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Bovine Spongiform Encephalopathy (BSE, or “Mad Cow Disease”) in North America: A Chronology of Selected Events

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Summary

This report provides a chronology of selected events leading up to and following the discoveries of bovine spongiform encephalopathy (BSE, or “mad cow disease”) in North America. These are primarily regulatory, legal, and congressional developments that are frequently referenced by policymakers as significant in the ongoing policy debate. The chronology does not contain entries for the introduction of the many BSE-related bills introduced into this or previous Congresses, except for those in recent years where committee or floor action has occurred. This report, which will be updated if significant developments ensue, is intended to be used alongside other CRS reports that provide more background and context for the BSE policy debate, and that cover many specific legislative proposals.

The chronology begins in 1986, when BSE was first identified by a British laboratory. As the United Kingdom and others attempted to understand and contain BSE, the U.S. and Canadian governments were establishing panels to study the disease and began instituting a series of safeguards aimed at keeping it out of North America or stopping any spread if it should occur here. The chronology proceeds into May 2003, when Canada reported the first native case in North America; December 2003, when the United States reported finding a case in a U.S. herd; and most of 2004, when both countries worked to reassure consumers of the safety of North American cattle and beef and to reopen foreign markets blocking these exports. U.S. and Canadian officials since 2003 also have been strengthening various regulatory safeguards aimed at protecting the cattle herd and the food supply from BSE.

The chronology concludes with major events of late 2004 and the first half of 2005, which have revolved around efforts to re-establish more open cattle and beef trade within North America, including a U.S. cattle group’s lawsuits to slow such efforts, and the steps being taken to regain the Japanese market, which was until December 2003 the leading buyer of U.S. beef. Japan remained closed well into 2005, as did South Korea, which was another important foreign customer until closing its market in December 2003. Congress can be expected to continue to play a role, holding oversight hearings, providing funding for BSE-related activities, and possibly considering legislative options to address one or more of the outstanding issues.

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Introduction

This report provides a chronology of selected events leading up to and following the discoveries of bovine spongiform encephalopathy (BSE, or “mad cow disease”) in North America. So far, five native cases have been confirmed on this continent, four in Canada and one in the United States.¹ BSE is a degenerative disease that is fatal to cattle, affecting their nervous system, and it has been linked to a rare but fatal human form of the disease which has occurred primarily in the United Kingdom, where most BSE cases also have been reported.

The following chronology is not intended to be comprehensive. It is intended to be a timeline for selected regulatory, legal, and congressional developments that are frequently referenced by policymakers as significant in the ongoing policy debate. It does not contain entries for the introduction of the many BSE-related bills introduced into this or previous Congresses, except for those in recent years where committee or floor action has occurred. Nor does it cover a number of policy developments that are not directly BSE-related, but that nonetheless have arisen within the context of BSE debate, such as a universal animal identification (ID) program and country of origin labeling (COOL) for meats and other commodities.

This report is intended to be used alongside other CRS reports that provide more background and context for this policy debate. These include:

- CRS Issue Brief IB10127, *Mad Cow Disease: Agricultural Issues for Congress*;
- CRS Report RL32414, *The Private Testing of Mad Cow Disease: Legal Issues*;
- CRS Report RS21709, *Mad Cow Disease and U.S. Beef Trade*;
- CRS Report RL32199, *Bovine Spongiform Encephalopathy (BSE or “Mad Cow Disease”): Current and Proposed Safeguards*.

Unless noted, the sources for the entries in this chronology are the above reports, as well as various U.S. Department of Agriculture (USDA) and Food and Drug Administration (FDA) press releases, fact sheets, and other publicly available materials, reports of hearings before the House and Senate Agriculture Committees,

¹ In Canada reported a BSE case in 1993; however, the animal was not born in Canada but rather imported in 1987 from Great Britain.

and for some entries, articles that appeared in leading food and agriculture trade periodicals including *Food Chemical News*, *Feedstuffs*, and *Cattle Buyers Weekly*.

Key to Acronyms

For an explanation of these and related BSE terms in this report, see the reports listed on the previous page, and also CRS Report 97-905, *Agriculture: A Glossary of Terms, Programs, and Laws, 4th Edition*. This glossary is accessible on the House Agriculture Committee website at [<http://www.house.gov/agriculture/>].

AMR	Advanced meat recovery
AMS	USDA's Agricultural Marketing Service
APHIS	USDA's Animal and Plant Health Inspection Service
BSE	Bovine spongiform encephalopathy ("mad cow disease")
CCC	USDA's Commodity Credit Corporation
CFIA	Canadian Food Inspection Agency
DHHS	U.S. Department of Health and Human Services
EU	European Union
FDA	U.S. Food and Drug Administration
FSIS	USDA's Food Safety and Inspection Service
GAO	U.S. Government Accountability Office
IHC	Immunohistochemistry
MBM	Meat and bone meal
SRM	Specified risk material
TSE	Transmissible spongiform encephalopathy
UK	United Kingdom
USDA	U.S. Department of Agriculture
vCJD	Variant Creutzfeld-Jakob disease

Chronology

Early BSE Developments (November 1986-December 2002)

When BSE was first identified in 1986 in a British laboratory, relatively little was known about its character, its cause, or how to contain it. The United Kingdom (UK) has so far been the hardest-hit region, where reported cases affecting cattle continued to climb through the late 1980s and early 1990s to a peak of more than 37,000 in 1992. Cases have been declining each year since then. Several other countries, primarily in other parts of Europe, also reported hundreds of additional cases, according to the world animal health organization (OIE, its French acronym).

As the UK and other countries were coping with BSE, the U.S. and Canadian governments were establishing panels to study the disease and instituting a series of safeguards aimed at keeping it out of North America or stopping any spread if it should occur here. Prior to 2003, the only known case of BSE in North America was in Canada, where a non-native case was discovered in late 1993. This animal is believed to have been born in and imported from Great Britain in 1987.

November 1986	BSE is first identified by a British laboratory. BSE becomes a reportable disease in the United States.
1987	A BSE-infected cow is believed to have been imported into Canada from Great Britain.
December 15, 1987	Initial British epidemiological studies conclude that feeding of ruminant-derived meat and bone meal (MBM) is the “only viable hypothesis” for the cause of BSE.
1988	USDA establishes a BSE committee to review current science and recommend appropriate regulatory controls.
July 7, 1988	The British Government announces that all cattle at risk of BSE will be destroyed — a number eventually reaching 3.7 million. Approximately 183,000 of these are confirmed as BSE-positive. Worldwide, about 4,000 additional BSE cases have since been diagnosed, mostly in Europe.
July 1989	USDA bans importation of live ruminants (cattle, sheep, goats, etc.) from the UK and other countries affected with BSE.
July 18, 1989	A UK ban on feeding meat and bone meal (MBM) to ruminants comes into force.
November 1989	USDA’s Animal and Plant Health Inspection Service (APHIS) implements an emergency ban on the importation

of high-risk products including MBM from countries with confirmed BSE cases.

- November 13, 1989** England and Wales ban human consumption of certain bovine parts including brain, spinal cord, thymus, spleen, and tonsils.
- 1990** APHIS develops a BSE response plan intended to spell out step-by-step actions in case BSE is detected in the United States. FDA establishes a BSE task force.
- May 1990** USDA initiates a surveillance program to examine brains of U.S. cattle for BSE.
- 1991** USDA conducts a BSE risk analysis, finding that conditions in the United States and UK differ regarding sheep rendered. (The disease may have jumped to cattle consuming sheep tissue containing Scrapie, another transmissible spongiform encephalopathy, or TSE.) This risk analysis would be updated several times in subsequent years.
- December 6, 1991** USDA restricts the importation of ruminant meat and edible products and bans most byproducts of ruminant origin from countries known to have BSE; previously such products had been prohibited by not issuing import permits (see November 1989).
- April 30, 1993** Surveillance is expanded to include random examination of brains from nonambulatory (“downer”) cattle. (The target population already had included field cases of cattle exhibiting signs of neurologic disease, cattle condemned at slaughter for neurologic reasons, rabies-negative cattle submitted to public health laboratories, and neurologic cases submitted to veterinary diagnostic laboratories and teaching hospitals.)
- December 1993** Canada reports its first BSE case; animal was not born in Canada but rather imported in 1987 from Great Britain.
- August 29, 1994** FDA advises manufacturers of vaccines and other biologics not to use materials derived from cattle that were born, raised, or slaughtered in countries where BSE is known to exist.
- March 1996** British authorities first announce a suspected causal link between BSE and a new form of a rare, fatal human illness, variant Creutzfeld-Jakob disease (vCJD), via consumption of beef from affected animals. Eventually about 150 vCJD cases occur, most of them in Great Britain.

March 29, 1996	The British Government imposes a total ban on the feeding of any mammalian meat and bone meal to any farm animals.
March 1997	A Black Angus cow, which later becomes the first native North American animal to test positive for BSE, is born on a Saskatchewan farm.
April 9, 1997	A Holstein cow is born on a farm in Calmar, Alberta, Canada. On December 2003, it would test positive for BSE in Washington State, becoming the first U.S. case.
June 5, 1997	FDA publishes a final rule, effective August 7, to prohibit the feeding of most mammalian proteins to ruminants. Exempted from the ban are certain bovine by-products, such as blood, milk, gelatin and restaurant plate waste, on the premise that the exempted materials pose a minimal risk of transmission.
August 4, 1997	Canada institutes its own mammalian-to-ruminant feed ban (with the exception of pure porcine and equine meal; and milk, blood, gelatin and rendered animal fat from all species).
August 7, 1997	The U.S. FDA feed rule takes effect (see June 5, 1997).
December 12, 1997	USDA extends the ban on importation of live ruminants and most ruminant products to cover all countries in Europe.
April 24, 1998	USDA enters into a cooperative agreement with the Harvard University Center for Risk Analysis to evaluate the risk of BSE and U.S. prevention methods.
December 7, 2000	USDA begins to prohibit all imports of rendered animal protein products from Europe regardless of species, applying to all products originating, rendered, processed, or otherwise associated with European products.
September 2001	The Holstein cow (born in Alberta in March 1997 and which would test positive for BSE in December 2003) is moved to the United States along with 80 other cattle from the same dairy.
September 10, 2001	Japan reports a case of BSE, the first in Asia. (By May 2005, Japan will have reported 18 BSE cases.)
September 18, 2001	Japan first bans the use of all ruminant MBM in cattle feed.

- September 30, 2001** Total U.S. cattle tested for BSE in FY2001 is 5,272, all negative.
- October 4, 2001** Japan bans the use of animal protein products to be used in feed products, including swine and poultry feed, as well as in fertilizers.
- October 18, 2001** Japan begins to test all cattle slaughtered for food for BSE.
- November 30, 2001** USDA releases the Harvard risk analysis, a mathematical model which indicates that the risk of BSE in the U.S. is extremely low, that U.S. early protection measures have been largely responsible for keeping it low, and that such measures would minimize BSE's spread if it did gain entry.
- January 17, 2002** USDA's Food Safety and Inspection Service (FSIS) publishes in the *Federal Register* a Current Thinking Paper, requesting comment on possible new regulatory and policy actions such as whether to: designate such tissue as the brains and spinal cords of cattle 24 months and older as higher-risk material (SRMs) and thus ban them from human food; prohibit the use of vertebral column from nonambulatory cattle and from those 24 months and older in mechanical meat recovery systems, among other possible regulation of such higher-risk tissues; and increase enforcement and/or regulation of those who handle dead, dying, disabled, or diseased livestock or their parts that die other than by slaughter.
- January 25, 2002** The U.S. Government Accountability Office (GAO) issues a report (GAO-02-183) criticizing the effectiveness of FDA's feed rules and enforcement.
- August 23, 2002** A Black Angus cow born in Saskatchewan in March 1997 is purchased with 35 other cows and calves by a cattle producer in Wanham, Alberta. (It would test positive for BSE in May 2003.)
- September 30, 2002** Total U.S. cattle tested for BSE in FY2002 is 19,990, all negative.
- November 6, 2002** FDA publishes an advance notice of proposed rulemaking, stating that it is considering revising its feed regulation and seeking comments on five relevant topics: excluding from feed the brain and spinal cord from rendered animal products; using poultry litter in cattle feed; using pet food in ruminant feed; preventing cross-contamination; and eliminating the exemption for plate waste as a feed ingredient.

December 2, 2002 FSIS issues a directive instructing inspectors at beef establishments using vertebral columns as source materials in advanced meat recovery (AMR) systems to take routine regulatory samples to verify that spinal cord is not present in AMR product. If spinal cord tissue is present, then the product does not meet FSIS labeling and inspection requirements for meat.

Developments Following First Reported Canadian Case (January-November 2003)

The first native-born case of BSE in North America was confirmed in a cow in Alberta, Canada, in May 2003. The United States almost immediately halted the importation of virtually all ruminants and ruminant products, including live cattle and beef, from Canada. (An interim final rule was published in the May 29, 2003, *Federal Register*, retroactive to May 20, 2003.) In August 2003, the U.S. Secretary of Agriculture announced that the U.S. border would reopen to boneless beef from cattle under 30 months old and other items considered to be of low risk for BSE. Rather than issuing a proposed or interim rule, USDA claimed authority to do so under a standing veterinary import permitting process.

USDA on November 4, 2003, proposed for comment a more extensive rule change that essentially would formalize and expand imports from Canada, to include among other things live cattle under 30 months old.

January 2003 A federal interagency working group led by USDA, in response to a legislative mandate (in P.L. 107-9) provides information on the economic impacts and public health risks if BSE or related diseases (and an unrelated disease, Foot and Mouth Disease) were introduced into the U.S., and information on federal prevention efforts and sufficiency of current legislative authority. The working group recommends a number of policy changes such as strengthening FDA authority to enforce its animal feed regulation and to control entry of imports that may risk bringing TSEs into the U.S.; an extended commitment of budgetary resources; and better interagency coordination, among other things.

January 21, 2003 In an advance notice of proposed rulemaking, APHIS solicits public comment to develop approaches to control the risk that dead stock and nonambulatory animals could serve as potential pathways for the spread of BSE, if that disease should ever be introduced into the United States. Comments were taken until March 24, 2003.

January 31, 2003 The Black Angus beef cow born in Saskatchewan in 1997, and now in Wanham, Alberta, shows signs of illness and is presented for slaughter. A government inspector declares

it unfit for human food. Its head is frozen at a provincial laboratory for later routine testing, and its remains go for rendering into feed. It would later test positive for BSE.

- February 20, 2003** The FY2003 omnibus appropriations act (P.L. 108-7) is signed into law, containing funding for USDA that includes \$8 million for increased BSE surveillance and laboratory activities; FDA is reported to receive a total of \$19 million for the fiscal year.
- March 3, 2003** FSIS releases the results of the AMR survey it conducted in 2002; they show that approximately 35% of final product samples had “unacceptable” central nervous system tissue detected. It also announces the start of the regulatory sampling program (issued as a directive in December 2002) to ensure beef products derived from AMR systems are accurately labeled.
- May 20, 2003** BSE is confirmed in the Canadian Black Angus cow, becoming the first native case reported in North America.
- May 29, 2003** APHIS publishes an interim rule (retroactive to May 20, 2003) adding Canada to list of regions where BSE exists, prohibiting or restricting the importation of meat, meat products, and other products/byproducts of ruminants from Canada. Officials subsequently ask Harvard to reassess its BSE risk model.
- June 26, 2003** Canada releases the report of an international review team (IRT) of BSE experts, which concludes that the most likely source of BSE would have been consumption of feed containing MBM of ruminant origin contaminated with the BSE prion before the US and Canada implemented a feed ban in August 1997. The original source of the BSE prion in MBM is likely to have been from a limited number of cattle imported directly into either Canada or the US from the UK in the 1980s, and it is likely that some of these animals were slaughtered or died and entered the animal feed system prior to a [Canadian] ban on further importations from the UK in 1990, the IRT reported. The team recommends a number of actions, including an immediate ban on SRMs (e.g., brain and spinal cord) believed to constitute a greater risk of disease, a review of animal feed regulations, strengthened tracking and tracing systems, and improved testing.
- July 18, 2003** Canada announces a requirement that, effective August 23, 2003, SRMs must be removed from cattle destined for human food. SRMs are defined as including the skulls, brains, eyes, tonsils, and spinal cords of all cattle over 30

months, and the distal ileum (part of the small intestines) of all cattle.

August 8, 2003

The Secretary of Agriculture announces that, after a “thorough scientific analysis,” the Department will begin accepting applications for import permits for certain “low risk” ruminant derived products from Canada. USDA said it will no longer prohibit importation of wild ruminant products intended for personal use (immediate), and will begin to accept applications for import permits for certain commercial products, including:

- boneless sheep/goat meat from animals under 12 months;
- boneless bovine meat from animals under 30 months;
- boneless veal from calves under 36 weeks;
- fresh or frozen bovine liver;
- vaccines for veterinary medicine if for non-ruminants;
- certain pet products and feed ingredients.

August 15, 2003

USDA posts an amended list of allowable Canadian products on its website as a clarification of the August 8 announcement. The list now includes “trim” from beef from cattle under 30 months of age and veal (including carcasses) from calves 36 weeks of age or under. Permit applications are subsequently submitted to APHIS for processed product made from allowable product. APHIS determines that processed product from trim and boneless beef from cattle under 30 months of age would be allowed, since processing would not increase the risk associated with the products.

August 23, 2003

The Canada SRM rule (see July 18, 2003) takes effect.

August 25, 2003

FSIS issues a revised directive intended to strengthen enforcement of measures to ensure that AMR systems do not introduce spinal cord into meat products. The directive notes that “Based on the first several months of regulatory ... sampling, FSIS has determined that some establishments are not adequately addressing the presence of spinal tissue in boneless comminuted [i.e., pulverized] beef.”

August 27, 2003

APHIS issues the first permit for the importation of approved ground product from Canada. Subsequent permits allow the entry of other processed meat from cattle under 30 months of age, such as hot dogs, pepperoni pizza toppings, hamburger patties, smoked briskets, dry cured beef cuts, and soups and TV dinners containing beef.

- September 4, 2003** The first Canadian veal imports reportedly resume.
- September 11, 2003** USDA reports this as the day that the first Canadian beef imports resume.
- September 30, 2003** Total U.S. cattle tested for BSE in FY2003 is 20,543, all negative.
- October 3, 2003** APHIS expands the list of Canadian products permitted for entry into the United States to include processed products containing otherwise eligible beef (e.g., roast beef, ground beef, lasagna, frozen hamburger patties).
- October 22, 2003** APHIS again expands the list of Canadian products permitted for entry into the United States to include edible beef lips, tongues, hearts, and kidneys.
- October 31, 2003** USDA releases the findings of a second Harvard assessment of BSE risk since the Canada case. The report notes that a group of cattle imported into Canada from the UK in 1993 included one that was found to have BSE, and that if other animals in this group harbored the disease, and were slaughtered and rendered, infectivity may have been introduced into the Canadian and U.S. cattle feed supplies before the 1997 feed ban was implemented in both countries. Harvard observed 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.
- USDA also announces it will publish a proposed rule (see November 4, 2003) to amend its BSE regulations.
- November 4, 2003** USDA publishes a proposed rule in the *Federal Register* that would amend its BSE regulations to establish a new category of regions that recognizes those that present a minimal risk of introducing BSE into the United States via the importation of certain low-risk live ruminants and ruminant products. (The rule, which is initially open for comments until January 5, 2004, will form the basis for the final rule that eventually will be published on January 4, 2005.) The proposed rule would add Canada to that risk category and would allow entry of certain commodities, including:
- bovine animals for immediate or subsequent slaughter (under 30 months);
 - sheep/goats for immediate or subsequent slaughter (under 12 months);

- cervids (e.g., deer and elk) for immediate slaughter;
- fresh (chilled or frozen) meat and whole/half carcasses from bovines less than 30 months;
- fresh (chilled or frozen) bovine liver;
- fresh meat of sheep.

November 25, 2003 APHIS decides to allow Canadian facilities that receive and process bone-in beef from the United States, New Zealand, and Australia to export it to the United States.

Developments Following First Reported U.S. Case (December 2003-December 2004)

At the time that USDA was accepting comments on the November 4, 2003, proposed rule, tests on a cow in Mabton, Washington, indicated the presence of the BSE agent. Confirmatory testing affirmed BSE, and the U.S. Secretary of Agriculture reported the findings on December 23, 2003. This became the first reported U.S. case, although investigators quickly determined that the animal was not native but rather was born in and imported from Canada. Nonetheless, most foreign countries closed their borders to U.S. beef.

The Secretary attempted to reassure the public that the case posed little or no risk to public health. Shortly after, U.S. authorities announced a series of regulatory changes aimed at strengthening BSE safeguards in meat slaughter plants; asked an international scientific panel to review the situation and the U.S. response; greatly expanded BSE testing and surveillance; and took other actions in response. Meanwhile, in the spring of 2004 a cattlemen's group successfully sued USDA to halt any further expansion of Canadian beef imports in a federal court. USDA then agreed to limit such beef imports to the types it began permitting in August 2003, until it promulgated a rule finalizing its November 4, 2003, proposal.

The enhanced BSE surveillance program began in earnest in June 2004; initial screening tests reported three possibly positive cases during the year (which USDA termed "inconclusives") that later were deemed to be negative for BSE. Nonetheless, cattle and beef markets reacted nervously to the reports; USDA was challenged sharply on the adequacy of their design and conduct of the testing program and how results were being reported prior to final confirmation. At FDA, where officials had promised early in 2004 to revise their animal feed rules to tighten controls over possible BSE contamination, deliberations over the rules continued through the end of the year.

Some countries, notably Canada and Mexico, were again accepting some U.S. beef in 2004, as were several smaller country markets. But Japan and South Korea, the other top two destinations for U.S. beef, remained closed, despite what appeared to be a hopeful joint announcement in October 2004 by the United States and Japan of a "framework" agreement for restarting U.S. exports there.

- December 9, 2003** The Holstein cow that was born in March 1997 in Alberta, Canada, arrives at Verns Moses Lake Meats slaughter plant in Washington State from a dairy in Mabton, Washington. The cow was reportedly nonambulatory, which was believed to be the result of complications from calving.
- December 11, 2003** Samples from the Washington State Holstein cow arrive at the Ames, Iowa, laboratories. Because the animal had no neurological signs at slaughter, it is not considered to be a higher priority for BSE and the samples are placed in the normal queue for testing. On the same day, products (mainly ground beef) that later would be subject to recall are shipped to outlets, mainly restaurants and grocery stores.
- December 22, 2003** Preliminary tests of the Holstein dairy cow in Washington are positive for BSE.
- December 23, 2003** The Secretary of Agriculture announces a presumptive positive case of BSE in the Holstein cow (hereinafter referred to as the “index” cow). APHIS quarantines the Mabton, Washington, herd where the cow had been, and begins its epidemiological investigations.
- December 23, 2003** FSIS announces a Class II recall of 10,410 pounds of meat from the group of 20 animals slaughtered with the BSE cow on December 9, 2003, at Verns Moses Lake Meats.
- December 24, 2003** Foreign countries begin to ban imports of U.S. ruminants and ruminant products, including Japan, Mexico, South Korea, and Canada, which account for 90% of U.S. beef exports. (Canada however remains open to some lower-risk U.S. beef.)
- December 29, 2003** FSIS determines that the recalled meat products were distributed to 42 locations from Interstate Meats and Willamette Valley Meats, with at least 80% of the products distributed to stores in Oregon and Washington.
- December 30, 2003** The Secretary of Agriculture announces additional safeguards, primarily in slaughter plants, to bolster the U.S. protection system against BSE and to further protect public health. These and several other regulatory changes will be published in the January 12, 2004, *Federal Register* (see below for details). The Secretary also announces that a verifiable system of national animal identification will be expedited, and that BSE testing will be expanded.
- December 31, 2003** The Secretary of Agriculture names an international review team of BSE experts (IRT, similar to the group that

conducted such a review in Canada) to review USDA's BSE investigation and make national recommendations.

January 5, 2004

Initial closing date for public comments on the November 4, 2003, proposed rule on Canada cattle and beef imports (see above). This comment period will later be reopened.

January 12, 2004

The Secretary of Agriculture publishes a "declaration of extraordinary emergency" in the Federal Register, which "authorizes the Secretary to (1) hold, seize, treat, apply other remedial actions to, destroy (including preventative slaughter), or otherwise dispose of, any animal, article, facility, or means of conveyance if the Secretary determines the action is necessary to prevent the dissemination of BSE and (2) prohibit or restrict the movement or use within the State of Washington, or any portion of the State of Washington, of any animal or article, means of conveyance, or facility if the Secretary determines that the prohibition or restriction is necessary to prevent the dissemination of BSE."

January 12, 2004

FSIS also publishes several BSE-related actions in the *Federal Register* (many were announced December 30, 2003):

- An interim final rule declaring that the skull, brain, eyes, vertebral column, spinal cord, and certain other parts of cattle 30 months of age or older, and the distal ileum of the small intestine of all cattle, are considered "specified risk materials" (SRM) and are prohibited in the human food supply. (Tonsils from all cattle were already prohibited.)
- The above rule also requires that all non-ambulatory (disabled) cattle presented for slaughter be condemned.
- An interim final rule articulating the criteria that the agency would use to ensure that AMR products can be represented as "meat" products and thus are not adulterated or misbranded (i.e., do not contain central nervous system tissues).
- An interim final rule prohibiting the use of penetrative captive bolt stunning devices that deliberately inject air into the cranial cavity of cattle (known as "air injection stunning").
- A notice announcing that FSIS inspectors will not mark ambulatory cattle that have been targeted for BSE surveillance testing as "inspected and passed" until negative test results are obtained.

- January 21, 2004** The House Agriculture Committee holds the first congressional oversight hearing on the U.S. BSE crisis.
- January 26, 2004** The Secretary of Health and Human Services announces coming changes in FDA feed rules (expected to be published within two months but which had not appeared as of late May 2005), which he says will:
- Eliminate the exemption that allows mammalian blood and blood products to be fed to other ruminants as a protein source;
 - Ban the use in ruminant feed of “poultry litter,” which consists of bedding, spilled feed, feathers, and fecal matter;
 - Ban the use in ruminant feed of “plate waste,” which consists of uneaten meat and other meat scraps that collected from restaurant operations and rendered into meat and bone meal;
 - Further minimize the possibility of cross-contamination of ruminant and non-ruminant animal feed by requiring equipment, facilities or production lines to be dedicated to non-ruminant animal feeds if they use protein that is prohibited in ruminant feed.
- January 27, 2004** The Senate Agriculture Committee holds an oversight hearing on the BSE situation.
- January 29, 2004** Agriculture Secretary Veneman announces that President Bush’s FY2005 budget for USDA will include a \$60 million request, or an increase of \$47 million, to fund multi-agency efforts to enhance USDA’s BSE prevention program.
- February 4, 2004** USDA releases findings of the international panel of BSE experts (the IRT). The IRT observes that although the infected U.S. animal may be the only one from the 81-cow herd that survived to adulthood, and its birth cohorts “do not represent significant risk ... 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 with the cattle population, so that cattle in the USA have also been indigenously infected.” The IRT also states that:
- Testing of all cattle for human consumption is “unjustified,” but an intensive one-time surveillance effort to determine the extent, if any, of U.S. BSE, and that testing a random sample of healthy cattle over 30 months “should be strongly considered;”

- The U.S. epidemiological investigation and the tracing and recall of meat and byproducts had conformed to international standards insofar as possible, but that implementation of an “appropriate” national ID system is needed;
- Because downers are now being banned from the food supply, “it is imperative” for USDA to ensure that dead and non-ambulatory cattle are properly sampled and disposed of;
- The U.S. should consider excluding all SRMs from both human and animal foods, including pet food, and unless “aggressive surveillance” proves the U.S. BSE risk to be minimal according to international standards, the SRM definition should be expanded to include the brain, spinal cord, skull, and vertebral column of all cattle over 12 months, and the entire intestine from all cattle;
- The partial ruminant-to-ruminant feed ban now in place is “insufficient.” A complete ban on the feeding of all mammalian and poultry byproducts to cows and other ruminants is justified due to the “practical difficulties of enforcement” and “... to the issues of cross-contamination as well as the current problems in differentiating mammalian and avian MBM.”

February 9, 2004

An “FSIS Update of Recall Activities” states that the total amount of meat distributed that was subject to recall had been expanded to approximately 38,000 pounds affecting 578 establishments.

February 9, 2004

APHIS also announces that the field investigation of the case of BSE in a cow in the State of Washington is complete, with the following results:

- The epidemiological tracing and DNA evidence proved that the BSE positive cow slaughtered in the State of Washington on December 9, 2003, was born on a dairy farm in Calmar, Alberta, Canada, on April 9, 1997.
- The epidemiological investigation to find additional animals from the source herd led to a total of 189 investigations, leading to complete herd inventories of 75,000 animals on 51 premises in Washington, Oregon and Idaho. The inventories involved the examination of the identification on more than 75,000 animals.
- A total of 255 “animals of interest” (those that could have been from the source herd in Alberta)

were identified on 10 premises in Washington, Oregon, and Idaho. All 255 were depopulated, and BSE testing was negative for all. The carcasses from all of the euthanized animals were properly disposed of in landfills. These 255 are in addition to the 449 animals slaughtered from the bull calf operation — bringing total slaughtered for BSE investigatory purposes to 674 cattle.

- Of the 255 animals of interest, 28 were positively identified back to the group of 80 cattle that entered the U.S. with the index cow, as well as 7 heifers out of a group of 17 heifers which were also known to be from the source herd. It is not believed that all of these 17 entered the United States, but all of them would be considered minimal risk and not significant to the investigation.
- International BSE guidelines state that animals born on a premises within one year before or after a BSE-affected animal should be considered of greater risk. USDA has focused on 25 of the 81 animals also born into the birth herd of the index animal. Based on normal culling practices of local dairies, APHIS estimated that the Agency would be able to locate approximately 11 of these animals. APHIS definitively located 13 of these animals, plus the index cow, for a total of 14.
- USDA expressed confidence that the remaining (unlocated) animals represent very little risk.
- Over 2,000 tons of meat and bone meal being held due to potential contamination with protein from the positive cow is on hold and will soon be properly disposed of in a landfill.
- All 255 adult animals depopulated were sampled and tested for BSE. The 449 bull calves depopulated were not sampled because they were too young for the BSE agent to be detected.

February 23, 2004

USDA releases the response of its full animal disease advisory committee to the subcommittee's report, among other things commending U.S. authorities for their handling of the case. The full committee recommends that federal officials ask the Harvard Center to review the subcommittee report, particularly to resolve the "major discrepancy" between the IRT's finding that BSE continues to circulate here and findings in the earlier Harvard University risk assessment that appeared to be more

qualified; and that USDA enhance surveillance and implement more quickly an animal ID program.

- February 24, 2004** The Senate Appropriations Committee holds an oversight hearing specifically on the BSE situation.
- March 3, 2004** The Secretary of Agriculture announces that Mexico has agreed to begin imports of some types of U.S. beef.
- March 8, 2004** In light of the discovery of the first confirmed case of BSE in the United States, APHIS reopens the comment period for its November 2003 proposed rule (which, among other things, proposed that Canada be identified as a “minimal risk” region for BSE). Additional comments on the proposed rule were due by April 7, 2004.
- March 15, 2004** USDA announces an expanded surveillance effort for BSE in the United States. Under the new program, to start on June 1, 2004, and expected to continue for 12 to 18 months, USDA says it wants to test as many as possible of a so-called higher-risk group of cattle (i.e., those which are nonambulatory, dead, or exhibiting signs of a central nervous system disorder or other BSE-associated signs). It estimates this target population to number 446,000.
- April 7, 2004** FSIS publishes a notice in the Federal Register requesting comment on its preliminary regulatory impact analysis of the three interim final rules issued by the agency on January 12, 2004. FSIS also extends the comment period on the January 12 rules to coincide with the close of the comment period for the impact analysis (on May 7, 2004).
- April 8, 2004** USDA denies the request of Creekstone Farms Premium Beef, a smaller packing company with markets in Japan, to test all of its cattle for BSE. USDA officials inform Creekstone that BSE tests have only been licensed for animal health “surveillance” purposes and “the test as proposed by Creekstone would have implied a consumer safety aspect that is not scientifically warranted.”
- April 18, 2004** A joint U.S.-Japanese press release states that the two sides will “actively engage in consultations” and “will respectively pursue domestic discussions and make efforts so as to reach a final conclusion by sometime around summer on the resumption of the importation of both American and Japanese beef.”
- April 19, 2004** USDA publishes on its website a memorandum and a new list of “Low Risk Canadian Products.” The new list of “Low Risk Canadian Products” permits “bovine meat and

meat products including boneless, bone-in, ground meat, and further processed bovine meat products.”

- April 22, 2004** A cattle producers’ group (Ranchers Cattlemen Action Legal Fund-United Stockgrowers of America, or R-CALF USA) files a lawsuit seeking federal judicial review of USDA’s actions on Canadian beef imports.
- April 23, 2004** Canada announces rule changes to permit a broader range of meat and meat products to be imported from the United States.
- April 26, 2004** In response to the R-CALF USA lawsuit, a U.S. District Judge in Montana issues a temporary restraining order blocking the expansion of importable Canadian products in the April 19 action. The judge specifically cites USDA statements indicating that any actions beyond those taken in August 2003 would be done through the rulemaking process.
- May 5, 2004** The April 26 temporary restraining order is converted to a stipulation that expires five days after the plaintiff (R-CALF USA) is notified of final agency action on the November 2003 USDA rulemaking. While the stipulation is in effect, the only bovine meats that can be imported for human consumption are fresh or frozen bovine liver, all veal from calves 36 weeks of age or less, and fresh or frozen boneless meat from animals under 30 months of age, including trim/manufacturing trim derived from skeletal muscle with associated tissues—but not including any ground meat, trim derived from mechanical separation processes including AMR or from vertebral columns (this is essentially the August 15, 2003, APHIS list). Canadian Food Inspection Agency (CFIA) verification that these products were subject to risk mitigation measures in Canada also is required.
- May 2004** Conflicting information circulates throughout the month as to exactly what types and quantities of Canadian beef products had been improperly allowed to enter since USDA began to ease import restrictions. R-CALF USA asserts that 33 million pounds of processed beef, more than 3 million pounds of bone-in beef, and 440,000 pounds of beef tongue were imported improperly from September 2003 to April 2004. USDA’s Under Secretary for Food Safety states at a press conference that what has come in from Canada that is not part of what was made eligible in August 2003 totals approximately 7.3 million pounds, and that all such products came from animals that were younger than 30 months of age.

- June 1, 2004** The enhanced BSE surveillance program reportedly begins. Early in the month, APHIS begins to post on its website weekly reports on test results.
- July 9, 2004** USDA and the Department of Health and Human Services (DHHS) announce three actions to strengthen federal safeguards against BSE: (1) a joint FSIS, APHIS, and FDA advance notice of proposed rulemaking that asks for public comment on additional preventive actions being considered; (2) an interim final FDA rule that prohibits the use of certain cattle-derived materials in human food (including dietary supplements) and medicines; and (3) a proposed FDA rule on recordkeeping requirements for the interim final rule relating to this ban. Specifically, in the advance notice, FDA asks the public to comment on measures related to animal feed (e.g., removing SRM from all animal feed and prohibiting materials from non-ambulatory cattle and dead stock from use in all animal feed); APHIS asks for comments on the implementation of a national animal identification system; and FSIS seeks comments on whether a country's BSE status should be a factor when determining whether its meat inspection system is equivalent to U.S. regulations.
- July 14, 2004** The House Committee on Agriculture and the House Committee on Government Reform conduct a joint hearing to review USDA's expanded BSE cattle surveillance program. USDA's Inspector General testifies on a draft OIG report which cites a number of limitations in the department's expanded surveillance plan. The final OIG report, issued in late August 2004, generally paralleled the preliminary findings. USDA defends its testing program at and after the hearing.
- August 4, 2004** APHIS announces changes in how it will announce inconclusive BSE tests, stating that it will not make such an announcement unless two screening tests (rather than one screening test) indicate other than a negative result for BSE. The change is made after two announced inconclusive tests caused market price disruptions earlier in the summer, even though they later were found to be negative upon confirmatory testing.
- September 30, 2004** USDA is reported to have spent a total of \$51 million for its BSE-related activities for the fiscal year just ended, \$44 million of it for surveillance and testing. FDA is reported to have spent more than \$21 million.
- October 23, 2004** The United States and Japan announce jointly that they have reached agreement on a framework for resuming two-

way beef trade. The joint statement includes the following elements:

- Japanese beef would be permitted in the United States following relevant U.S. rulemaking procedures.
- The United States would establish, with Japanese concurrence, an interim marketing program [a modified version of the Beef Export Verification (BEV) Program established by USDA's Agricultural Marketing Service (AMS) in 2003] that would enable a resumption of some U.S. beef exports to Japan, by certifying that all beef shipments are from cattle under 21 months old.
- The United States would expand its definition of cattle parts having a higher risk of harboring BSE. These "specified risk materials" (SRMs) would include — for cattle of *all ages* — the entire head except tongues and cheek meat; tonsils; spinal cords; distal ileum; and part of the vertebral column. This is broader than the current U.S. SRM definition, which applies mainly to cattle over 30 months old.
- The two countries would evaluate this interim marketing program by July 2005, based in part on a scientific evaluation by international health experts, and modify it if appropriate.

November 18, 2004

USDA announces that a U.S.-born, nonambulatory cow is "inconclusive" (possibly positive) for BSE in a screening test. The carcass is destroyed to prevent its use in the food or feed supply.

November 23, 2004

USDA announces that two confirmatory tests using the IHC method ("an internationally-recognized gold standard test for BSE," according to officials) both are negative for the disease. APHIS does not conduct a confirmatory "Western blot" test, another internationally recognized method, nor does it send the sample to the BSE World Reference Laboratory in Weybridge, England, for further examination.

December 8, 2004

The President signs into law the FY2005 Consolidated Appropriations Act (P.L. 108-447), which contains annual funding for USDA, including its BSE activities. Including funds it had transferred administratively from the Commodity Credit Corporation (CCC) earlier, USDA says it will spend a total of \$123 million on BSE-related activities in FY2005, including \$69 million for surveillance and testing and \$49 million for animal ID work. The

measure also contains nearly \$30 million for FDA's BSE activities.

- December 29, 2004** USDA unveils a new APHIS final rule (1) establishing a category of regions that present a minimal risk of introducing BSE into the United States from live ruminants and ruminant products, including the conditions that must be met to qualify as a minimal-risk region; and (2) accepting Canada as the first such region. The rule is published in the January 4, 2005, *Federal Register*, to take effect on March 7, 2005. The rule explicitly permits imports of, among other things, live Canadian cattle and other bovines for feeding and for immediate slaughter.
- December 31, 2004** According to USDA, 176,468 cattle are tested for BSE in calendar (not fiscal) 2004, all negative for the disease. (A total of 17,152 head had been tested in FY2004 through May 31, when the special 12-18-month surveillance program was initiated.)

Developments Following Second and Third Reported Canadian Cases (Since January 2005)

In early 2005, as USDA was unveiling its new rule for permitting Canadian imports, Canada was announcing two additional discoveries of BSE. This brought to four Canada's reported native-born cases (including the one found in the United States). U.S. officials expressed confidence in Canadian BSE safeguards but sent a team to confirm that feed controls there were effective.

R-CALF USA again sued USDA to halt Canadian beef and live cattle imports, winning a temporary injunction in early March 2005 against implementation of USDA's January 4, 2005, final rule. (The next section describes a higher court's reversal of this decision.) In Congress, the agriculture committees have held hearings on the BSE situation. The Senate voted in early March 2005 to block the USDA Canada rule, but necessary House action was not expected to occur.

Japan took several steps in 2005 toward lifting its ban on U.S. beef imports, but its regulatory process and continued consumer resistance there could delay an opening at least until later in 2005, many observers predict.

- January 2, 2005** CFIA reports that BSE has been confirmed in an Alberta dairy cow born in October 1996, prior to the 1997 "feed ban" on use of prohibited mammalian material. Canadian officials say that preliminary testing first detected the presence of the disease in December 2004. No part of the animal entered the human food or animal feed supply, CFIA states.

- January 4, 2005** APHIS publishes the final version of its November 4, 2003, proposed rule. In addition, because it is a “major” rule, it cannot take effect for 60 days from publication in the *Federal Register* or presentation to Congress (whichever is later), as provided for in the Small Business Regulatory Enforcement Fairness Act of 1996. This delay allows time for Congress to review the rule; Congress also has the option, for 60 legislative days, to pass a joint resolution overturning the rule.
- January 10, 2005** R-CALF USA files another lawsuit in the U.S. District Court in Montana to halt implementation of the January 4 rule, charging among other things that the rule is based on a faulty risk assessment not supported by scientific evidence.
- January 11, 2005** CFIA reports that BSE has been confirmed in an Alberta beef cow born in March 1998, more than six months after Canada had announced its ban on feeding ruminant material back to ruminants. Canadian officials say they have launched investigations to ascertain the whereabouts of any other at-risk animals and to determine what the animal had consumed. They speculate that the cow may have consumed BSE-contaminated feed that had been manufactured either before the ban, or shortly afterward, before it had been fully implemented.
- January 31, 2005** R-CALF requests a preliminary injunction in its lawsuit against USDA on the January 4 final rule.
- February 3, 2005** The Senate Agriculture Committee holds an oversight hearing on the Canada BSE situation, where Secretary of Agriculture Johanns testifies that the Department intends to implement the rule on March 7 as scheduled.
- February 7, 2005** The Administration releases its FY2006 budget proposal, which includes a request for \$66 million for USDA’s BSE activities and nearly \$30 million for FDA’s BSE activities.
- February 14, 2005** USDA’s OIG releases the results of its audit *Oversight of the Importation of Beef Products from Canada*. OIG finds 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 generally agrees to implement recommendations for improvement.

- February 25, 2005** USDA releases its positive assessment of the effectiveness of the Canadian ban on feeding most ruminant materials back to ruminants.
- February 25, 2005** GAO issues a report (GAO-05-101) concluding that FDA had made improvements in its management of the U.S. feed ban, but that program weaknesses continue to limit its effectiveness, placing U.S. cattle at risk of spreading BSE.
- March 1, 2005** The House Agriculture Committee holds a hearing on the Canadian beef import rule, taking testimony from Secretary Johanns, two cattle producer groups, and two meat packers.
- March 2, 2005** The U.S. district court in Montana issues a preliminary injunction to halt implementation of the January 4th rule and orders attorneys for both USDA and R-CALF to develop a proposed schedule for trial on the merits of whether a permanent injunction should be granted.
- March 3, 2005** The full Senate votes, 52-46, to approve a resolution (S. J.Res. 4) providing for the disapproval of the January 4th USDA rule. However, House passage and the President's signature are required for the resolution to take effect, neither of which is considered a strong likelihood.
- March 11, 2005** APHIS publishes a rule to delay until further notice the applicability of its January 4th rule on minimal risk regions.
- March 17, 2005** USDA appeals the Montana U.S. district court judge's ruling to block the Canadian import rule to the 9th Circuit Court of Appeals.
- April 29, 2005** APHIS releases a summary of its epidemiological review of Canada's BSE cases, reporting that Canada's epidemiological efforts have exceeded levels recommended by an international team of BSE experts.
- May 6, 2005** The Japanese Food Safety Commission (FSC) adopts a final report recommending that cattle under 21 months of age could be excluded from universal BSE testing, thus clearing the way for the Japanese Ministry of Health, Labor, and Welfare (MHLW), and Ministry of Agriculture, Forestry, and Fisheries (MAFF) to begin promulgating changes in their domestic BSE testing rules. (A public comment period is scheduled for May 9 to June 9, 2005.)
- May 26, 2005** The Japanese FSC initiates deliberations on the content of consultations with the Japanese MHLW and MAFF on conditions for resuming U.S. beef imports.

May 29, 2005 At the end of 52 weeks of testing under its special 12 to 18-month surveillance program that began June 1, 2004, USDA reports that 369,477 high-risk cattle have been tested, all but one negative for BSE, in the United States.

May 31, 2005 An expert subcommittee of the Japanese FSC begins deliberations on U.S. imports.

Developments Following Second Reported U.S. Case (Since June 2005)

June 10, 2005 Agriculture Secretary Johanns announces the possibility of BSE in sample material from a U.S.-born cow that in November 2004 had tested negative for BSE. He adds that samples from the cow are being retested and also being sent to the BSE World Reference Laboratory in Weybridge, England, for further examination. The cow tested negative for BSE last year after an initial screening had indicated an “inconclusive” (i.e., possibly positive) result. The latest, possibly positive, result, occurred using a different test method (the so-called “Western blot,” which, like the IHC method, also is OIE-recognized). The retest was conducted by USDA scientists at the request of the Office of Inspector General (OIG), not the Secretary.

June 24, 2005 The Secretary of Agriculture announces that more testing has confirmed the presence of BSE in a brain sample first taken from a U.S. beef cow in November 2004. This is the first confirmed case of BSE in a U.S.-born animal. The World Reference Laboratory in Weybridge, England, found after a series of tests that all except one detected BSE, including another IHC test. USDA and Weybridge officials explain that the positive IHC test by Weybridge used a different procedure than the one used in November 2004 by USDA at Ames, and that IHC methods differ and do not perform equally. USDA also reveals that a USDA laboratory had actually found possible BSE in the animal in 2004 when it applied an “experimental” version of the IHC test. But USDA asserts that the laboratory did not report this result because the test was not a proven one.

June 29, 2003 APHIS reports on its epidemiological investigation to determine the BSE animal’s origin, movements, and herd mates. Officials state that the cow in question was a 12-year-old Brahman cross beef cow from a Texas farm, initially reported to be nonambulatory. The animal was sampled at a plant that renders dead, dying, diseased, or disabled animals for non-human uses such as pet food, but

this animal's remains never entered the food or feed chain and were incinerated.

- July 12, 2005** Officials report that 67 herd mates have been destroyed and tested for BSE, all negative, and that they are continuing to look for other cattle born at about the same time that have since left the herd.
- July 13, 2005** A three-judge panel of the 9th Circuit Court of Appeals conducts a hearing on USDA's appeal of the Montana court's preliminary injunction on the Canada import rule.
- July 14, 2005** The appeals court rules to stay (reverse) the lower court's ban. The Secretary says the Department is taking immediate steps to resume the importation of Canadian cattle under 30 months of age.
- July 18, 2005** The first load of Canadian cattle since May 2003 reportedly enter the United States.
- July 25, 2005** The appeals court issues its opinion explaining reasons for reversing the district court's ban on the Canada import rule.
- July 27, 2005** APHIS announces that a brain sample from an older cow taken in April but not tested until more recently produced a "non-definitive" result using the IHC test, so more testing is underway to determine whether BSE might be present.
- August 1, 2005** Japan eases its rule requiring all cattle to be tested for BSE regardless of age; now, only cattle over 20 months of age must be tested. However, all local governments in Japan reportedly are continuing to test all cattle. (A separate rule change actually to permit U.S. beef imports is still under consideration.)
- August 3, 2005** APHIS reports that further tests of the suspicious cow tissue (see July 27) are negative for BSE. Tests were conducted both by APHIS and the international reference laboratory for BSE at Weybridge, England.

Postscript

At the time of this report, the Administration and many Members of Congress were focusing on efforts to reopen more major foreign markets to U.S. beef, particularly Japan and Korea. At hearings and other venues, U.S. policymakers and industry officials have expressed frustration with the pace of these efforts. Also, a group of U.S. cattlemen who have wanted to keep the U.S. border closed to cattle from Canada until all of their scientific and other concerns were adequately addressed

initially won a court-ordered delay in implementation of the Canada rule, but that delay later was reversed by an appeals panel. So, Canadian cattle are again entering the United States.

After 14 months of intensive surveillance, including 426,164 tests of higher-risk cattle, one additional BSE case has been confirmed in the United States, according to USDA. This is the first U.S.-born animal to be confirmed for BSE. USDA has not tested the 20,000 older adult cattle from the apparently healthy population, which it said in spring 2004 that it had intended to do.

USDA and industry officials have long argued that the overall U.S. risk profile is unchanged. They had long warned that one or even several additional BSE-positive cattle might be found. However, officials have repeatedly attempted to reassure consumers and foreign buyers that U.S. cattle and beef are safe and pose no risk to animal health or to human food safety (although research into the disease and the TSE family of diseases, and consideration of additional regulatory safeguards, continue). Nevertheless, few observers expect the trade and economic issues to be resolved quickly. U.S. beef may not be eligible for Japanese importation for at least several more months, and then the industry faces the difficult task of regaining the market share there that other countries, notably Australia, have since captured.

USDA's efforts to expand more ruminant trade between the United States and Canada bore fruit in July 2005; the next steps are likely to be consideration of the meat industry's requests to permit older as well as younger Canadian cattle across the border. Meanwhile, Congress can be expected to play a continued role, holding oversight hearings, providing funding for BSE-related activities, and possibly considering legislative options to address one or more of the problems at hand.