Harvard Center for Risk Analysis, based on a three-year risk analysis, stated in part that "BSE is extremely unlikely to become established in the United States.... Similarly there appears to be no potential for an epidemic of BSE resulting from scrapie, chronic wasting disease, or other cross-species transmission of similar diseases found in the U.S.... If the disease does indeed occur spontaneously in cattle, as some have suggested, it would result in one to two cases per year with little spread. Only a small amount of potentially dangerous tissues would reach the human food supply and be available for possible human consumption."

After a BSE case was found in Canada in May 2003, USDA asked Harvard to reassess the risk. Harvard responded that although "the possible introduction of BSE into the U.S. from Canada cannot be dismissed," the likelihood is very low, and U.S. protective measures by now would have contained any possible spread. The Harvard study is based on a computer simulation, which several critics indicate could be based upon arguable assumptions. The study authors acknowledge that their model is "not amenable to formal validation because there are no controlled experiments in which the introduction and consequences of BSE introduction to a country has been monitored and measured." But the

authors assert that they tested the model's predictions against an actual small BSE outbreak in Switzerland and found them "reasonably close to empirical observations."

However, the Harvard 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. The report observed that if additional animals in this group harbored BSE, 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 previous five years, the U.S. on average imported over 1.2 million cattle and 185,000 tons of feed annually from Canada."<sup>5</sup>

**International Review Team (IRT).** After the U.S. BSE discovery in December 2003, USDA named a panel of international BSE experts to examine the government's response, and its findings were released on February 4, 2004.<sup>6</sup> Although the infected animal may be the only one from the 81-cow herd that survived to adulthood, and its birth cohorts "do not represent significant risk," the panel concluded, "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." Urging the type of expanded testing program USDA later began (see below), the panel noted that "the BSE agent is circulating in North America," and the magnitude of the problem should be measured.

The panel concluded that USDA's epidemiological investigation and the tracing and recall of meat and byproducts had conformed to international standards insofar as possible. However, it said that an "appropriate" national ID system was needed. The panel also observed that the partial ruminant to ruminant feed ban now in place is "insufficient," and that a complete ban on the feeding of all mammalian and poultry byproducts to cows and other ruminants is justified.

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<sup>5</sup> 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](http://www.aphis.usda.gov/lpa/issues/bse/harvard_10-3/text_wrefs.pdf)]. The Harvard risk analysis considered import as well as domestic practices in its assessment. Both the GAO and the Harvard study did note that noncompliance with the feed ban could occur at many points in the feed chain. Moreover, FDA does not actually test the feed for prohibited material.

<sup>6</sup> The panel, a subcommittee of the Secretary'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 APHIS official. The *Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States* can be viewed at [[http://www.aphis.usda.gov/lpa/issues/bse/US\\_BSE\\_Report.pdf](http://www.aphis.usda.gov/lpa/issues/bse/US_BSE_Report.pdf)].

USDA officials conceded that there might be other BSE cases found in North America but pointed out that the panel also noted that government agencies already had instituted the most important safeguards. Some IRT critics, including the National Cattlemen's Beef Association (NCBA), argued that the panel had overstated BSE risks and the steps needed to prevent its spread here, including the proposal to expand greatly the animal feed ban. NCBA and industry officials suggested that the panel was heavily weighted with experts from Europe, where BSE was far worse, and that some of its findings lacked a firm scientific basis. Others, including some consumer advocates, asserted that the panel's findings underlined their own concerns that authorities have not done enough to keep BSE out of North America.

## **Policy Changes After the U.S. BSE Case**

**USDA.** The U.S. BSE incident caused USDA officials to re-examine their existing safeguards. On December 30, 2003, the Secretary of Agriculture announced the following steps to strengthen the safeguards, most focusing on FSIS-regulated practices where cattle are slaughtered and processed. The Secretary at this time also announced that BSE surveillance would be expanded and asked the IRT to review BSE safeguards (see above).

**Downers.** USDA banned all nonambulatory cattle from slaughter establishments, to ensure that they cannot be passed for human food use, though they still can go to rendering plants for other uses, including nonhuman food. The number of such animals was estimated by the Secretary to be 150,000-200,000 out of the roughly 35 million U.S. cattle slaughtered yearly. The downer ban has been among the most controversial changes for producers, who say they incur large losses when they cannot sell cattle unable to walk for reasons unrelated to BSE (e.g., a broken leg). (Interim final rule, January 12, 2004, *Federal Register*.)

**Specified Risk Material (SRM).** USDA declared as SRM (and thus unfit for human food) the skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord, and dorsal root ganglia of cattle over 30 months, and the small intestine of cattle of all ages. (Tonsils already were considered inedible for human food.) An SRM declaration prohibits the use of these cattle parts in the human food supply. The rule requires cattle packers to develop and implement procedures to remove and dispose of SRMs so that they cannot enter the food chain. (Interim final rule, January 12, 2004, *Federal Register*.)

**Advanced Meat Recovery (AMR).** AMR mechanically removes muscle tissue from bone, and the paste-like tissue can be labeled as "meat." FSIS previously had regulations to prohibit such products to be labeled as "meat" if they contain spinal cord. This newer rule expands that prohibition to include additional nerve tissue. Also, AMR no longer can be used for cattle 30 months and older. Earlier FSIS sampling had found nervous system tissue in about a third of AMR beef. (Interim final rule, January 12, 2004, *Federal Register*.)

**"Test and Hold"**. All products from a carcass being tested for BSE must be held until FSIS confirms that the BSE test is negative. (Notice, January 12, 2004, *Federal Register*.)

**Stunning.** USDA banned air-injection stunning, to ensure that brain pieces are not dislocated into carcass tissues during slaughter. USDA stated that this method was now rarely used. (Interim final rule, January 12, 2004, *Federal Register*.)

**Animal Identification and Traceability.** The Secretary also said that USDA would “begin immediate implementation” of a national animal ID system. A government-industry committee already had been working on the framework for a system, and it had anticipated that states would have individual IDs in place for cattle for interstate movement by July 2005. On April 27, 2004, USDA announced that the White House had approved spending \$18.8 million in Commodity Credit Corporation (CCC) funds to begin implementation, which has started with a study of existing animal ID projects and cooperative agreements with states. On August 5, 2004, USDA announced 29 states and tribal agencies would receive \$11.64 million of the total, to register premises, collect data, and test ID technologies. These activities are still underway; APHIS now projects that states will have the capability to register individual premises (but not yet animals) by this year (See CRS Report RL32012, *Animal Identification and Meat Traceability*.)

**FDA Rules.** On January 26, 2004, FDA said it would enhance its own BSE safeguards for the food and cosmetic products it regulates. FDA said it intended to ban from human products the same SRMs being newly prohibited in FSIS-regulated meats and to ban any materials from downer or dead cattle. Also, it said it intended to ban from ruminant feed the following materials: ruminant blood and blood products, poultry litter (which can contain spilled feed that may contain ruminant material), and restaurant plate waste. Further, FDA said it would require feed mills to segregate ruminant and non-ruminant feed production lines/facilities if the mills use proteins prohibited in ruminant feeds. The agency promised to step up its inspections of the mills and of renderers to ensure compliance.

Portions of the long-awaited FDA rulemaking were published in the July 14, 2004, *Federal Register*. One is an interim final rule to prohibit higher-risk material from the human foods, dietary supplements, and medicines that it regulates. The materials are those banned under USDA rules: SRMs which are brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column and related tissue, and dorsal root ganglia from animals over 30 and tonsils and distal ileum of all cattle; mechanically separated beef; and material from nonambulatory cattle. An accompanying proposed rule would require that affected food manufacturers maintain records for two years to ensure compliance. This proposal was still pending as of mid-March 2005.

**Joint FDA-USDA Rulemaking.** Although it did not issue a concurrent rule to tighten feed restrictions, FDA on July 14 did publish jointly with USDA an advanced 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 in the rule that it “has reached a preliminary conclusion that it should propose to remove SRM’s from all animal feed and is currently working on a proposal to accomplish this goal.” More specifically, the ANPR says that these FDA options are under consideration, aimed at controlling feed cross contamination risks:

- Removing SRMs from all animal feed, including pet food;
- Requiring dedicated equipment or facilities for handling and storing feed and ingredients during manufacturing and transportation;
- Prohibiting the use of all mammalian and poultry protein in ruminant feed;
- Prohibiting materials from non-ambulatory disabled cattle and dead stock from use in all animal feed.

Regarding USDA policies, the ANPR sought comments on the FSIS regulatory measures put in place in January 2004; on whether a country's BSE status should be taken into account when FSIS determines whether its meat inspection system is equivalent to U.S. regulations; and on implementation of a national animal ID system, including if and how it should move from voluntary to mandatory and which species should be covered.

Reaction to the FDA portion on feed rules has been mixed. Some industry groups argued that enforcing existing feed restrictions is sufficient to prevent any spread of BSE, and that further actions like removal of SRMs from all animal feed both are unnecessary and would cost the industry many hundreds of millions of dollars in lost market revenues and waste disposal expenses. Critics, however, contended that the ANPR simply delayed the stronger actions they believe are needed to protect the feed supply — and ultimately consumers — from BSE. Explaining the delays, FDA officials noted that shortly after their January 26, 2004, announcement, the expert panel (IRT) recommended additional actions, which needed to be fully considered, and which the July 14, 2004, ANPR addresses (see previous section, and also “International Review Team,” above).

**Expanded Surveillance.** In June 2004, USDA began a greatly expanded testing program in an attempt to reach, over a 12-18 month period, as many as it can of higher-risk cattle, which it estimated to number 446,000. The effort also is supposed to sample about 20,000 apparently healthy adult bulls and cows, USDA said. By using newly approved rapid test kits, and by contracting with a network of participating state veterinary laboratories to conduct tests, in addition to using its Ames, Iowa, diagnostic facility, officials estimate they will have tested approximately 300,000 of the target population before the effort is ended, likely in May or June 2005. Samples are collected from slaughter establishments, on farms, at rendering facilities, cattle marketing sites, and veterinary and public health laboratories. Any rapid test that is not negative for BSE (“inconclusive” in USDA parlance) is sent to the national reference laboratory in Ames for confirmatory testing, which takes longer but is considered more accurate. As of March 23, 2005, nearly 285,000 cattle had been tested, all negative for BSE, according to the APHIS website.<sup>7</sup>

**Funding.** The Administration's FY2006 budget, released in early 2005, requests a total of \$66 million for USDA's BSE-related activities, including \$33 million to continue work on an animal ID program, \$21 million for BSE testing/surveillance, and \$12 million for research. Total USDA spending for BSE in FY2005 is estimated at \$123 million, of which \$69 million was for BSE testing (and most of that for the special surveillance program noted above), \$49 million to launch the animal ID effort, and \$3 million for research. Much of the FY2005 funding was through transfers from the CCC account rather than through direct appropriation by Congress. USDA's BSE spending in FY2004 was an estimated \$51 million. (Additional BSE amounts are requested for FDA and other agencies.)

## Testing Issues

**Testing Protocol.** BSE testing was the focus of a joint hearing held July 14, 2004, by the House Government Reform and Agriculture Committees. USDA's Inspector General (IG) testified on a draft OIG report which cites a number of limitations in the department's

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<sup>7</sup> Test results are posted at [[http://www.aphis.usda.gov/lpa/issues/bse\\_testing/](http://www.aphis.usda.gov/lpa/issues/bse_testing/)].

expanded surveillance plan. For example, testing results may be unreliable because the plan: is not truly random because 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; 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.

Secretary Veneman and other USDA officials defended their testing, noting among other things that the OIG observations were based on the plan before it was implemented and that many of the report's recommendations have been addressed. APHIS is receiving a representative mix of samples from all locations, reaching deeply into the higher-risk cattle population, and the statistical basis for the sampling is sound, officials asserted. They added that adjustments have been made as the result of ongoing assessments of the program.

After it was widely reported that USDA had failed to test a suspicious cow in Texas in late April 2004, the department announced revisions in its BSE sampling procedures. (The cow was condemned so its meat never entered the food supply, USDA said.) USDA stated that it was retraining inspectors, mandating that FSIS rather than APHIS personnel collect brain samples, and requiring that all cattle condemned antemortem (before slaughter for human food) be tested for BSE, not just those with suspicious symptoms. In a review of the Texas case, OIG found that officials had erred — but did not engage in intentional misconduct or knowingly provide misleading information — in failing to test the suspicious Texas cow. OIG reached similar conclusions about how the department had characterized the Washington BSE cow as nonambulatory in December 2003.

**Private Testing.** Several smaller firms (notably Creekstone Farms Premium Beef) expressed interest in testing all of their cattle for BSE — as the Japanese were demanding. USDA has asserted that 100% testing is not scientifically based. USDA, which claims authority to approve test methods and their uses under the Virus-Serum-Toxin Act, denied the Creekstone request that it be allowed to test all of its bovines. USDA and meat industry officials apparently are concerned, among other things, that consenting to 100% testing could undermine trade negotiations, be costly, and imply that BSE-tested meat is safer than untested meat.<sup>8</sup>

## U.S. Industry and Trade Implications

Cattle production is the largest single segment of U.S. agriculture (accounting for 20% of U.S. farm sales annually). Exports of U.S. beef and other cattle products are viewed as critical to long-term market growth. The value of beef and beef variety meat exports was estimated by USDA to be \$3.9 billion in 2003 (or about 10% of farm value for cattle/calves). Four countries bought approximately 90% of these exports: Japan (\$1.394 billion), South Korea (\$816 million), Mexico (\$877 million), and Canada (\$331 million). According to a

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<sup>8</sup> The text of the act is available online from the USDA/APHIS Center for Veterinary Biologics at [<http://www.aphis.usda.gov/vs/cvb/vsta.htm>]. See also CRS Report RL32414, *The Private Testing of Mad Cow Disease: Legal Issues*.

more recent USDA estimate, when all types of beef and ruminant product exports are counted, their 2003 export value was \$7.5 billion.

Most importing countries had halted imports of some or all U.S. beef and cattle soon after the December 2003 U.S. BSE announcement. As of early March, 59% (\$3.1 billion) of the overall market (of \$7.5 billion) had not been recovered, with Japan and Korea accounting for three-fourths of the existing closures.<sup>9</sup> However, both Mexico and Canada have reopened their borders to some U.S. beef and veal, and by early 2005, officials were reporting progress toward regaining other markets, including Taiwan and Egypt. USDA estimated that U.S. beef and veal exports globally reached 434 million pounds in 2004, or 17% of the 2003 level of 2.523 billion pounds. USDA predicted that unless more markets reopen, exports would reach only 640 million pounds in 2005. In Japan, other countries, notably Australia, are filling the U.S. lost market share of beef sales.

**Japan.** 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 will establish, with Japanese concurrence, a marketing program — a modified version of its Beef Export Verification (BEV) Program — to enable resumption of some U.S. exports to Japan for an interim period. BEV would certify that only beef from cattle of 20 months or younger are shipped. The United States agreed to an expanded SRM definition, to include — for cattle of *all ages* — the entire head except tongues and cheek meat, tonsils, spinal cords; distal ileum (two meters from connection to caecum); and vertebral column (excluding the transverse processes of the thoracic and lumbar vertebrae, the wings of the sacrum and the vertebrae of the tail). So, in addition to proving that the beef is from cattle under 21 months old, a firm also would have to remove these materials from cattle of all ages in order to satisfy Japan. USDA's current SRM list is somewhat different and generally covers only cattle over 30 months.

The announcement stated that the two countries would evaluate this interim system by July 2005 and modify it if appropriate. The United States would permit Japanese beef and products into its market following relevant domestic rule-making procedures. (Japan exported an average of less than \$1 million annually of Kobe or Wagyu specialty beef to the United States through 2001, prior to a U.S. ban on its beef.)

Japanese authorities, who have reported 15 cases of BSE in their cattle, have been considering a plan to scale back their BSE testing from all cattle to only those over 20 months old. Even as negotiating details get resolved, both countries still must undergo rulemaking procedures that can be quite lengthy. That, along with statements by various Japanese officials that consumers there are not ready to accept U.S. beef, have led many industry analysts to predict that Japan (and Korea) will remain closed well into 2005.

U.S. industry may have difficulty satisfying the Japanese requirements, some industry observers believe. 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. Age verification

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<sup>9</sup> Mike Johanns, Secretary of Agriculture, March 1, 2005, prepared testimony for the House Agriculture Committee.

and the expanded SRM definition would create new compliance costs for packers and their suppliers. “This leaves the U.S. beef industry in the unenviable position of having to accept an agreement that may be economically unviable until Japan relents on the age issues,” *Cattle Buyers Weekly* commented.<sup>10</sup> Another industry analyst told Reuters, “Stopping short of testing every one of our animals, all we did was acquiesce to every other demand they made.”

The seemingly sluggish pace of the negotiations has frustrated the beef industry and many Members of Congress, who believe opening the Japanese market will convince other Asian nations, including Korea, to follow suit. (See “Congressional Response.”)

**Industry Impacts.** Domestic cattle and beef prices by late 2003 had reached record highs due to a tight supply-demand situation. The immediate impact of the BSE case was reflected in a drop in cash prices for Nebraska steers from \$91 per 100 pounds (cwt.) to about \$75 per cwt. the following week. Cattle futures markets also dropped by allowable limits for three consecutive days before closing at 15% below pre-BSE levels. Prices have recovered substantially since January 2004. A decline in U.S. cattle inventories due in part to widespread drought conditions in cattle country, along with strong domestic demand for beef, kept farm prices relatively high during much of 2004.

USDA has reported that average U.S. fed steer (i.e., slaughter-ready cattle) prices were nearly \$85 per cwt. for all of 2004, compared with an earlier 2004 prediction of \$72-\$77; this is near the lower end of a USDA forecast, made just before the BSE case, of \$84-\$91 per cwt. The 2005 price forecast (as of early 2005) was \$80-\$85. Average fed steer prices were \$85 in 2003 and \$67 in 2002.

Cattle producers were losing about \$10 per cwt. or \$125 per head due to lost access to the Japanese, Korean, and other Asian markets, Cattle-Fax, a marketing information service associated with the industry, reported in July 2004. NCBA recently placed losses at \$175 per head or \$4.7 billion total. The U.S. Meat Export Federation (USMEF) in August 2004 said that lost export premiums on the top 10 cuts exported were costing the beef industry about \$80 per head or more than \$2.2 billion annually, plus another \$100 per head due to the price impacts of additional beef supplies.<sup>11</sup>

In a preliminary analysis released April 7, 2004, FSIS estimated that its major January 12 rules (see “Policy Changes After the U.S. BSE Case,” above) would result in total annual costs to industry of between \$110 million and \$149 million, exclusive of some costs such as segregating animals over 30 months and their carcasses, and foreign equivalency measures. On the other hand, in discussing potential benefits, FSIS notes: “Failure to assure consumer confidence in the U.S. beef supply could easily reduce cash receipts to the cattle sector by \$5 to \$10 billion annually. Net farm income could decline by \$3 to \$6 billion annually...”<sup>12</sup>

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<sup>10</sup> “Beef to Japan Is Still Months Away,” *Cattle Buyers Weekly Newsflash*, October 25, 2004.

<sup>11</sup> The NCBA figures were used at the House’s March 1, 2005, hearing on BSE. See also CRS Report RS21709, *Mad Cow Disease and U.S. Beef Trade*; and the special ERS report *U.S. 2003 and 2004 Livestock and Poultry Trade Influenced by Animal Disease and Trade Restrictions*, July 2004.

<sup>12</sup> *Preliminary Analysis of Interim Final Rules and an Interpretive Rule to Prevent the BSE Agent From Entering the U.S. Food Supply*, which can be accessed via the FSIS website. Address:

## Canadian BSE Cases

The BSE situation in Canada has weighed heavily on U.S. policy and trade considerations. Some argue that too hastily expanding U.S. imports of beef and cattle from Canada, where all four North American BSE cattle were born, will endanger the U.S. cattle herd and undermine negotiations with the Japanese. Others argue that, to the contrary, USDA's steps to reopen the border for Canada demonstrate to the Japanese and other foreign countries that the United States is acting on the basis of scientific evidence that Canada's safeguards are effective — and that they should do likewise for the United States.

**May 2003 Announcement.** Canadian officials announced on May 20, 2003, that they had discovered BSE in an Alberta cow (later found to have been born in Saskatchewan or Alberta in early 1997). The cow's brain had been pulled for testing in late January 2003. No meat from the cow became human food, according to the Canadian Food Inspection Agency (CFIA). An investigation concluded that the infected cow most likely contracted BSE through consumption of feed containing BSE-contaminated meat and bonemeal (MBM) from ruminants, probably before the feed ban. Canadian authorities focused on, among other possibilities, the slaughter and rendering into feed (at either a U.S. or Canadian feed plant) of some imported British cattle that included one with BSE that was found in 1993.<sup>13</sup> A total of 2,800 cattle were killed and tested for BSE, with no other cases found.

**January 2005 Announcements.** A second BSE case was found in Canada in December 2004, and was confirmed by Canadian authorities on January 2, 2004. The CFIA announced that the animal was an Alberta dairy cow born in 1996, and suspected that it had become infected by contaminated feed before the 1997 feed ban. On January 11, 2004, CFIA announced its third confirmed case, this in an Alberta beef cow born in March 1998 — some seven months after the feed ban was published. CFIA stated that no part of either animal entered the human food or animal feed supply. CFIA said it had launched investigations to identify any other animals of risk, focusing on recently born offspring and on other cattle born on the same farm within a year of both infected animals, several of which entered the United States.<sup>14</sup>

Government veterinary experts on both sides of the border agree that some additional BSE discoveries in older U.S. and Canadian cows are “not unexpected,” particularly in light of enhanced surveillance activities, and that Canada could have as many as 11 reported cases and still satisfy the U.S. criteria for a “minimal risk” country (see next section).

**Canadian Feed Ban.** However, the relatively younger age of the most recent BSE cow added a new dimension to the issue. Canadian officials have stated that the cow most

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<sup>12</sup> (...continued)

[[http://www.fsis.usda.gov/Fact\\_Sheets/Bovine\\_Spongiform\\_Encephalopathy\\_BSE/index.asp](http://www.fsis.usda.gov/Fact_Sheets/Bovine_Spongiform_Encephalopathy_BSE/index.asp)].

<sup>13</sup> Harvard Center for Risk Analysis, *Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the United States from Canada*, released October 2003, at [[http://www.aphis.usda.gov/lpa/issues/bse/harvard\\_10-3/text\\_wrefs.pdf](http://www.aphis.usda.gov/lpa/issues/bse/harvard_10-3/text_wrefs.pdf)]. The review noted it is possible some infected Canadian feed also has entered the United States. Both countries have vigorous cross-border trade in beef and cattle, including dairy cattle, and in feed.

<sup>14</sup> See [<http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/bseesbindexe.shtml>].

likely consumed BSE-contaminated feed sometime after its birth, indicating that farmers likely were still using the last of such prohibited feeds in the months following the ban. This time period was well past the 60-day grace period that farmers were granted to use up existing feed stocks — and followed a much longer period prior to that when the rule was being proposed and explained to the feed industry and to cattle producers.

In January 2005, USDA and CFIA undertook separate reviews of the effectiveness of the Canadian feed ban. In its February 2005 report on the review, USDA concluded that the ban has been effective. Among other things, USDA endorsed CFIA findings that compliance by renderers and feed mills has exceeded 90% (with most unsatisfactory ratings due to “minor record-keeping infractions”) and that compliance continues to improve over time. CFIA issued its findings on March 2, 2005, also reporting high adherence to the feed rule. It stated: “On average, 95% of feed mills and 93% of renderers inspected over the past three years were either fully compliant or reported only minor compliance issues.” Companies are moving increasingly toward segregated plants or production lines that handle either prohibited or non-prohibited materials but not both.<sup>15</sup>

Some critics remained skeptical of these findings, arguing among other things that the reviews were inadequate. For example, they relied largely on reviewing paperwork to ascertain compliance, and generally did not examine the ban’s implementation by Canada’s 246,000 livestock farms — including some 25,000 on-farm feed mills, these critics assert.

**USDA Rulemaking to Readmit Canadian Beef and Cattle.**<sup>16</sup> In late May 2003, the United States had issued an interim final rule placing Canada under its standing BSE import restrictions — that is, all Canadian ruminants (cattle, sheep, goats, deer, elk, etc.) and ruminant products were prohibited from entering the United States. It began to ease that ban on August 8, 2003, when USDA announced that it would accept applications for permits to import selected ruminant products from Canada, including boneless beef from cattle under 30 months old and boneless veal from calves no older than 36 weeks at slaughter; and boneless sheep and goat meat from animals under 12 months old. USDA’s decision was based on what it said was a “thorough scientific analysis” that found minimal risk from these imports. The August 2003 announcement was not accompanied by formal rulemaking.

On November 4, 2003, USDA did publish in the *Federal Register* a proposed rule to change its standing BSE policy so as to allow imports of certain live ruminants and products from “minimal risk” regions, including Canada. Permitted would be imports of cattle for slaughter under 30 months old; sheep and goats for slaughter under 12 months; cervids (e.g., deer and elk) for immediate slaughter; and various other products from these animals.

However, APHIS already was further expanding the list of allowed (so-called low risk) products. A list published on August 15, 2003, included, in addition to the products announced on August 8 (see above), bone-in as well as boneless veal (but not bone-in beef),

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<sup>15</sup> See USDA’s *Assessment of the Canadian Feed Ban*, accessed on the web at [<http://www.aphis.usda.gov/lpa/issues/bse/CAN-FeedBanReview.pdf>], and CFIA’s *Feed Ban Review*, at [<http://www.inspection.gc.ca/english/anima/feebet/rumin/revexa/revintroe.shtml>].

<sup>16</sup> See the APHIS website at [<http://www.aphis.usda.gov/lpa/issues/bse/bse.html>], and CRS Report RL32627, *Bovine Spongiform Encephalopathy (“Mad Cow Disease”) and Canadian Beef Imports*.

and trimmings (if such trim was from otherwise low-risk boneless cuts). A reported October 22 version of the list included beef lips, tongues, hearts and kidneys. The August 15 and October 22 lists were posted on the APHIS website, but neither was accompanied by a *Federal Register* issuance or public communication.

On April 19, 2004, USDA published on its website, again without further rulemaking or public notice, another list and memorandum effectively expanding permitted Canadian products to include bone-in as well as boneless beef from under-30-month cattle. A group of cattlemen led by Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of America (R-CALF USA), filed a lawsuit to stop the expanded imports, and, on April 26, a federal judge in Montana issued a temporary restraining order to halt the imports. Among other issues, the judge cited concerns about whether USDA followed appropriate rulemaking procedures.<sup>17</sup> USDA subsequently reached an agreement with plaintiffs that it would not allow beef and veal products beyond the types listed on August 15, 2003 (see above), until issuance of the final rule that was first proposed on November 4, 2003. USDA Officials stated further that then-Secretary Veneman had been unaware that APHIS had expanded the list of eligible products after August 8, 2003.

The final version of the November 4, 2003, proposal was announced on December 29, 2004, several hours before Canada revealed its second possible BSE finding. The new rule was 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 first such region to qualify, based on what USDA declared was “a thorough risk analysis.” (In addition, a region with effective BSE regulatory measures that has never detected the disease, but cannot be considered BSE-free, can qualify as a “minimal risk.”) The following additional products are being made eligible for importation from Canada:

- Cattle and other bovines for feeding and for immediate slaughter. All cattle must be under 30 months of age and be slaughtered at less than 30 months. All cattle must be moved in closed containers, be tagged on the ear to enable traceback to their birth herds, and be accompanied by health and other information, among other requirements. Feeder cattle must be branded and can only be moved to a single feedlot, and from that lot directly to slaughter.
- Sheep and goats (ovines and caprines) for feeding and immediate slaughter, which must be under 12 months of age and slaughtered by 12 months. Similar movement and identification rules apply to these animals.
- Most meat from bovines, ovines, caprines, and cervids (deer, elk, etc.). This includes, for example, bone-in cuts and cuts from cattle over 30 months. (On February 9, the Secretary of Agriculture announced that he would delay the part of the rule allowing beef from over-30-month-old cattle.)
- Certain other products and byproducts including bovine livers and tongues, gelatin, and tallow.

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<sup>17</sup> *Ranchers Cattlemen Action Legal Fund USA vs. USDA* (CV-04-51-BLG-RFC).

R-CALF USA again sued to block the rule. On March 2, 2005, the same federal judge issued a preliminary injunction to halt implementation. (Later, he set July 27, 2005, for a hearing on whether a permanent injunction should be granted.) 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 ... pending a review on the merits.”<sup>18</sup>

The Administration on March 17, 2005, filed an appeal with the U.S. Court of Appeals for the Ninth Circuit, which is pending. Secretary Johanns earlier had expressed disappointment with the ruling and said: “USDA remains confident that the requirements of the minimal-risk rule, in combination with the animal and public health measures already in place in the United States and Canada, provide the utmost protection to both U.S. consumers and livestock. We also remain fully confident in the underlying risk assessment, developed in accordance with the OIE guidelines, which determined Canada to be a minimal risk region.”

Several agricultural leaders in Congress have expressed their support for the rule as well. For example, the House Agriculture Committee Chairman stated: “The ramifications of this judicial ruling are devastating for the U.S. livestock and beef industry.” He added that “the status quo is causing adverse economic harm to our processing industry which has grave long term implications for cattle producers. Moreover, the decision further undermines our nation’s credibility as we seek to eliminate non-tariff trade barriers around the world.” (At its March 1, 2005 hearing, the panel heard testimony that in 2004 Canada increased its cattle processing capacity by 22%, as an alternative to shipping them to the United States.)

Others have defended USDA’s assertion that — because Canada has in place safeguards that are at least equivalent to those of the United States, and because the North American market has become an integrated one — the rulemaking is reasonable. Supporters believe it is necessary if the United States wants to convince other countries that U.S. beef also is safe. Several believe USDA should have gone further. For example, the American Meat Institute (AMI), representing meat packers, had filed a federal lawsuit seeking a preliminary injunction to block enforcement of the continuing ban on imports of Canadian cattle, including those over 30 months old. AMI charged that USDA lacks any scientific basis for continuing to ban such imports. A federal judge in early March 2005 denied the request.

Elsewhere, a group of Canadian beef producers announced that they will seek remedies for the cattle ban under Chapter 11 of the North American Free Trade Agreement (NAFTA), on the grounds that it has given unfair advantage to U.S. producers. They will seek at least \$300 million in damages, according to trade press reports.

Nonetheless, it appears that implementation of the rule, if it occurs, will be delayed for weeks if not months. Further clouding the rule’s future was a Senate vote on March 3, 2005, to overturn the rule (although final enactment appears doubtful; see below).

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<sup>18</sup> *Ranchers Cattlemen Action Legal Fund USA vs. USDA* (CV-05-06-BLG-RFC).

USDA officials' handling of the border opening was criticized sharply by the Office of Inspection General (OIG). In a February 2005 audit report, OIG concluded that the department's actions were sometimes arbitrary and undocumented, that policy decisions were poorly communicated to the public and between APHIS and FSIS, and that controls over the regulatory process were inadequate. USDA agreed with and promised to implement most of the report's findings.<sup>19</sup>

## Congressional Response

BSE remains a high priority for many Members of the 109<sup>th</sup> Congress. A number of them already have joined others in calling for a delay or rescission of the Canada rule, and a vote to overturn it was successful in the Senate. More specifically, Congress has 60 legislative days from publication of the rule to review it, as provided for in the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801-808). On March 3, 2005, after a morning of floor debate, the Senate approved a resolution of disapproval (S.J.Res. 4) by a vote of 52-46. A related resolution (H.J.Res. 23) is pending in the House, but passage is considered more difficult there. And a final measure would have to be signed by the President, who opposes it.

Other bills addressing the Canada rule include H.R. 187, to prohibit the rule "unless United States access to major markets for United States exports of cattle and beef products is equivalent or better than the access status accorded such exports as of January 1, 2003"; and H.R. 384/S. 108, to prohibit the Canada rule unless mandatory retail country of origin labeling (COOL) is implemented. The current statutorily set deadline for COOL for fresh meats is September 30, 2006 (see CRS Report 97-508, *Country-of-Origin Labeling for Foods*). S. 294 would prohibit imports (from a minimal risk region like Canada) of meat, meat byproducts and meat food products from bovines over 30 months old unless the Secretary reports to Congress that the region "is in full compliance with a ruminant feed ban and other [BSE] safeguards."

On a different BSE trade matter, H.Res. 137 calls for economic sanctions against Japan if it does not permit U.S. beef. Also, 20 Senators on February 18, 2005, wrote directly to the Japanese ambassador, indicating that consideration of economic sanctions is possible. Other BSE-related bills introduced in the 109<sup>th</sup> Congress include S. 73, to ban specified risk material from all animal feeds; and S. 135, to include processed as well as fresh meats as COOL-covered commodities, and to advance implementation to September 30, 2005.

In the House, H.R. 1254 would require the establishment of a nationwide electronic animal identification system. Other BSE-related measures also could be introduced and/or considered during the 109<sup>th</sup> Congress.

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<sup>19</sup> USDA, OIG. *Animal and Plant Health Inspection Service Oversight of the Importation of Beef Products from Canada*, on the web at [<http://www.usda.gov/oig/webdocs/33601-01-HY.pdf>]. On the other hand, GAO informed the Agriculture Committees in a January 18, 2005, letter that USDA had complied with applicable procedural requirements. It is available through GAO's website at [<http://www.gao.gov/decisions/majrule/d05260r.htm>].