

CRS Report for Congress

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Bovine Spongiform Encephalopathy ("Mad Cow Disease") and Canadian Beef Imports

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Summary

Bovine spongiform encephalopathy (BSE or "mad cow disease") is a degenerative, fatal disease affecting the nervous system in cattle. In May 2003, BSE was confirmed in a cow in Alberta, Canada — the first known native North American case. In December 2003, BSE was confirmed in a Canadian-born cow in Washington State — the first known U.S. occurrence. On January 2 and 11, 2005, Canada announced two more cases of BSE, also in Alberta cows.

As the 2003 cases emerged, the Administration undertook a number of steps designed to strengthen U.S. BSE protections. The U.S. Department of Agriculture (USDA) at one point in 2003 had banned all Canadian beef imports, but several months later, began to gradually reopen the border to some of them. The method by which it eased its initial Canadian beef ban raised concerns among some lawmakers, and has been one of a number of BSE-related issues of interest to Congress.

Specifically, shortly after the May 2003 Canadian BSE discovery, USDA published an interim final rule in the *Federal Register* prohibiting the importation of cattle and other ruminants and ruminant products from Canada. Then in August 2003, using its authority to permit imports from BSE countries "in specific cases," USDA began to relax this prohibition by allowing the importation of certain products, including boneless beef from animals under 30 months old, that it considers to be of much lower risk for BSE contamination.

After USDA acted on several subsequent occasions to expand the types of permitted products beyond those announced in August 2003, and to ease the conditions for their entry into the United States, a federal judge in April 2004 halted the expansion. He concluded that USDA had not followed rulemaking procedures as spelled out in the Administrative Procedure Act (APA). The judge noted, among other things, that import restrictions were being relaxed "at the very same time when USDA is in the middle of a rulemaking to determine whether to take such a step."

The judge was referring to a November 4, 2003, proposed rule that would allow entry of additional types of Canadian beef, other ruminant products, including younger cattle. After the court's ruling, USDA officials agreed to limit bovine imports only to those they had approved for entry in August 2003, until after a final rule could be published. USDA published this rule in final form on January 4, 2005, which was to take effect March 7, 2005. However, the same federal judge, responding to another lawsuit, granted a temporary injunction that blocks implementation of the rule. So, the timing and extent of additional Canadian cattle and beef imports remain unclear as of this writing.

This report, which will be updated if significant developments ensue, provides a narrative chronology of selected U.S. actions after the discovery of BSE in North America, presenting in sequence this often confusing chain of events. The report focuses on USDA's steps to reopen the U.S. border to Canadian beef, and concludes with a discussion of USDA's actions in the context of APA rulemaking procedures.

Contents

Introduction	1
Background	3
U.S. Import Safeguards	3
Harvard Risk Analysis	4
U.S.-Canada Trade in Beef and Cattle	4
Chronology of U.S. Actions (2003)	5
Chronology of U.S. Actions (2004)	12
Chronology of U.S. Actions (2005)	16
Federal Rulemaking Procedures	20
Appendix A. Selected “Low Risk Canadian Products”	23
Appendix B. Canadian Beef Imports	24

Bovine Spongiform Encephalopathy ("Mad Cow Disease") and Canadian Beef Imports

Introduction¹

Bovine spongiform encephalopathy (BSE, or "mad cow disease") has been discovered four times in North America since 2003, all in cattle of Canadian birth. Three of the animals were found in western Canada, and one was discovered in Washington State. The discoveries triggered worldwide bans on first Canadian, and then U.S., beef and cattle. Although some countries have partially lifted their bans, exports from the two countries remain disrupted. Also, though the U.S. Department of Agriculture (USDA) has restored U.S. imports of Canadian beef, mostly boneless products from younger animals, U.S. imports of Canadian live cattle and a number of other ruminant products remain suspended.²

BSE is a degenerative, fatal disease affecting the nervous system in cattle. The most likely cause of infection is feed composed of BSE-contaminated animal protein. BSE was first discovered in Great Britain in 1986, and the great majority of the world's approximately 187,000 cases have occurred there (in declining numbers in recent years). Approximately 160 people, most of them in Great Britain, have contracted new-variant Creutzfeldt-Jakob disease (vCJD), which is assumed to be linked to exposure to BSE, more specifically through consumption of cattle products contaminated with the BSE agent.

In May 2003, the Canadian Food Inspection Agency (CFIA) announced the first native North American case of BSE, in a Black Angus cow in Alberta that was born in 1997.³ Seven months later, in December 2003, USDA confirmed BSE in a Holstein dairy cow in Washington State, the first case discovered inside the United States. The Washington State animal was born in Canada in 1997, shortly before both countries banned the practice of feeding most ruminant material back to cattle and other ruminants.

On January 2, 2005, Canadian officials confirmed a third North American BSE case, in an Alberta dairy cow born in 1996. Nine days later on January 11, they

¹ For questions on BSE issues discussed in this report, contact Geoffrey S. Becker at 7-7287. For questions on administrative procedure matters, contact Curtis W. Copeland at 7-0632.

² Ruminants are animals that have multiple stomachs, such as cattle, sheep, goats, bison, deer, elk, caribou, moose, and camels.

³ In December 1993, Canada reported its first case of a BSE-infected cow, but in an animal believed to have been imported from Great Britain in 1987.

confirmed a fourth case, in an Alberta beef cow born in March 1998, after the 1997 feed ban had been announced.

The May 2003 discovery of BSE in Canada caused the United States to immediately prohibit the importation of cattle, beef, and other ruminant products into the United States from Canada; other countries followed suit. After the discovery of BSE in the United States, other countries quickly banned the importation of U.S. ruminants and ruminant products. The two BSE cases led both countries to undertake extensive epidemiological investigations to determine their source and whether other cattle were infected, and to make additional policy changes aimed at improving their existing BSE safeguards.⁴

In August 2003, several months after the Canadian BSE announcement but before the United States reported the Washington State case, USDA officials began to approve for import some types of Canadian beef (and some other ruminant products). On November 4, 2003, USDA published a proposed rule to expand imports of beef, live cattle, and other ruminants and ruminant products.

However, prior to publication of a final rule on the matter, USDA on several occasions between August 2003 and April 2004 had already clarified and/or expanded the types of permitted products. A federal judge in late April 2004 halted any beef imports beyond the types of products the Department had approved in August 2003. The judge concluded that the Department had not followed proper rulemaking procedures (see “April 26, 2004” entry).

USDA subsequently published the final rule on January 4, 2005, to take effect March 7, 2005. But the same judge temporarily blocked implementation, pending a full trial on the rule’s merits. USDA’s actions on Canadian imports also came under criticism by its Office of Inspector General (OIG), and by a number of Members of Congress, although others have defended the Department’s rulemaking on the matter (see 2005 date entries).

This report provides a narrative chronology of selected U.S. actions after the discovery of BSE in North America, presenting in sequence this often confusing chain of events. The report focuses on USDA’s steps to reopen the U.S. border to Canadian beef; it is not intended to be exhaustive of all BSE-related events. Not covered, for example, are (1) the Administration’s efforts to reopen foreign markets to U.S. beef products; (2) USDA’s and the Food and Drug Administration’s regulatory changes to tighten domestic BSE safeguards; and (3) congressional actions (prior to 2005), which include BSE oversight hearings, a variety of BSE-related bills, and communications with Administration officials about BSE matters.

The description of the following events is taken from a number of sources, with an emphasis on official U.S., Canadian, and other public documents where possible. More on these sources and other BSE-related issues can be found in:

⁴ For more detailed background on these safety measures, please refer to the CRS reports on BSE listed here.

- CRS Issue Brief IB10127, *Mad Cow Disease: Agricultural Issues for Congress*, by Geoffrey S. Becker;
- CRS Report RL32199, *Bovine Spongiform Encephalopathy (BSE, or “Mad Cow Disease”): Current and Proposed Safeguards*, by Sarah A. Lister and Geoffrey S. Becker;
- CRS Report RS21709, *Mad Cow Disease and U.S. Beef Trade*, by Charles E. Hanrahan and Geoffrey S. Becker.

Background

U.S. Import Safeguards

USDA’s Animal and Plant Health Inspection Service (APHIS) is responsible for among other things protecting U.S. animal health, including the exclusion of foreign diseases that can potentially harm U.S. herds and flocks. USDA’s Food Safety and Inspection Service (FSIS) oversees the safety of most U.S. meat and poultry for human consumption, including imported products. (The Food and Drug Administration (FDA) within the U.S. Department of Health and Human Services oversees the safety of most other human foods and of animal feeds.)

In 1989, APHIS began to ban the importation of live ruminants (i.e., cattle, sheep, goats, deer, elk, buffalo) and many ruminant products from the United Kingdom and other countries where native cases of BSE has been diagnosed.⁵ APHIS amended these import restrictions over subsequent years as scientists learned more about BSE and its means of transmission. The practical effect of these rules (published in parts of 9 CFR 93, 94, and 95) has been that virtually no ruminants, and very few products of ruminants, can be imported from any country with BSE, even those with a single case and/or that have BSE safeguards that meet or exceed international standards.⁶ In August 2003, Canada became the exception to this more extensive U.S. ban. USDA stated at the time that a review of scientific evidence indicated that the risk to public health from the single Canadian case was extremely low (see “August 8, 2003” entry).

U.S. import restrictions constitute one of what authorities have termed “three firewalls” erected (prior to the 2003 North American cases) to keep BSE out of the United States and to contain it if it should occur. The other two firewalls are a 1997

⁵ As of July 7, 2004, 23 countries had reported one or more indigenous cases of BSE, and another three, including the United States, reported only imported cases. OIE provides updated information on countries with BSE at [http://www.oie.int/eng/info/en_esb.htm].

⁶ The international standards are set by the International Office of Epizootics (OIE). Other sources for this section include various APHIS backgrounders and briefing materials, available at [<http://www.aphis.usda.gov/lpa/issues/bse/bse.html>]. Also, under FSIS’s foreign inspection program, no establishments in countries with BSE have been permitted to ship beef to the United States.

FDA ban on feeding most mammalian proteins to cattle and other ruminants, and a targeted APHIS domestic BSE testing and surveillance program.⁷

Harvard Risk Analysis

Shortly after discovery of the Canadian BSE case, USDA officials asked the Harvard Center for Risk Analysis to reassess its November 2001 analysis of the potential for an outbreak and spread of BSE in the United States. The reassessment, released in October 2003, concluded in part that “the possible introduction of BSE into the United States from Canada cannot be dismissed,” but said that the likelihood was very low and that U.S. protective measures would contain any possible spread.⁸ However, the reassessment also noted that a group of cattle imported into Canada from the United Kingdom in 1993 included one that was found to have BSE:

If additional animals in this group harbored the disease and were slaughtered and rendered, infectivity may have been introduced into the Canadian and U.S. cattle feed supplies before the 1997 feed ban was implemented in both countries.... If additional animals were infected, they may have been exported to the U.S. as well.... [It] appears that any related introduction of BSE into the U.S. from Canada would have been due to the import of either infected animals or contaminated feed. Imports are a plausible source of introduction of BSE into the U.S. from Canada because the American and Canadian beef industries are closely linked.⁹

U.S.-Canada Trade in Beef and Cattle¹⁰

Prior to the BSE cases, the United States was Canada’s most important market for cattle as well as beef exports. In 2002, nearly 1.1 billion pounds of Canadian beef and veal were imported into the United States, representing approximately one-third of all U.S. beef imports and nearly 4% of total U.S. beef consumption. Canada also exported nearly 1.7 million live cattle and calves to the United States in 2002,

⁷ The FDA Center for Veterinary Medicine (CVM), responsible for the safety of animal feed ingredients, began prohibiting the use of most mammalian protein in feeds for ruminants in August 1997, a restriction commonly called the “feed ban,” which was published as a final rule June 5, 1997 (*Federal Register*, vol. 62, no. 108, p. 30935). CRS Report RL32199, *Bovine Spongiform Encephalopathy (BSE or “Mad Cow” Disease: Current and Proposed Safeguards*, by Sarah A. Lister, and Geoffrey S. Becker, describes the three “firewalls” in more detail.

⁸ Cohen, Joshua, 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. See [http://www.aphis.usda.gov/lpa/issues/bse/harvard_10-3/text_wrefs.pdf].

⁹ *Ibid.*

¹⁰ Sources: USDA, Economic Research Service, “Background statistics on U.S. beef and cattle industry,” at [<http://www.ers.usda.gov/news/BSECoverage.htm>]. Also see the ERS report *U.S. 2003 and 2004 Livestock and Poultry Trade Influenced by Animal Disease and Trade Restrictions* (LDPM-120-01), July 2004. Although most of USDA’s administrative actions on Canadian imports affect other types of ruminants, this CRS report focuses primarily on beef and cattle, which by far are the most prevalent of such imports.

accounting for more than two-thirds of all U.S. cattle imports and 4.6 percent of total U.S. slaughter.

By contrast, the United States exported about 241 million pounds of beef and veal and about 134,000 live cattle and calves to Canada in 2002, giving the United States a negative trade balance. According to USDA, one reason that more cattle have moved south than north is that Canadian producers have expanded production of younger animals to supply the much greater feeding and slaughter capacities, as well as to restock dairy herds, in the United States, where more feed grains are grown and feeding costs are lower. However, U.S. firms also have packing plants and other cattle and meat facilities in Canada.

The May 2003 discovery of BSE in a Canadian cow virtually shut Canada out of the U.S. market. U.S. imports of some types of Canadian beef resumed later in 2003, but not the importation of live cattle imports and certain other types of beef such as “bone-in” product. Because of the BSE-related import ban on live Canadian cattle, Canada has been expanding significantly its meat plant capacity in order to slaughter more of its own cattle, and then export the allowable beef cuts to the United States, according to USDA and U.S. meat firms, who contend that they have begun to reduce production and lay off workers in large part due to the inability to import Canadian cattle.

Chronology of U.S. Actions (2003)

Shortly after the announcement of the Canadian BSE case in May 2003, APHIS officials issued a final rule banning the importation of virtually all Canadian ruminants and ruminant products. Several months later, APHIS reopened the border to some of these products (without going through the rulemaking process). Over subsequent months, APHIS on several separate occasions added to the list of permitted Canadian items and amended some “risk mitigations” — essentially, the safety requirements each of these items must satisfy to qualify for entry. USDA officials asserted that the subsequent versions of the list in no way reflected an expansion to products that might carry a higher BSE risk; by and large, list modifications merely were intended to clarify the types of beef that already were acceptable and safe to import, officials have maintained.

Underlying the Administration’s overall policy toward Canadian beef has been a recognition that it would be difficult to convince foreign trading partners to accept U.S. beef if the United States were unwilling to make similar concessions to nations (like Canada) where BSE poses only a very low or minimal risk, and where scientifically based BSE safety practices are in place.

A group of cattle producers filed suit directly challenging APHIS’s April 19, 2004, action to further expand permitted beef imports without a formal rule. In response, a federal judge concluded that the Department had not adhered to the Administrative Procedure Act (APA) of 1946 (codified at 5 U.S.C. 551 *et seq.*), which generally requires the agency to provide notice and opportunity for public comments before taking final action. Responding to a second lawsuit by the cattle group, the judge granted a temporary injunction blocking USDA from implementing

the January 4, 2005, final rule to permit imports of some Canadian cattle. The lawsuit, described later in this report, alleges procedural and substantive problems with the rule. Following is a narrative timeline of U.S. actions and related events.

May 20, 2003

The Canadian Food Inspection Agency (CFIA) reported that BSE had been confirmed in an older Black Angus beef cow from an Alberta farm. It was later determined that the cow had been born before publication in August 1997 of separate but similar U.S. and Canadian rules that prohibit the feeding of most ruminant materials back to ruminants. CFIA said the cow had been discovered to be nonambulatory (unable to stand up), was delivered to a packing plant on January 31, 2003, and was condemned for pneumonia, and a brainstem sample was frozen for later, routine BSE testing. CFIA said its meat did not enter the food supply. After initial screening was presumptive positive for BSE, confirmatory testing was conducted, BSE was confirmed, and the announcement made by CFIA. USDA immediately announced a ban on imports of live ruminants, including live cattle, and most ruminant products, including beef and veal, from Canada. Excluded from the ban were milk, milk products, ruminant hides and hide-derived products, bovine semen, and embryos.¹¹

May 29, 2003

The U.S. ban on the importation of Canadian cattle, beef, and other ruminant products was formalized with the publication of an APHIS interim final rule in the *Federal Register*, which placed Canada on a list of regions where BSE had been detected.¹² As a result, the importation of ruminants that had been in Canada and any associated products and byproducts of those ruminants was prohibited as of May 20, 2003, the date the disease was confirmed in Canada. APHIS said it published the rule on an emergency basis without going through the traditional APA process of publishing a proposed rule and asking for comments because “the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C 553 for making this rule effective less than 30 days after publication in the *Federal Register*.” That section of the APA states that traditional notice and comment procedures generally do not apply when an agency finds, for “good cause,” that those procedures are “impracticable, unnecessary, or contrary to the public interest.” When agencies use the good cause exception, the act requires that they explicitly say so and provide a rationale for its use when the rule is published in the *Federal Register*.¹³

¹¹ Agriculture Secretary Ann M. Veneman, “Statement Regarding Canada’s Announcement of BSE Investigation,” May 20, 2003. A May 21 memorandum from APHIS to its regional offices contains a more detailed list of prohibited imports, and notes that the prohibition was effective as of 1:30 p.m. eastern time on May 20.

¹² USDA, APHIS, “Change in Disease Status of Canada Because of BSE,” 68 *Federal Register* 31939, May 29, 2003.

¹³ For a discussion of this issue, see CRS Report RL32240, *The Federal Rulemaking Process: An Overview*, by Curtis W. Copeland.

August 8, 2003

The Secretary of Agriculture held a press conference to announce that USDA would begin to accept applications for permits to import selected ruminant products from Canada. The Secretary's authority to issue import permits from countries with confirmed cases of BSE is codified in 9 CFR 93.401. This authority states that the Administrator of APHIS may, upon request "in specific cases," permit products to be imported from countries with confirmed BSE when he or she determines "in the specific case" that doing so will not endanger U.S. livestock or poultry.

Later, in February 2005, USDA's Office of Inspector General (OIG) observed: "At that time, APHIS did not have a history of issuing permits for the importation of edible meat products. Veterinary import permits were generally issued for items derived from animals, such as blood, cells or cell lines, hormones, and microorganisms including bacteria, viruses, protozoa, and fungi."¹⁴

The products announced on August 8th included:

- Boneless beef from cattle under 30 months old at slaughter;
- Fresh or frozen bovine liver;
- Boneless veal from calves no older than 36 weeks at slaughter;
- Boneless sheep or goat meat from animals under 12 months old;
- Veterinary vaccines for non-ruminants;
- Pet products and feed ingredients that contain processed animal protein and tallow of nonruminant sources when produced in facilities with dedicated manufacturing lines.¹⁵

These items were spelled out in more detail on a list of "Low Risk Canadian Products" issued by APHIS's Veterinary Service (VS) and posted on the APHIS website.¹⁶ However, neither USDA's August 8 announcement nor the VS list was published in the *Federal Register*.

Before bringing these products into the United States, importers were required to obtain permits and satisfy "required risk mitigations" specific to each of the eligible products. For example, officials said that they would permit "bovine meat, boneless fresh or frozen from animals under 30 months of age — (no manufacturing trim derived from bone, advanced meat recovery, mechanically separated meat, ground meat, or low-temperature rendered product)." The required risk mitigations for this category of imports are "CFIA verification that the animals were under 30

¹⁴ USDA, OIG. *Animal and Plant Health Inspection Service Oversight of the Importation of Beef Products from Canada*, Audit Report No. 33601-01-Hy, February 2005 (p. i).

¹⁵ The announcement and accompanying press release also stated that hunters could immediately begin to import wild ruminant meat products (e.g., deer; elk) for personal use, with the appropriate paperwork.

¹⁶ USDA-VS, "Low Risk Canadian Products," August 7, 2003. Although the list was dated August 7, its contents were announced August 8. A side-by-side comparison of the language in the bovine meat and other ruminant product categories, as it appeared (and changed) in each of the subsequent "Low Risk" lists, appears in Appendix A of this CRS report.

months of age when slaughtered and are not known to have been fed prohibited products during their lifetime; brain and spinal cord removed; slaughter plant only kills animals less than 30 months of age.”

According to USDA’s August 8 press release, “Today’s announcement comes after a close review of the international standards set by the International Office of Epizootics (OIE) — the standard-setting organization for animal health for 164 member nations; an exhaustive epidemiological investigation into the case by Canada, during which no other animals were found to be infected; and additional risk mitigation measures put in place by Canada in response to a review by an independent expert panel.”¹⁷

USDA indicated on August 8 that a decision on whether to allow the importation of live cattle and other higher-risk ruminants and ruminant products (e.g., bone-in beef) would be determined through forthcoming rulemaking, and that this rulemaking process would begin immediately. During the press conference, a USDA official told reporters that the August 8 announcement would open the U.S. market to about 40% of Canadian beef and that the forthcoming proposed rule would cover the other 60%.

Also on August 8, USDA announced that the United States, Canada, and Mexico would jointly ask the OIE to develop and adopt “more practical, consistent guidance to countries regarding the resumption of trade with countries that have reported cases of BSE.” Later, in a July 14, 2004, advance notice of proposed rulemaking, USDA explained that under the OIE guidelines, beef imports from a country with BSE become increasingly restrictive as that country’s BSE risk status rises. However, the OIE Code “does not suggest a total embargo of animals and animal products coming from BSE affected countries, not even from countries considered as having high BSE risk, as long as the proper risk mitigation measures are applied.”¹⁸

¹⁷ “Veneman Announces that Import Permit Applications for Certain Ruminant Products From Canada Will Be Accepted,” USDA press release, August 8, 2003. Canada released the report of the international expert panel on June 26. It had concluded that the “most likely source of BSE for the infected cow would have been the consumption of feed containing meat and bonemeal (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, before BSE was detected in that country. 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 team recommended a number of actions, one of which Canada took by announcing on July 18, 2003, that (effective August 23) the following specified risk materials must be removed from cattle destined for human food: skulls, eyes, tonsils, and spinal cords of all animals over 30 months, and the distal ileum of all cattle. See *Report on Actions Taken by Canada in Response to the Confirmation of an Indigenous Case of BSE* at [<http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/internat.html>].

¹⁸ July 14, 2004 69 *Federal Register*, p. 42295. The notice also makes reference to the the international panel of BSE experts USDA asked to assess its BSE response and to make recommendations for the future. One of its recommendations was that the United States

August 15, 2003

APHIS posted on its website a modified list of low risk Canadian products eligible for permits. Newly added items included beef “trim” from cattle under 30 months of age, and veal (including carcasses, which contain bone) from calves 36 weeks of age or under. More specifically, this included “trim/manufacturing trim derived from skeletal muscle with associated tissues, not including any ground meat, trim derived from a mechanical separation process (including advanced meat recovery, or AMR, systems), or derived from vertebral column.”¹⁹ Also on the this list (but not on the August 8 list) were veal carcasses. (For a side-by-side comparison of each of the lists and how they changed, see Appendix A.)

Other than posting this August 15 list on the APHIS website, the agency did not otherwise notify the general public about it by issuing another press release or publishing a notice or rule in the *Federal Register*.

Around this time, APHIS was receiving requests to permit processed products to be imported, if such products were made from allowable product (i.e., items announced on August 8). APHIS said it had “determined that the processing of the approved trim and other low risk cuts of meat under strict conditions would not increase the risk associated with these products,” and began allowing the entry of these products, under permit, on a case-by-case basis.²⁰ The import permits required accompanying risk mitigation measures; APHIS relied on Canadian inspection officials to certify that such measures were in place.²¹

August 27, 2003

The first permit for such a processed product was approved. Subsequent permits allowed 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.²² Many of the

¹⁸ (...continued)

“...should demonstrate leadership in trade matters by adopting import/export policy in accordance with international standards, and thus encourage the discontinuation of irrational trade barriers when countries identify their first case of BSE.” See *Report on Measjures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States*, February 2, 2004, at [http://www.aphis.usda.gov/lpa/issues/bse/US_BSE_Report.pdf].

¹⁹ APHIS, *Low Risk Canadian Products*, as posted August 15, 2003. A June 10, 2004, USDA paper, *Background on Importation of Processed Canadian Beef Products Between August 2003 and April 2004*, states that trim “is boneless beef trimmed from carcasses originating from cattle under 30 months and veal (including carcasses) from calves 36 weeks of age or under.”

²⁰ USDA, *Background on Importation of Processed Canadian Beef Products Between August 2003 and April 2004*.

²¹ OIG. *Animal and Plant Health Inspection Service Oversight of the Importation of Beef Products from Canada* (p. 2).

²² USDA, *Background on Importation of Processed Canadian Beef Products Between* (continued...)

permitted products were from U.S.-origin beef that had previously entered Canada for processing there, USDA officials reported.

September 4, 2003

APHIS began to allow Canadian facilities that slaughter cattle over 30 months of age to produce beef for export to the United States as long as the facilities had an approved plan for segregating products from these animals.

September 10, 2003

A Canadian Food Inspection Agency (CFIA) update noted that (1) CFIA had arrived at an agreement with USDA to allow Canadian processors to segregate products from animals over 30 months of age in order to meet U.S. import requirements; (2) CFIA was in the process of finalizing the requirements of export certificates to allow segregated beef across the border; and (3) “exports of veal, beef liver, and specific processed beef products have begun to move across the border.”

October 3, 2003

APHIS decided to expand the list of low-risk products to include processed products including roast beef, ground beef, lasagna and frozen hamburger patties.²³

October 22, 2003

APHIS reposted an updated list of low risk Canadian products. Newly added to this version of the list were bovine lips, tongues, hearts and kidneys. Also, a risk mitigation requirement that meat packing plants kill only cattle under 30 months of age was now modified, allowing them to ship product to the United States so long as “an approved segregation procedure is in place” (to keep over-30 and under-30-month-old animals and tissues separated). In another change, a previous risk mitigation requirement that CFIA verify, for beef and veal, that the animals “are not known to have been fed prohibited products during their lifetime,” was restated to say that the animals “were subject to a ban on the feeding of prohibited materials during their life span.” Also changed was a risk mitigation requirement that the brains and spinal cords of animals be removed before their meat was eligible for shipment. The October 22 list no longer contained this explicit requirement.²⁴

²² (...continued)
August 2003 and April 2004.

²³ OIG. *Animal and Plant Health Inspection Service Oversight of the Importation of Beef Products from Canada* (p. 3).

²⁴ Possibly, USDA considered the reference to brain and spinal cord to be redundant because those tissues are not “specified risk materials” if they come from cattle under 30 months old — and no beef from any cattle 30 months or older can be imported from Canada.

Although this updated list was posted on the APHIS website, the agency did not otherwise notify the public through a notice or rule in the *Federal Register*, a press release, or other communication.

November 4, 2003

APHIS published a proposed rule that would, if made final, (1) amend the agency's BSE regulations to recognize a new category of regions that present a "minimal risk" of introducing BSE into the United States; (2) add Canada to that risk category; and (3) allow entry of certain products from Canada and other minimal-risk regions.²⁵ Specifically, these products would include:

- Live bovine animals under 30 months of age for immediate slaughter or those moved to a designated feedlot for slaughter before 30 months;
- Live sheep and goats under 12 months old under the same conditions;
- Cervids for immediate slaughter;
- Fresh chilled or frozen meat, or carcasses, from bovines under 30 months old;
- The same items from sheep under 12 months.

Also proposed for entry were a number of other ruminant products. Also, the proposed rule would no longer require import permits for such products.

In the *Federal Register* document, APHIS discussed the factors that APHIS would consider in classifying a region as being a minimal risk, why it believed Canada qualified as a minimal-risk region, and the mitigations that it would apply to specific commodities from Canada. The comment period for this proposal was set to end on January 5, 2004.

November 25, 2003

APHIS decided 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.²⁶

December 23, 2003

The U.S. Secretary of Agriculture announced that an older Holstein dairy cow slaughtered earlier in the month in Washington State had tested positive for BSE. During the subsequent investigation, the cow was determined to have been born in

²⁵ USDA, APHIS, "Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities," 68 *Federal Register* 62386, Nov. 4, 2003.

²⁶ OIG. *Animal and Plant Health Inspection Service Oversight of the Importation of Beef Products from Canada* (p. 4).

Canada before the 1997 U.S. and Canadian ruminant feed rules were in effect, and no other animals were found to be infected.

December 30, 2003

USDA announced new BSE safeguards, most aimed at using FSIS regulatory authority to keep higher-risk cattle parts out of the human food supply. They were published as interim final rules in the *Federal Register* on January 12, 2004.²⁷

Chronology of U.S. Actions (2004)

February 4, 2004

USDA released findings of the international BSE review team it had named to look into the U.S. case and the federal response. The panel observed that the infected animal may have been the only one from the herd that survived to adulthood, and that its birth cohorts “do not represent significant risk.” Nevertheless, the panel, which made a number of recommendations for strengthening the U.S. BSE program, said “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.”²⁸

March 8, 2004

In light of the U.S. BSE case and related developments, USDA published a *Federal Register* notice reopening the public comment period for its November 4, 2003, proposed rule, accepting additional comments until April 7, 2004. The notice explained that because FSIS had recently published rules prohibiting high-risk cattle parts from the human food supply, APHIS believed it no longer necessary to require that all beef imports from Canada (which had equivalent measures in place) be from cattle under 30 months old.²⁹

April 19, 2004

APHIS posted on its website another version of the list of low risk Canadian products. This version and an accompanying memo to “U.S. Importers, Brokers, and

²⁷ FSIS, USDA, “Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disable Cattle,” 69 *Federal Register* 1862; “Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems,” 69 *Federal Register* 1874; “Prohibition on the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter,” 69 *Federal Register* 1885.

²⁸ Some critics argued that the panel’s findings contradict other scientific findings, notably the examination of the U.S. BSE situation by the Harvard Center for Risk Analysis.

²⁹ OIG. *Animal and Plant Health Inspection Service Oversight of the Importation of Beef Products from Canada* (p. 4).

other Interested Parties,” expanded permitted Canadian products to include bone-in beef. The memo said “existing permits will be deemed to cover all edible bovine meat products originating from a Canadian establishment certified to FSIS provided it is accompanied with a new agreed CFIA certificate.” Specific bovine meats on the April 19 list included “bovine meat and meat products including boneless, bone-in, ground meat, and further processed bovine meat products.” The web posting and memo were not accompanied by a *Federal Register* notice or rule, or press release.

April 22, 2004

A cattle producers group, Ranchers-Cattlemen Action Legal Fund United Stockgrowers of America (R-CALF USA), filed a lawsuit in the U.S. District Court in Montana seeking judicial review of USDA’s April 19 action and asking for a temporary restraining order.

April 26, 2004

The federal judge issued the temporary restraining order, which immediately prohibited USDA from permitting the importation of “all edible bovine meat products beyond those authorized” on August 8, 2003. The judge concluded that USDA’s August 8, 2003, and April 19, 2004, actions “do not appear on their face to be the kind of case-by-case exception to the general ban on imports, determined on the facts of the specific case, that [the Code of Federal Regulations] authorizes.... (T)hese actions appear to be across-the-board relaxations of the ban on importation of Canadian beef established in the May 29, 2003, emergency rule, rather than case-specific exceptions to the ban.”³⁰

The judge further stated that the April 19 action “was a statement of general applicability covering all existing permits to import beef from Canada, and that it was intended to affect individual rights and have the force of law. Thus, notice-and-comment rulemaking was required before its adoption.” Referring to the November 2003 proposed rule, the judge said it was:

... troubling to the Court how USDA could believe it is appropriate procedure to authorize all imports of bovine meat products from Canada, through the April 19, 2004 memorandum, at the very same time when USDA is in the middle of a rulemaking to determine whether to take such a step. Moreover, the Court is concerned by the manner in which, according to counsel for USDA, USDA has been authorizing imports of virtually all edible bovine meat products, apparently through individual permits, at a time when it was assuring the public that such authorization would take place through the rulemaking process.³¹

³⁰ *Ranchers Cattlemen Legal Action Fund United Stockgrowers of America v. U.S. Department of Agriculture, Animal and Plant Health Inspection Service*, CV-04-51-BLD-RFC, Apr. 26, 2004.

³¹ *Ibid.*

May 4, 2004

The temporary restraining order was converted to a preliminary injunction to expire five days after R-CALF is notified of final agency action on the November 2003 USDA rulemaking. While the injunction was in effect, the only Canadian bovine meats that could be imported for human consumption were those identified in the August 8 announcement (as modified by the August 15 list): fresh or frozen bovine liver, all veal (including carcasses) from calves 36 weeks of age or less, and fresh or frozen boneless meat from animals under 30 months of age, which could include trim/manufacturing trim derived from skeletal muscle with associated tissues, but could not include any ground meat, trim derived from mechanical separation processes, including advanced meat recovery systems, or from vertebral columns.

The injunction also restored several explicit risk mitigation factors — specifically, “CFIA verification that the animals were under 30 months of age when slaughtered and are not known to have been fed prohibited products during their lifetime; brain and spinal cord are removed; slaughter plant only kills animals less than 30 months of age.”³² The injunction also required USDA to provide a status report on the rulemaking process every 45 days until a final agency rule appears in the *Federal Register*.

May 6, 2004

APHIS republished its August 15, 2003, list of low risk Canadian products. This list was accompanied by another memorandum to importers, brokers and other interested parties.³³

May 20, 2004

Conflicting information had been circulating throughout May 2004 as to exactly what types and quantities of Canadian beef products had been improperly allowed to enter since USDA began to ease import restrictions. The lawsuit plaintiff, R-CALF USA, said that it had compiled U.S. Census and USDA data indicating 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. These data were widely quoted by the news media, including a story in the May 20 *Washington Post*.

May 21, 2004

At a press briefing on BSE, USDA officials sought to clarify their import data and to reassure consumers that no unsafe products had been permitted entry. They explained that out of a total of more than 500 million pounds of Canadian beef and veal products which had entered the United States between September 1, 2003, and

³² *R-CALF USA vs. USDA* (CV-04-BLG-RFC), Stipulation Exhibit 1, May 4, 2004.

³³ As of early March 2005, the list could be accessed through the APHIS BSE website at [http://www.aphis.usda.gov/lpa/issues/bse/bse_hunter_CANADA.html].

April 30, 2004, only 7.3 million pounds incorrectly came in under categories beyond those announced in August 2003. The officials stressed that although they may have erred administratively, there was never a public health risk. They said all of the beef — even product that may have entered improperly — was safe, because it was from cattle under 30 months old. USDA spokesmen also told reporters that neither the Secretary nor the Under Secretary for Marketing and Regulatory Programs had been aware that APHIS had expanded the list of eligible products after August 8, 2003.³⁴

July 1, 2004

USDA's Inspector General (IG) sent a letter, in response to a request by three Senators, that her office was initiating a review of USDA's actions on Canadian beef imports and would be interviewing USDA officials and examining relevant records. As of late 2004, OIG had not published the results of such a review.

August 12, 2004

A group of Alberta cattle feeders called Canadian Cattlemen for Fair Trade filed notice of five claims under Chapter 11 of the North American Free Trade Agreement (NAFTA) to recover \$113 million (U.S. dollars) in investment losses because the United States has kept the border closed “in an arbitrary and discriminatory manner.”

August 19, 2004

APHIS issued a “clarification” of its August 15, 2003, list, stating: “Meat from the diaphragm (i.e., from the beef plate, e.g., beef skirt steak, hanging tender) is considered boneless beef” and therefore may be imported when accompanied by a valid permit for boneless beef.

December 30, 2004

The American Meat Institute (AMI), representing major meat packers, filed a lawsuit charging that there is no legal or scientific justification for continuing to ban Canadian cattle 30 months of age and older. The lawsuit came after USDA said it was publishing a final rule to permit imports of younger Canadian cattle (see January 4, 2005, below). AMI stated that it is not challenging the rule itself, but is seeking an injunction against enforcement of the original May 2003 ban.³⁵

³⁴ See Appendix B of this CRS report for a more detailed breakout of these Canadian bovine imports. The breakout is based on a June 15, 2004, entry on the APHIS website at [http://www.fsis.usda.gov/pdf/canada_import_update_061404.pdf]. Other sources for this section include the following: transcript of May 21, 2004, Technical Briefing with Bill Hawks, Under Secretary for Marketing and Regulatory Services, Elsa Murano, Under Secretary for Food Safety, APHIS Administrator Ron DeHaven, and FSIS Acting Administrator Barbara Masters; background information posted on the APHIS website on June 15, 2004, at [<http://www.aphis.usda.gov/lpa/issues/bse/bse.html>]; and various news reports.

³⁵ *American Meat Institute v. Ron DeHaven*, No. 04CV2262 (D.D.C. filed Dec. 30, 2004).

Chronology of U.S. Actions (2005)

January 2, 2005

CFIA reported that BSE had been confirmed in an Alberta dairy cow born in October 1996. Canadian officials said that preliminary testing had first detected the presence of the disease in December. No part of the animal entered the human food or animal feed supply, CFIA stated. Later, the agency said that it had not found any other related animals (i.e., recent offspring and animals born at the same place within a year of the infected cow) to have BSE, although a few were not traced due to missing records. Six had been sent to the United States for slaughter. CFIA added that the cow was fed a dairy ration containing some ruminant material just prior to the 1997 “feed ban” on use of such material, which likely was the cause of infection.

January 4, 2005

APHIS published the final version of its November 4, 2003, proposed rule.³⁶ The final rule (1) establishes a new 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) accepts Canada as the first such region. The rule was set to take effect on March 7, 2005. Because it is a “major” rule under the Congressional Review Act (5 U.S.C. 801-808), it cannot take effect for 60 days from publication in the *Federal Register* or presentation to Congress (whichever is later). This delay also 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.³⁷

The new rule explicitly permits imports of, among other things, live Canadian cattle and other bovines for feeding and for immediate slaughter. All cattle must be under 30 months of age, and feeder cattle must be slaughtered before 30 months of age. Most additional types of Canadian beef also are permitted, including product from animals slaughtered after 30 months of age (the provision of the rule allowing beef from animals over 30 months later was delayed by the Secretary of Agriculture).

In announcing the final rule, USDA stated that its approach is consistent with OIE guidelines “and relies on appropriate, science-based risk mitigation measures.”³⁸ In a separate statement on January 3, USDA said that despite the new BSE finding in Canada, it remains confident that Canada’s BSE protections, along with U.S. safeguards, are providing “the utmost protections to U.S. consumers and livestock.”

³⁶ USDA, APHIS, “Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities,” 70 *Federal Register* 460, Jan. 4, 2005.

³⁷ For more on the congressional review process, see CRS Report RL30116, *Congressional Review of Agency Rulemaking: An Assessment After Nullification of OSHA’s Ergonomics Standard*, by Morton Rosenberg.

³⁸ “USDA Releases Rule to Establish Minimal-Risk Regions for Bovine Spongiform Encephalopathy,” December 29, 2004. For additional information see the APHIS BSE website, [<http://www.aphis.usda.gov/lpa/issues/bse/bse.html>].

and that “[t]he extensive risk assessment conducted as part of USDA’s rulemaking process took into careful consideration the possibility that Canada could experience additional cases of BSE.”³⁹ USDA also said that under OIE guidelines, Canada could have up to 11 cases of BSE in its population of 5.5 million cattle over 24 months of age and still be considered a “minimal risk” country.⁴⁰

January 10, 2005

R-CALF USA filed 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.⁴¹

January 11, 2005

CFIA reported that BSE had 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 said they had launched investigations to ascertain the whereabouts of any other at-risk animals and to determine what the animal had consumed. They speculated 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. They also announced a comprehensive assessment of the effectiveness of their ban, with results expected by late February. USDA and cattle industry officials also went to Canada to assess the situation. USDA officials continued to assert that the January 4 final rule remained on track to take effect March 7, 2005.

February 1, 2005

R-CALF filed a motion requesting a preliminary injunction in its lawsuit against USDA concerning the January 4 final rule. If granted, the injunction would prevent USDA from implementing the rule until after the court has fully considered the facts in the lawsuit.

February 3, 2005

The Senate Agriculture Committee held an oversight hearing on the Canada BSE situation, where Secretary of Agriculture Johanns testified that the Department intended to implement the rule on March 7 as scheduled.⁴²

³⁹ Statement by Ron DeHaven, APHIS Administrator, January 3, 2005.

⁴⁰ *Ibid.*

⁴¹ *Ranchers Cattlemen Legal Action Fund United Stockgrowers of America v. U.S. Department of Agriculture*, CV-05-06-BLG-RFC (D. Mont. filed Jan. 10, 2005).

⁴² The Senate Committee’s website is at [<http://agriculture.senate.gov/>].

February 14, 2005

USDA's Office of Inspector General (OIG) released the results of its audit report *Oversight of the Importation of Beef Products from Canada*. OIG found 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. The report's executive summary noted that the gradual expansion of permissible Canadian imports:

...occurred because the agency employees tasked with administering the permit process did not consider the initial announcement made by the Secretary to exclude products similar to those on the published list of low-risk products, if APHIS had concluded that the products posed similar risk levels. However, APHIS did not develop documentation to support the agency's conclusions that the additional products were low-risk products. APHIS also did not have a review structure or other monitoring process in place to identify discrepancies between publicly stated policy and agency practice. According to APHIS officials, they considered the initial announcement made by the Secretary to be part of an effort to demonstrate to the world that such trade with Canada was safe and appropriate. Accordingly, they allowed the import of products they considered low risk in an attempt to further that greater effort. However, APHIS did not document the process it used to determine the additional products were low risk.

As a result of the "permit creep" that occurred between August 2003 and April 2004, APHIS issued permits for the import of beef tongue as well as other permits for products with questionable eligibility. Further, the agency allowed the import of products from Canadian facilities that produced both eligible and ineligible products, thus increasing the possibility that higher-risk product could be inadvertently exported to the United States. This practice contrasted with APHIS' publicly stated policy that only Canadian facilities that limited production to eligible products would be allowed to ship to the United States. In addition, APHIS did not communicate its decisions to all interested parties and USDA was criticized by segments of the public, the cattle industry, and the U.S. Congress.⁴³

Among other criticisms, OIG said that APHIS issued 1,155 import permits without ensuring that the agency had an appropriate system of internal controls to manage the process, which was originally developed for handling permit requests for small amounts of product. The process was not adequate to deal with the high volume of requests for large quantities of commercial beef, OIG observed. It added that because of inadequate monitoring of import requirements, "there was reduced assurance that Canadian beef entering the United States was low-risk. Some product with questionable eligibility, as described above, entered U.S. commerce." USDA

⁴³ USDA, OIG. *Animal and Plant Health Inspection Service Oversight of the Importation of Beef Products from Canada*, (pages iii-iv), at [<http://www.usda.gov/oig/webdocs/33601-01-HY.pdf>].

agreed with several OIG recommendations for improving its procedures, and generally promised to implement them.⁴⁴

February 25, 2005

USDA released its assessment of the effectiveness of the Canadian ban on feeding most ruminant materials back to ruminants. USDA reported that “Canada has a robust inspection program, that overall compliance with the feed ban is good and that the feed ban is reducing the risk of transmission of bovine spongiform encephalopathy in the Canadian cattle population.” The Department stated that it “is confident that the animal and public health measures that Canada has in place to prevent BSE, combined with existing U.S. domestic safeguards and additional safeguards provided in the final rule, provide the utmost protections to U.S. consumers and livestock.”⁴⁵

March 1, 2005

The House Agriculture Committee held a hearing on the Canada beef import rule, taking testimony from Secretary Johanns, two cattle producer groups, and two meat packers.⁴⁶

March 2, 2005

A federal judge in Montana (the same judge who took action in April 2004) issued a preliminary injunction to halt implementation of the January 4 final rule and ordered 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. The judge stated in part that R-CALF had “demonstrated the numerous procedural and substantive shortcomings of the USDA’s decision to allow importation of Canadian cattle and beef. The serious irreparable harm that will occur when Canadian cattle and meat enter the U.S. and co-mingle with the U.S. meat supply justifies issuance of a preliminary injunction ... pending a review on the merits.”⁴⁷

Secretary Johanns expressed disappointment with the ruling and said “USDA remains confident that the requirements of the minimal-risk rule, in combination with the animal and public health measures already in place in the United States and Canada, provide the utmost protection to both U.S. consumers and livestock. We also remain fully confident in the underlying risk assessment, developed in

⁴⁴ Ibid.

⁴⁵ “USDA Releases Technical Assessment on the Implementation of the Canadian Feed Ban,” February 25, 2005, press release. The USDA findings generally echo those of a separate CFIA assessment. See CFIA, “Feed Ban Review Executive Summary,” March 2, 2005, at [<http://www.inspection.gc.ca/english/anima/feebet/rumin/revexa/revintroe.shtml>].

⁴⁶ The House Committee’s website is at [<http://www.house.gov/agriculture/>].

⁴⁷ *Ranchers Cattlemen Action Legal Fund USA vs. USDA* (CV-05-06-BLG-RFC).

accordance with the OIE guidelines, which determined Canada to be a minimal risk region.”⁴⁸

March 3, 2005

The full Senate voted, 52-46, to approve a resolution (S.J.Res. 4) providing for the disapproval of the January 4 USDA rule. Senate procedural rules allow such a resolution to reach the floor without clearing committee if at least 30 Senators request it. However, House passage and the President’s signature are required for the resolution to take effect. The House Agriculture Committee must agree to report the companion House measure (H.J.Res. 23), which is not considered likely. Also, the President has stated his opposition to the resolution.

March 4, 2005

APHIS posted a notice on the internet to importers, brokers, and other interested parties, about the March 2 preliminary injunction, adding: “Therefore, until further notice, the current import requirements for ruminant and ruminant commodities from Canada will remain unchanged. Only those commodities that were listed in the August 15, 2003 notice (republished May 6, 2004) will be eligible for importation from Canada, under the risk-mitigation measures specified in that notice.”

March 7, 2005

The federal judge in the AMI lawsuit denied the meat packer group’s request for a preliminary injunction to, in effect, allow imports of cattle over 30 months (see December 30, 2004 entry).

March 11, 2005

APHIS published a final rule to delay until further notice the applicability of its January 4 rule on minimal risk regions.

Federal Rulemaking Procedures

Among other observations in his April 26, 2004, temporary restraining order, the judge stated: “It is especially important, for an issue as important to human and animal health and to the agricultural economy as BSE, that USDA make and explain its decisions publicly, rather than confuse the public about what bovine product imports are being allowed.” Later in the order, he observed:

USDA counsel offered that the justification for USDA’s April 19, 2004 action was the same as for the August 8, 2003 decision, but there is very little in the August 8th decision to explain what the risk of importing boneless cuts of beef is or why that risk is acceptable. Where increased risk to human health is at issue, it is particularly critical that USDA be required to provide not only its conclusion

⁴⁸ Johans, Mike, Secretary of Agriculture, March 2, 2005, press release.

that its action carries an acceptable risk to public health, but also the specific basis for that conclusion and the data on which each of the agency's critical assumptions is based.⁴⁹

The federal rulemaking process is designed by law to enable the public to comment in advance on potential regulatory changes, but this process also allows agencies the flexibility to act quickly in times of emergency. More specifically, the Administrative Procedure Act (APA) generally requires that agencies, including USDA and its agencies, publish a notice of proposed rulemaking (NPRM) in the *Federal Register*. The notice must contain (1) a statement of the time, place, and nature of public rulemaking proceedings; (2) reference to the legal authority under which the rule is proposed; and (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

After giving "interested persons" an opportunity to comment on the proposed rule, and after considering the public comments, the agency may then publish the final rule, incorporating a general statement of its basis and purpose. Although the APA does not specify the length of this public comment period, agencies commonly allow at least 30 days. Public comments as well as other supporting materials (e.g., hearing records or agency regulatory studies but generally not internal memoranda) are placed in a rulemaking "docket" which must be available for public inspection. Finally, the APA states that the final rule cannot become effective until at least 30 days after its publication unless (1) the rule grants or recognizes an exemption or relieves a restriction, (2) the rule is an interpretative rule or a statement of policy, or (3) the agency determines that the rule should take effect sooner for good cause, and publishes that determination with the rule. The final rule cannot adopt a provision if the NPRM did not clearly provide notice to the public that the agency was considering adopting it. If challenged in court under the APA, an agency rulemaking can be held unlawful or set aside if it is found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law."

Although the APA generally requires agencies to publish NPRMs before promulgating a final rule, the act provides exceptions to this requirement. For example, the APA states that the notice and comment procedures generally do not apply when an agency finds, for "good cause," that those procedures are "impracticable, unnecessary, or contrary to the public interest." When agencies use the good cause exception, the act requires that they explicitly say so and provide a rationale for the exception's use when the rule is published in the *Federal Register*. An agency can use what is known as "interim final" rulemaking, in which an agency issues a final rule without an NPRM that is generally effective immediately, but with a post-promulgation opportunity for the public to comment. If the public comments persuade the agency that changes are needed in the interim final rule, the agency may revise the rule by publishing a final rule reflecting those changes. Interim final rulemaking can be viewed as another particular application of the good cause

⁴⁹ *R-CALF USA vs. USDA*, CV-04-51-BLD-RFC, Apr. 26, 2004.

exception in the APA, but with the addition of a comment period after the rule has become effective.⁵⁰

For example, USDA's May 2003 action (banning all Canadian imports) was issued as an interim final rule, which took effect immediately but was subject to further refinement because it allowed an opportunity for subsequent public comment. USDA's November 2003 action (proposing to loosen the restrictions and allow importation of certain products and live ruminants from Canada) was published as a proposed rule which allowed for public comment and full consideration before a final decision was made and implemented.

In contrast, the changes in policy that APHIS posted on its website August 15, 2003, October 22, 2003, and April 19, 2004, were not issued as formal rules. The federal district court viewed the April 19 change in particular as a final agency action that should have been made through the rulemaking process. USDA later agreed that it had made procedural errors, and said it had put in place protocols regarding how any similar actions would be made and communicated to the public in the future.

The R-CALF lawsuit did not ask for a ruling on USDA's initial announcements in August 2003 which had first opened the U.S. border to Canadian imports. In fact, the legal stipulation agreed to by both parties uses the August 15, 2003, list as a benchmark for what bovine products can be imported from Canada. Nonetheless, the judge in the case, and some legal observers, have indicated that even these August actions also could have been vulnerable to legal challenge because they were not taken through the rulemaking process.

In agreeing to rescind their April 19 action, USDA officials acknowledged that they had skirted rulemaking requirements by changing import requirements without public input. USDA spokesmen also said that neither the Secretary of Agriculture nor the Under Secretary for Marketing and Regulatory Programs were aware that APHIS had been issuing import permits for Canadian beef products other than those the Secretary had announced on August 8, 2003. Adhering to statutorily-prescribed rulemaking procedures also has a practical advantage — helping to ensure that policy-level officials are aware of, approve, and are held accountable for policy changes, particularly those with far-reaching effects and/or those that are likely to be controversial.

⁵⁰ For additional details, see CRS Report RL32240, *The Federal Rulemaking Process: An Overview*, by Curtis W. Copeland, from which the preceding discussion is excerpted.

Appendix A. Selected “Low Risk Canadian Products”

Permitted Bovine Meat Products* as of:	Required Risk Mitigations
August 8, 2003: Bovine Meat, Boneless Fresh or Frozen from animals under 30 months of age — (no manufacturing trim derived from bone, advanced meat recovery, mechanically separated meat, ground meat, or low-temperature rendered product)	CFIA verification that the animals were under 30 months of age when slaughtered and are not known to have been fed prohibited products during their lifetime; brain and spinal cord are removed; slaughter plant only kills animals less than 30 months of age
August 15, 2003: Bovine Meat, Boneless Fresh or Frozen from animals under 30 months of age — (no manufacturing trim derived from bone , advanced meat recovery, mechanically separated meat, ground meat, or low-temperature rendered product) <i>[includes trim/manufacturing trim derived from skeletal muscle with associated tissues, not including any ground meat, trim derived from a mechanical separation process (including AMR), or derived from vertebral column]</i>	CFIA verification that the animals were under 30 months of age when slaughtered and are not known to have been fed prohibited products during their lifetime; brain and spinal cord are removed; slaughter plant only kills animals less than 30 months of age
October 22, 2003: Bovine Meat, Boneless Fresh or Frozen from animals under 30 months of age — (no advanced meat recovery, mechanically separated meat, ground meat, or low-temperature rendered product) [includes trim/manufacturing trim derived from skeletal muscle with associated tissues, not including any ground meat, trim derived from a mechanical separation process (including AMR), or derived from vertebral column]	CFIA verification that the animals were under 30 months of age when slaughtered and are not known to have been fed prohibited products during their lifetime ; <i>that the animals were subject to a ban on the feeding of prohibited materials during their life span; brain and spinal cord are removed</i> ; slaughter plant only kills animals less than 30 months of age <i>or an approved segregation procedure is in place</i>
April 19, 2004: Bovine meat <i>and meat products including: boneless, bone-in, ground meat, and further processed bovine meat products</i> fresh or frozen from animals under 30 months of age — (no advanced meat recovery, mechanically separated meat, ground meat, or low-temperature rendered product) [includes trim/manufacturing trim derived from skeletal muscle with associated tissues, not including any ground meat, trim derived from a mechanical separation process (including AMR), or derived from vertebral column]	CFIA verification that the animals were under 30 months of age when slaughtered; that the animals were subject to a ban on the feeding of prohibited materials during their life span; slaughter plant only kills animals less than 30 months of age or an approved segregation procedure is in place <i>Personal use amounts under 50 lbs. are exempt from requiring an import permit. Shipments need to be accompanied with CFIA Annex (E)1 stating USDA and CFIA agreed upon certification statements and VS Import Permit Form 16-6. For edible use. Not for use in animal feed or pet food.</i>
May 6, 2004: Identical to August 15, 2003	Identical to August 15, 2003

*Bovine meats only, excerpted from complete lists posted on these dates by APHIS. Veal, bovine liver, hearts, kidney, tripe, lips, as well as various sheep, goat, cervid, and other ruminant products also are in some or all lists. Strikeouts show language removed from prior list; italics show language added since last list.

Appendix B. Canadian Beef Imports

September 1, 2003 - April 30, 2004

Products Permitted Aug. 8, 2003 as Clarified Aug. 15, 2003:	Pounds
Veal carcasses (all veal from calves 36 weeks & under)	8,624,012
Veal cuts, bone-in and boneless	6,130,747
Boneless veal for manufacturing	704,374
Veal tongues	993,814
Veal bones	1,073,893
Beef cuts, boneless (from animals under 30 months)	241,468,001
Beef boneless trim (for manufacturing, animals under 30 months)	238,445,951
Liver (beef and veal)	4,867,215
Beef cheek meat	21,110
Beef cuts, bone-in (from animals originating from non-BSE region)	3,164
Tripe (from animals originating from non-BSE region)	3,386,973
Total Beef & Veal (From Above)	505,719,254
Further Processed Products (beef sourced from product eligible for entry under Aug. 8 & 15 notices as noted above):	
Ground beef	486
Canned beef, shelf-stable	388,543
Not heat treated, shelf stable beef (includes dry fermented sausages such as pepperoni)	1,513
Heat treat, shelf stable beef (includes Jerky)	41,490
Fully cooked, not shelf stable beef (includes hot dogs, deli meats, cooked sausages, etc.	2,630,751
Total Further Processed Products	5,611,580*
Miscellaneous Products:	
Beef cuts, bone-in (after April 19)	139,298
Beef organs/offals (tongue, heart, kidney)	1,504,656
Total Miscellaneous Products	1,643,954
GRAND TOTAL, ALL BEEF/VEAL IMPORTS	512,974,788

Source: FSIS. *2,232,459 lbs. imported on permits allowing for importation of product that either originated in U.S. or other BSE free country *or* that originated in Canada, *provided* that the product was processed strictly from animals under 30 months of age, and in accordance with a number of processing requirements designed to further mitigate any risk (based on APHIS permit requirements and CFIA certification).