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Mad Cow Disease: Agricultural Issues for Congress

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Mad Cow Disease: Agricultural Issues for Congress

SUMMARY

In December 2003 USDA 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. The animal was born in April 1997 in Canada, shortly before both countries banned the practice of feeding most ruminant material back to ruminants, including cattle (BSE-contaminated feed is considered the most likely cause of infection).

Most countries banned U.S. beef after the December discovery. A few have partially reopened, but Japan, the leading U.S. market, has insisted that all cattle killed for its market be tested for BSE. USDA contends that 100% testing is unscientific. USDA projects that total 2004 exports will reach only 18% of their 2003 level (of about 2.5 billion pounds). However, strong domestic demand and tight cattle supplies have kept U.S. meat and cattle prices relatively high.

USDA and other experts contend that the risk to human health from one or a few U.S. BSE cases is minimal. Nonetheless, USDA 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.

On January 26, 2004, the Food and Drug Administration (FDA) announced that it would strengthen its own BSE rules, banning higher-risk bovine materials from the human foods and cosmetics it regulates and tightening feed restrictions. On July 14, 2004, FDA published an interim final rule to prohibit

certain cattle-derived materials in agency-regulated products. Also on July 14, FDA joined USDA in publishing an advance notice of proposed rulemaking seeking comment on possible additional preventive actions, including possibly tighter animal feed rules.

USDA in June 2004 began an expanded surveillance program to test at least 220,000 mostly higher-risk cattle for BSE over a 12-18 month period. The Department's testing has come under criticism in recent months as statistically and procedurally flawed; USDA has vigorously defended it even while making modifications. As of early September, more than 50,000 had been tested, none positive for BSE.

In May 2004, in response to a lawsuit, USDA officials acknowledged they had erred administratively by permitting millions of pounds of previously suspended Canadian beef cuts to enter. A court agreement now limits such imports to lower-risk products until appropriate rulemaking is completed (although 40,000 pounds of incorrectly labeled, banned Canadian beef subsequently was allowed entry and had to be recalled in July).

Various congressional committees have been holding BSE hearings. BSE-related bills include legislation to ban downers for food (H.R. 2519, S. 1298), to prescribe mandatory animal ID and/or meat traceability rules (H.R. 3546, H.R. 3787, H.R. 3822, H.R. 3961, H.R. 4005, S. 1202, S. 2008, S. 2070), and to require BSE tests on most cattle (H.R. 3705), as well as other bills (S. 2051, S. 2007, S. 2451, H.R. 3714, H.R. 4001, H.R. 4121, H.R. 4576).

MOST RECENT DEVELOPMENTS

In early September, Japanese authorities were widely reported to be considering whether to change BSE testing requirements, from all cattle slaughtered for food to just those over 20 months of age. Although the reports provided some optimism over efforts to reopen this once-largest foreign market to U.S. beef, no quick resolution appears imminent.

In late August, USDA's Office of Inspector General released the final version of its audit of the Department's BSE surveillance program, generally confirming preliminary findings that there are limitations in the testing plan which need to be clarified. The preliminary findings were presented at a July 14 joint hearing before the House Government Reform and Agriculture Committees (see "Testing Issues").

On July 28, USDA announced a recall of 170,000 pounds of ground beef patties after their manufacturer inadvertently included 41,000 pounds of Canadian product that should not have been imported. Officials stressed that the product was safe and simply had been mislabeled in Canada, but the incident brought renewed criticism of the Department over its handling of the BSE situation.

On July 14, FDA published in the *Federal Register* a long-awaited interim final rule to prohibit higher-risk ruminant materials in agency-regulated products, as well as an advance notice of proposed rulemaking (jointly with USDA) seeking public comments on other possible preventive actions, including tighter FDA animal feed rules.

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.) 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 in animals 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 150 people have been diagnosed with vCJD since 1986, most of them in Great Britain. The human incubation period is approximately 13 years, according to the U.S. Food and Drug Administration (FDA).¹

U.S. Case

USDA announced on December 23, 2003, that brain samples taken from a Holstein dairy cow in Washington State on December 9 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 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. The only other native North American BSE case, discovered in Alberta in May 2003, was a Black Angus beef cow. U.S. authorities announced on February 9, 2004, that their field investigation had located 28 of the 80 animals at eight different facilities, mostly in Washington. They had focused particularly on the whereabouts of 25 in the herd that were born within one year before or after the BSE-infected cow, “of special significance” because they are most likely to have consumed feed from the same source. By the conclusion of the investigation, 14 of these were located. 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.

¹ 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>]. More extensive discussion of U.S. regulatory actions on BSE may be found in CRS Report RL32199, *Bovine Spongiform Encephalopathy (BSE, or “Mad Cow Disease”): Current and Proposed Safeguards*.

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 meat and meat products from BSE countries (since 1991); and a prohibition on importing both ruminant 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.²

Targeted Domestic Surveillance. Among other duties, meat inspectors must examine every head of cattle entering slaughter plants for human consumption. FSIS indicates it has not permitted animals showing suspicious neurological symptoms to be slaughtered for human consumption.³ It has sent the brains of such animals to an APHIS laboratory in Ames, Iowa, as part of what USDA called a broader “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.”

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 36 million slaughtered each year. Critics argued that U.S. surveillance was inadequate to detect BSE, and that it remains to be seen whether the positive cow from Washington State is an isolated case. 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 had 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”. FDA, which regulates animal feed ingredients, banned most mammalian proteins from cattle feed on August 4, 1997. Exceptions have existed for blood and blood products; gelatin; inspected, processed, and cooked meat

² The United States, Canada, and Mexico have been working through the OIE 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].

³ Source: USDA backgrounder on BSE, July 10, 2003. For more details see CRS Issue Brief IB10082, *Meat and Poultry Inspection Issues*. The APHIS website on surveillance is at [<http://www.aphis.usda.gov/lpa/issues/bse/bse-surveillance.html>].

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, and 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).⁴ The “feed ban” may be expanded; see the discussion later in this report.

Assessments of the BSE Safeguards

Some had criticized the effectiveness of the 1997 feed ban. For example, 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. FDA in July 2003 began to assert that industry compliance has been exceeding 99%.⁵

The GAO report also asserted that the FDA was using flawed data to track compliance, and had no clear enforcement strategy for firms that were not obeying the ban. The 2002 GAO report states, “Federal actions do not sufficiently ensure that all BSE-infected animals or products are kept out or that if BSE were found, it would be detected promptly and not spread to other cattle through animal feed or enter the human food supply.” The report also had 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.

On the other hand, a study issued in November 2001 by the Harvard Center for Risk Analysis, based on a comprehensive 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.”

USDA in 2003 asked Harvard to reassess the risk after BSE was found in Canada. 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 “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

⁴ 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*.

⁵ See [<http://www.fda.gov/cvm/index/updates/bse72001.htm>] and [<http://www.gao.gov/>].

tested the model's predictions of an actual small BSE outbreak in Switzerland and found them "reasonably close to empirical observations."⁶

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" (Harvard, 2003).

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 also asked an international panel to assess U.S. actions, and she also announced that BSE surveillance would be expanded.

Downers. USDA has 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 36 million U.S. cattle slaughtered yearly. The downer ban has been among the most controversial changes for producers, who say they are now experiencing large losses because they are no longer permitted to sell cattle unable to walk for reasons unrelated to BSE (e.g., a broken leg). In response to concerns that a ban will make it more difficult for veterinarians to find and test such animals for BSE, USDA said it intends to work more closely with the industry to collect samples at rendering facilities, on farms, and elsewhere. (Interim final rule, January 12, 2004, *Federal Register*.)

Specified Risk Material (SRM). USDA has 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 are considered inedible for human food.) An SRM declaration prohibits the use of these cattle parts in the human food supply, and is consistent with a Canadian rule issued after its BSE discovery. The rule requires cattle packers to develop and implement

⁶ 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]. 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. This topic is discussed in more detail in CRS Report RL32199 (see footnote 1).

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 has had regulations to prohibit such products to be labeled as “meat” if they contain spinal cord. A new rule expands that prohibition to include additional nerve tissue. Also, AMR cannot be used for cattle 30 months and older. An FSIS sampling program found nervous system tissue in about one-third of sampled AMR beef.⁷ (Interim final rule, January 12, 2004, *Federal Register*.)

“Test and Hold”. All product 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. Another new rule bans air-injection stunning, to ensure that brain pieces are not dislocated into carcass tissues during slaughter. USDA states this method is now rarely used. (Interim final rule, January 12, 2004, *Federal Register*.)

Animal Identification and Traceability. The Secretary also said on December 30 that USDA would “begin immediate implementation” of a national animal ID system, and offer its computer resources to support it. 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 for implementation this year. The April 27 announcement also contained some information on early implementation plans, which include studying existing animal ID projects and entering into cooperative agreements with states to start voluntary ID. On August 5, 2004, USDA announced the 29 states and tribal agencies that will receive \$11.64 million of the total, to register premises, collect data, and test ID technologies. (See CRS Report RL32012, *Animal Identification and Meat Traceability*.)

Funding. In early 2004 the Administration requested, as part of its FY2005 budget proposal, a total of \$60 million for USDA’s BSE-related activities, or \$47 million more than available for FY2004. Of the total, \$33 million would be used to accelerate development of the animal ID system; and \$17 million for BSE testing (that cost will rise due to the expanded testing begun in June 2004). BSE funding is contained in a USDA money bill (H.R. 4766) for FY2005 now moving through Congress. USDA already has transferred money from its Commodity Credit Corporation to help finance some of these activities in FY2004. The Secretary earlier had announced that USDA intended to commit \$178 million to complete renovations at the Ames, Iowa, testing lab. (See “Congressional Response.”)

FDA. 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

⁷ Information on AMR is at the FSIS website: [<http://www.fsis.usda.gov/OA/topics/amr.htm>].

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 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 the same as 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.

Joint FDA-USDA Rulemaking. Rather than a concurrent rule to tighten feed restrictions, however, FDA on July 14 also published 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 seeks 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.⁸

Reaction to the FDA portion on feed rules was mixed. Some industry groups believe that enforcing the current 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. Several consumer groups, however, complained that the ANPR simply delayed the stronger actions they believe are needed to protect the feed supply — and ultimately consumers — from BSE. Explaining delays to date, FDA officials noted that shortly after their January 26 announcement, an international advisory panel recommended a series of additional U.S. actions, which need to be fully considered (see “International Panel Report,” below).

⁸ The FDA asked for comments within 30 days of publication and the USDA within 60 days. Both agencies’ websites contain press releases, fact sheets, and the text of the documents.

Expanded Surveillance. On March 15, 2004, USDA announced it would greatly expand testing 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 expanded testing, which began in June 2004, also was 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 them, in addition to using its Ames, Iowa, diagnostic facility, officials estimate they can test at least 200,000 and perhaps many more of the target population, they said. 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 its national reference laboratory in Ames for confirmatory testing, which takes longer but is considered more accurate. APHIS also began posting all test results on its website.

Testing Issues

Publicizing Test Results. In late June 2004, USDA had announced that preliminary screening tests had shown “inconclusive” (i.e., possible positive) results for BSE in two animals. They emphasized that neither animal, whose whereabouts they refused to identify, had entered the food supply and that they posed no safety threat. Subsequent tests at the Ames laboratory found that neither animal had BSE.

These were the first “inconclusive” results among the more than 50,000 cattle tested (through early September) under the new program. Earlier, officials had warned the public that the rapid screening tests might produce so-called false positives that later may prove to be BSE negatives. Still, the department has come under intense criticism for both its test sampling procedures and its reporting of results. For example, cattle markets were extremely volatile during the several days it took to conduct more rigorous tests: the industry first reacted negatively to USDA’s early reports of the two “false positives,” and prices then seemed to rise and fall in response to rumors about the animals’ type, location, and status.

Officials defended their decision to make preliminary results known as quickly as possible. It argued further that even if subsequent testing finds a U.S. cow to have BSE, the various BSE safeguards now in place are protecting public health by assuring that no infective materials reach consumers (or can spread to other animals). By early August USDA had altered its announcement policy. Now, if the initial screening test is “inconclusive,” the Department will screen two more samples from the same carcass, and only make an announcement if one of the two samples also tests inconclusively, and necessitates confirmation at the Ames laboratory.

Testing Procedures. BSE testing matters were 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 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 was issued in late August 2004 and generally parallels the preliminary findings.

At the hearing and in press briefings, 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 are now being addressed. APHIS is in fact 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 assert. They add that adjustments are being made as the result of ongoing assessments of the program.

After widespread press reports 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 has been 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) have expressed interest in testing all of their cattle for BSE — as the Japanese have been demanding. USDA has long 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,⁹ has denied the Creekstone request. USDA and meat industry officials are concerned, among other things, that permitting 100% testing would undermine trade negotiations, be costly, and misleadingly imply that such meat is safer than untested meat.

International Panel Report

A panel of international BSE experts examined the government's response to the U.S. BSE discovery, and its findings were released on February 4, 2004.¹⁰ 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

⁹ 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>].

¹⁰ 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].

indigenously infected.” Endorsing the type of expanded testing program USDA later began in June (see above), the panel had 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 stated that because downers are now being banned from the food supply, “it is imperative” for USDA to ensure that dead and nonambulatory cattle are properly sampled and disposed of, which likely will entail funding to help pay for the costs and supplemental measures to encourage compliance. 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

Initial reactions to the report were mixed. USDA officials conceded that there might be other BSE cases found in North America but pointed out that the panel also had noted that government agencies already are taking the most important steps necessary to protect consumers. Some, including officials of National Cattlemen’s Beef Association (NCBA), argued that the panel had overstated the risks of BSE here and the steps needed to prevent its spread, including the proposal to expand greatly the animal feed ban. NCBA and other industry officials observed 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 underline their own concerns that the government has not done enough to keep BSE out of North America.

U.S. Economic 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 at \$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).

Within days of the BSE announcement, most importing countries had halted some or all U.S. beef and cattle imports. U.S. officials have worked to reassure foreign authorities about the safety of U.S. beef. Of the major markets, both Mexico and Canada have been reopening their borders to some U.S. beef and veal. Exports to Mexico resumed in March 2004 and had reached about 37% of year-earlier levels by June 2004. Exports to Canada (January-May 2004) appeared to be approximately 10% of year-earlier levels.

Japan and Korea remain closed. Japan has been demanding that all cattle slaughtered for food be tested. In early September numerous press reports indicated that Japanese authorities were considering whether to limit testing to animals over 20 months of age, providing some optimism that negotiations to reopen that market can make progress. However, the two sides still disagree on a number of points besides testing, such as whether higher risk cattle parts should be removed from all animals or just older ones. These issues

remained unresolved in August after three scientific meetings between the countries; some observers predict that U.S. beef may not begin to enter Japan until mid-2005 at the earliest.¹¹

USDA has predicted that unless more markets reopen, beef and veal exports will be 446 million pounds in 2004, or 18% of the 2003 level of 2.518 billion pounds, rising only to 600 million pounds in 2005.

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. (They again dropped by allowable limits in late June after two inconclusive BSE tests were reported, but subsequently recovered.) But prices have recovered substantially since January. 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 the first part of 2004.

In August 2004 USDA forecast average U.S. fed steer (i.e., slaughter-ready cattle) prices at \$85-\$87 per cwt. for all of 2004, compared with an earlier 2004 prediction of \$72-\$77; this is close to a USDA forecast, made just before the BSE case, of \$84-\$91 per cwt. The 2005 price forecast is \$83-89. Average fed steer prices were \$85 in 2003 and \$67 in 2002.

Cattle producers are 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 on July 30, 2004. The U.S. market will have to absorb 23 million more pounds of beef weekly or 1.2 billion pounds for the year due to lost exports, according to Cattle-Fax. The U.S. Meat Export Federation 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.¹²

Increased business costs are anticipated in order to comply with new and/or future BSE safeguards adopted in response to the U.S. case. 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..."¹³

¹¹ "Japan Talks Have Long Way to Go," *Cattle Buyers Weekly*, July 26, 2004.

¹² 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.

¹³ *Preliminary Analysis of Interim Final Rules and an Interpretive Rule to Prevent the BSE Agent*
(continued...)

Canadian BSE Case

Investigation. 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 1993.¹⁴ A total of 2,800 cattle were killed and tested for BSE, with no other cases found. CFIA said Canadian actions had contained any possible spread. Canadian and provincial governments have provided hundreds of millions of dollars in various aid to the industry for economic losses caused by the BSE incident. The CFIA website is at [<http://www.inspection.gc.ca/english/anim/heasan/disemala/bseesb/bseesbindexe.shtml>].

USDA Actions to Readmit Canadian Beef. 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. On August 8, 2003, USDA announced that it would begin to 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 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 had begun to permit additional products beyond those announced on August 8, 2003. On August 15, 2003, APHIS listed the so-called low risk Canadian products for which it would grant permits. In addition to the products announced on August 8 (see above), the August 15 list now included bone-in as well as boneless veal (but not bone-in beef), and trimmings (if such trim was from otherwise low-risk boneless

¹³ (...continued)

From *Entering the U.S. Food Supply*, which can be accessed via the FSIS website. Address: [<http://www.fsis.usda.gov/oa/topics/bse.htm#3>].

¹⁴ 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]. 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.

cuts). A reported October 22 reposting of the list was expanded to include beef lips, tongues, hearts and kidneys. The August 15 and October 22 lists were posted on the APHIS website, but neither was accompanied by *Federal Register* issuance, press release or other public communication.

On April 19, 2004, USDA published on its website, again without further rulemaking or public notice, yet 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 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. The judge observed that two BSE cases in Canadian-raised cows have been detected in the past 11 months “through very limited testing. If imported Canadian beef products contain the BSE agent, USDA’s April 19, 2004, action may result in a fatal, non-curable disease in humans who consume those products.” Among other issues, the judge cited concerns about whether USDA followed appropriate rulemaking procedures.¹⁵ USDA subsequently reached an agreement with plaintiffs that it would no longer allow beef and veal products beyond the types listed on August 15, 2003 (see above). Any additional Canadian products (including bone-in beef or live cattle) will not be permitted until after issuance of the final rule that was first proposed on November 4, 2003, USDA promised.

According to the department, a total of 518.6 million pounds of Canadian beef and veal products entered the United States between September 1, 2003, and April 30, 2004. Of this, 18.9 million pounds were boneless or bone-in veal; 241 million pounds were boneless beef cuts; 238 million pounds were boneless beef trim; nearly 7 million pounds were liver, tripe or cheek meat; 1.5 million pounds were tongue, heart or kidney; 5.6 million pounds were “further processed” including partly or fully cooked hamburger, hot dogs, deli meats, sausages, jerky, etc., and about 142,000 pounds were bone-in beef cuts. USDA officials stated that only 7.3 million pounds of the 518.6 million pound total incorrectly came in under categories not covered by the August 8 announcement (as modified by the August 15 list), and that none of these additional products posed any food safety risk. Officials stated further that Secretary Veneman had been unaware that APHIS had expanded the list of eligible products after August 8, 2003.

Canadian imports came under renewed scrutiny after USDA announced on July 28, 2004, a recall of 170,000 pounds of ground beef patties after their U.S. manufacturer inadvertently included 41,000 pounds of Canadian beef in them that should not have been imported. FSIS stressed that the product was safe and simply had been mislabeled by a Canadian inspector.

Congressional Response

BSE is expected to remain a priority for many Members of Congress this year. A number of Senators and Representatives have been sharply critical of USDA’s handling of various aspects of the BSE issue in hearings, speeches, and communications to the Department. The House and Senate Agriculture Committees held hearings on the issue on January 21 and January 27, 2004, respectively. The Senate Appropriations Committee held

¹⁵ *Ranchers Cattlemen Action Legal Fund USA vs. USDA* (CV-04-51-BLG-RFC).

a BSE hearing on February 24, 2004. The House Agriculture and Government Reform Committees held a joint hearing on July 14, 2004, on BSE testing and related issues.

Although both USDA and FDA are using existing statutory authorities to implement the various changes, it is conceivable that amendments to such laws might be considered for further enhancements. With regard to funding, the House Appropriations Committee on June 23 marked up a FY2005 USDA appropriation measure (H.R. 4766) that it says is adequate to cover the Administration's requested spending increases for BSE. The measure passed the full House on July 13, 2004. Senate Appropriations subcommittee action on H.R. 4766 began in early September.

Companion bills offered in 2003 (S. 1202 and H.R. 3546) would require USDA to establish a traceability system for all stages of production, processing, and distribution of both meat and poultry and their products, essentially from the birthplace of source animals to the consumer. In the second session, other bills (H.R. 3787, H.R. 3822, H.R. 3961, H.R. 4005, S. 2008, S. 2070) setting various requirements for a national livestock ID system have been introduced. Ruminant ID systems are required in wider-ranging BSE and other prion prevention-related bills (S. 2007 and H.R. 3714, respectively). Hearings on animal ID were held in the Senate and House Agriculture Committees on March 4 and 5, 2004, respectively.

The BSE issue was raised in the debate over whether to delay and/or modify mandatory country-of-origin labeling (COOL) of meats and other foods, once set to take effect in September 2004. The conference agreement on the consolidated FY2004 appropriations bill (H.R. 2673) postpones mandatory COOL for two years. It was signed into law (P.L. 108-199) on January 23, 2004. Several bills (H.R. 3732, H.R. 3993, S. 2451) have since been introduced to reinstate the original 2004 implementation date. However, the House Agriculture Committee on July 21, 2004, approved H.R. 4576, which would replace mandatory COOL with a voluntary program. Other bills amending COOL include H.R. 2270 and H.R. 3083 (see also CRS Report 97-508, *Country-of-Origin Labeling for Foods*).

In November 2003, the Senate had approved an amendment to the FY2003 appropriations bill to prohibit FSIS inspections of downed animals (effectively keeping them out of the food supply). A similar House floor amendment to the bill last summer was narrowly defeated, and the Senate amendment was removed in the House-Senate conference on the measure. Earlier, both houses of the 107th Congress had included in their respective farm bills a ban on marketing downers unless they were humanely euthanized. Farm bill conferees dropped the provision from the final version (P.L. 107-171), instead directing the Secretary to study industry downer practices and issue rules if necessary. Pending bills to ban downers include H.R. 2519 and S. 1298.

Another bill, H.R. 3705, would require BSE tests on all cattle destined for human food. S. 2051 focuses on strengthening animal feed rules. Several (H.R. 2057, H.R. 2430, H.R. 2431, H.R. 2636, H.R. 4001, S. 1036) have been introduced to increase support for research and surveillance on chronic wasting disease (CWD) in deer and elk or on other TSEs.