Charles E. Hansberry
HOLLAND & HART LLP
401 North 31st Street, Suite 1500
P. O. Box 639
Billings, Montana 59103-0639
Telephone: (406) 252-2166
Facsimile: (406) 252-1669
Email: chansberry@hollandhart.com

Maureen E. Mahoney
Cassandra Sturkie
LATHAM & WATKINS LLP
555 Eleventh Street, N.W.
Suite 1000
Washington, DC 20004-1304
Telephone: (202) 637-2200
Facsimile: (202) 637-2201
Email: maureen.mahoney@lw.com
Email: cassandra.sturkie@lw.com

Counsel for the
Government of Canada

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
BILLINGS DIVISION

RANCHERS CATTLEMEN ACTION LEGAL FUND UNITED STOCKGROWERS OF AMERICA, Plaintiff, vs. UNITED STATES DEPARTMENT OF AGRICULTURE, ANIMAL AND PLANT HEALTH INSPECTION SERVICE, *et al.*, Defendants, and NATIONAL MEAT ASSOCIATION, Proposed Intervenor-Defendant and Cross-Plaintiff.	Cause No. CV-05-06-BLG-RFC **BRIEF *AMICUS CURIAE* OF THE GOVERNMENT OF CANADA**

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INTRODUCTION

The Government of Canada ("Canada" or the "Canadian Government") submits this brief to provide information and correct substantial misrepresentations about the effectiveness of Canada's measures to minimize human exposure to Bovine Spongiform Encephalopathy ("BSE") and limit the spread of BSE among cattle in North America.

The Final Rule at issue reflects the Federal Defendants' expert judgment that Canada poses only a minimal risk of transmitting BSE into the United States through the importation of certain live cattle and beef products.[1] In attempting to prevent the Final Rule from taking effect, Plaintiff Ranchers Cattlemen Action Legal Fund United Stockgrowers of America ("R-CALF") ignores the extensive record of facts demonstrating that Canada has contained the incidence of BSE in its country to extremely low levels. Instead, R-CALF argues that the detection of a total of four cases of BSE in Canadian-born cows (three in Canada and a fourth in the United States) makes it a "virtual certainty" that "Canadian cattle infected with BSE" will be imported into the United States. Memorandum of Points and Authorities in Support of Plaintiff's Application for Preliminary Injunction (Jan. 31, 2005) (hereafter "R-CALF Br."), at 13. This argument is a speculative leap that has no support in the established body of scientific evidence that the United States Department of Agriculture ("USDA") relied upon in

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[1] The Final Rule is entitled "Bovine Spongiform Encephalopathy: Minimal-Risk Regions and Importation of Commodities," 70 Fed. Reg. 460 (Jan. 4, 2005). The Final Rule places Canada in a "minimal risk" category and, on that basis, lifts prohibitions on the importation of certain ruminants and ruminant products and byproducts from Canada that were imposed after Canada detected its first case of BSE in 2003. *See id*. at 460-61. Only the imports of live cattle under 30 months of age and beef products from cattle of any age are at issue in this brief. Further, the beef products that are currently imported from Canada into the United States are not at issue in this brief, nor are the provisions of the Final Rule relating to other ruminants, such as sheep and goats.

promulgating the Final Rule. *See* 70 Fed. Reg. at 511 (stating that, based on such "qualitative and quantitative evidence," USDA concluded that the risk associated with imports of specified cattle and beef products from Canada is "very low").

To the contrary, the detection of four cases of BSE, all in older Canadian-born cattle, demonstrate that Canada has succeeded in limiting the spread of BSE by instituting comprehensive risk mitigation measures. Furthermore, the confirmation of two of the four cases in January 2005 is *not*, as R-CALF contends, "inconsistent" with USDA's determination that "the BSE incidence rate in Canada is 'minimal' or 'very low.'"[2] R-CALF Br. at 13. The Final Rule expressly recognizes that Canada may detect a small number of additional cases of BSE, yet still not pose a threat of spreading BSE into the United States due to the proven effectiveness of Canada's ruminant-to-ruminant feed ban, food safety controls, and other mitigation measures. *See*, *e.g.*, 70 Fed. Reg. at 515; *see also* "BSE in Canada Status Update – February 2005," Report of the Government of Canada (hereafter "Canada Report") (attached as Exhibit A hereto), at 31-33. The January 2005 cases thus do not undercut the Final Rule or cast doubt on USDA's determination that the Canadian cattle and beef imports at issue present an acceptable "minimal risk" of transmitting BSE into the United States.

Canada rigorously enforces its BSE mitigation measures – which are virtually identical to the controls used by the United States – in order to protect its citizens from exposure to the BSE agent. Those same controls protect United States citizens who consume Canadian meat and beef products. As explained below, there is no basis to credit R-CALF's claims that

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[2] Canada confirmed the detection of two cases of BSE on January 2 and 11, 2005, respectively. *See* Canada Report, Exh. A, at 15.

public health would be threatened by USDA's decision to allow imports of the Canadian products at issue:

- ***Not a single case*** of variant Creutzfeldt-Jakob Disease ("vCJD") has been linked to the consumption of Canadian beef.[3] *See* Canada Report, Exh. A, at 6.

- The potential for human exposure to BSE through Canadian beef has been effectively eliminated. Canada, like the United States, eliminates virtually 100% of the potential BSE infectivity from all cattle slaughtered for human consumption by requiring the removal of their potentially infected tissues ("specified risk materials" or "SRM").[4] *See id*. at 8-9, 16.

- Canada's BSE surveillance program, which exceeds guidelines established by the World Organization for Animal Health (or "OIE"), has detected only three cases of BSE out of 35,000 high risk animals sampled since 2003 from Canada's adult cattle population, which numbered 6.7 million animals in 2004. *See id*. at 27-31.

- Canada's incidence rate of BSE in 2004 was ***0.15 cases*** per million adult cattle (this rate reflects the case detected on December 29, 2004, and confirmed on January 2, 2005). Even if the January 11, 2005 case were included in the 2004 test results, the resulting incidence rate for 2004, correlating to these two cases, would be ***0.3 cases*** per million adult cattle. These incidence rates are well ***below*** the guideline established by the World Organization for Animal Health (or "OIE") for a minimal-risk region, which is less than two cases per million adult cattle. *See id*. at 30.

- To put these incidence rates into context, at the height of Switzerland's BSE epidemic in 1995, the Swiss incidence rate was 73 cases per million adult

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[3] Variant Creutzfeldt-Jakob Disease or "vCJD" is a "chronic and fatal" disease in humans that "has been linked via scientific and epidemiological evidence to exposure to the BSE agent, most likely through consumption of cattle products contaminated with the BSE agent." 70 Fed. Reg. at 462 (stating that vCJD was first diagnosed in the United Kingdom in 1996, and that the "majority of . . . cases have either been identified in the United Kingdom or were linked to exposure that occurred in the United Kingdom").

[4] The BSE agent has a limited distribution in cattle where it is confined to certain tissues collectively referred to as SRM. These tissues consist of the brain, eyes (retina), spinal cord, clusters of nerve cells closely attached to the head and vertebral column (the trigeminal and dorsal root ganglia respectively), tonsils, and a part of the small intestine known as the distal ileum. *See* Canada Report, Exh. A, at 7 n.8.

cattle. That rate is more than 485 times higher than the Canadian incident rate in 2004 (and more than 240 times higher than the 2004 incident rate if the January 11, 2005 case is attributed to 2004), and yet the Swiss have not had a single case of vCJD in humans. *See* Canada Report, Exh. A, at 6-7.

- Canada, like the United States, implemented its feed ban in August 1997 as a preemptive measure, years before the first case of BSE was detected in Canada in May 2003. The feed ban, which is equivalent to the feed ban imposed in the United States, has dramatically reduced the spread of BSE among Canadian cattle. *See id*. at 34-35.

- The Canadian Food Inspection Agency ("CFIA") has determined that the single case of BSE linked to an animal born after the feed ban was implemented (*i.e.*, the case confirmed on January 11, 2005) may have been exposed to contaminated feed materials that had been manufactured during the transition period after the feed ban was implemented. *See id*. at 40.

In sum, USDA's considered determination that Canada qualifies as a minimal-risk region based on "the sum total of [Canada's] prevention and control mechanisms" for BSE (70 Fed. Reg. at 510) should carry far more weight than R-CALF's argument. The Government of Canada therefore respectfully urges this Court to deny R-CALF's application for a preliminary injunction.

ARGUMENT

I. CANADA'S BSE RISK MITIGATION MEASURES PROTECT HUMAN HEALTH AND QUALIFY CANADA AS A MINIMAL-RISK REGION

R-CALF's principal attack on the Final Rule is that "USDA lacks a scientific basis for subjecting U.S. consumers to the risk of contracting variant Creutzfeldt-Jakob Disease . . . from Canadian bovine meat and meat products." R-CALF Br. at 6. R-CALF further suggests that, because four cases of BSE have been detected in Canadian-born cows, human consumption of beef from Canada "carries with it an elevated risk of vCJD" that warrants enjoining the Final Rule. *Id*. at 35; *see also id*. at 10. R-CALF's alarmist statements about the alleged threats to public health posed by the Final Rule are at odds with the extensive scientific

evidence supporting USDA's decision to list Canada as a minimal-risk region. *See, e.g.*, 70 Fed. Reg. at 470, 511.

Moreover, they fundamentally mischaracterize the effectiveness of the mitigation measures utilized by Canada and the United States to minimize human exposure to BSE and limit the spread of BSE in North America. As explained below, in finding that Canada meets the minimal-risk criteria established in the Final Rule, USDA rightly concluded that Canada's continuum of mitigation measures is effective and, accordingly, that the risk of United States consumers contracting vCJD from Canadian beef contaminated with BSE is extremely low. *See, e.g.*, 70 Fed. Reg. at 470 (enumerating "all of the actions Canada has taken to prevent the introduction and control the spread of BSE").

A. The Risk Of Humans Contracting vCJD From Canadian Beef Has Been Effectively Eliminated

R-CALF fails to acknowledge that, of the approximately 150 cases of vCJD that have been reported worldwide, ***not a single case of vCJD has been linked to the consumption of Canadian beef***. *See* Canada Report, Exh. A, at 6 (explaining that the only two North American cases of vCJD involved a man in Canada and a woman in the United States who are believed to have been infected during their prolonged stays in the United Kingdom at the peak of the BSE epidemic). Because the risk of the BSE agent contaminating Canadian beef is very low, if not non-existent, the risk of consumers contracting vCJD from eating Canadian cattle products contaminated with the BSE agent is likewise extremely improbable. *See* Canada Report, Exh. A, at 6-7; *see also, e.g.*, 70 Fed. Reg. at 510-11.

To put into context the low risk of contracting vCJD from Canadian beef, the annual incidence (or "prevalence") rate of BSE in the United Kingdom during the height of its epidemic was 7,500 cases per million adult cattle (based on 37,380 confirmed cases in 1992

alone). *See* Canada Report, Exh. A, at 6. That level of exposure produced 140 reported cases of vCJD. *See id*. At the height of Switzerland's BSE epidemic in 1995, the annual incidence rate of BSE was 73 cases per million adult cattle, a fraction of the United Kingdom rate. *See id*. at 6-7. By comparison, Canada's incidence rate of BSE in 2004 was only ***0.15 cases*** per million adult cattle (one detected case) and, as described *infra* at § II(C)(2)), is only ***0.3 cases*** per million adult cattle if the case confirmed on January 11, 2005, is included in the 2004 incidence rate. *See id*. at 7, 30. The Swiss incidence rate in 1995 is thus more than 485 times higher than the Canadian incidence rate in 2004 (and more than 240 times higher if the January 11, 2005 case is attributed to 2004), and yet the Swiss have not identified a single case of vCJD in humans. *See id*. at 6-7.

Because of the low incidence of BSE in Canadian cattle, together with the fact that Canada eliminates virtually 100% of the potential BSE infectivity from all cattle slaughtered for human consumption by requiring the removal of their SRM, the potential for human exposure to vCJD through Canadian beef contaminated with BSE has been effectively eliminated. *See* Canada Report, Exh. A, at 8-10; *see also* 70 Fed. Reg. at 462 (stating that "the number of cases of vCJD identified to date suggest a substantial species barrier that may protect humans from widespread illness due to BSE").

B. Canada Relies On Extensive, Overlapping Risk Mitigation Measures To Protect The Public From Exposure To BSE

In adding Canada to the minimal-risk category in the Final Rule, USDA recognized that United States citizens who consume Canadian beef will be protected from exposure to BSE by the risk mitigation measures that Canada has successfully used to protect its own citizens. *See, e.g.*, 70 Fed. Reg. at 463-64 (explaining that, although Canada has detected BSE-infected animals, the effectiveness of its risk mitigation measures makes it unlikely that

BSE would be transmitted from Canada into the United States). USDA distinguished the BSE epidemic in Europe in the 1990's, which "clearly" was "an example of widespread exposure and establishment" of BSE, *id*. at 473, to the discovery of a limited number of BSE cases in Canada – a country that USDA observed had "[c]ontrol measures . . . in place before the detection of the disease," *id.*, and that "has taken ***every necessary step*** to prevent an epidemic," *id*. at 514 (emphasis added). Indeed, Canada's science-based mitigation measures, like the equivalent United States controls, constitute a series of overlapping safeguards that systematically limit the risks associated with BSE. *See id.* at 514 (explaining that Canada's "comprehensive mitigations" exert a "downward pressure" on the number of new cases of BSE in North America). In recognition of the growing BSE threat, Canada initiated mitigation measures in 1990. Since that time, Canada has continued to expand and supplement the measures. They include the following:

1. Import restrictions established in 1990, 13 years before the first indigenous case of BSE was detected in Canada in May 2003. In 1990, Canada imposed a ban on all imports of cattle from the United Kingdom and Ireland, where the incidence rate of BSE was skyrocketing in the absence of scientific understanding about how the disease was spread. While a low level of BSE had already infiltrated North America by 1990, Canada's import restrictions effectively halted and continue to prevent the entry of BSE from foreign sources into Canada.[5] *See* Canadian Food Inspection Agency ("CFIA") Factsheet, "Overview of Canada's

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[5] In 1978, long before it implemented the import restrictions in 1990, Canada stopped the importation of ruminant meat-and-bone meal (the primary source of BSE infectivity) for livestock feed from the United Kingdom and other countries that were subsequently affected by BSE. *See Canada Report*, Exh. A, at 13.

BSE Safeguards" (hereafter "CFIA Factsheet"), *available at* http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/bseesbfs2e.shtml (last viewed Feb. 21, 2005) (attached hereto as Exhibit B), at 2; *see* also 70 Fed. Reg. at 464 (observing that, because Canada implemented import restrictions and other control measures before it detected BSE in any indigenous animals, it is more likely that the incidence rate of BSE in Canada is on the "down slope" of the epidemic curve).

2. A ruminant-to-ruminant feed ban, implemented as a preemptive safeguard in August 1997, to limit the recycling and prevent amplification of BSE among animals. Of the small number of potentially BSE-infected animals that were imported into Canada before 1990,[6] some may have been rendered and processed into animal feed, which in turn could have led to the development of additional cases of BSE in Canada. *See* Canada Report, Exh. A, at 14; *see also id*. at 20-22 (discussing the origin of BSE in Canada). Acting on the recommendation of the World Health Organization to control such "recycling" of BSE, Canada introduced a feed ban on the same date as the United States in August 1997. *See id*. at 34; *see also* 70 Fed. Reg. at 467 (explaining that the Canadian feed ban is equivalent to the feed ban in place in the United States, with the addition that it prohibits the feeding of plate waste and poultry litter to ruminants). Unlike the United Kingdom and other countries affected with BSE, Canada (as well as the United States) introduced its feed ban as a preemptive measure, six years *before* it detected the

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[6] In the 1980's, Canada imported 191 cattle from the United Kingdom. Following the detection of BSE in one of these animals in 1993, all but 68 of these cattle (which had already died or been slaughtered) were identified, euthanized, and tested negative for BSE. Of the 68 untraceable animals, 10 are believed to have posed the greatest risk of transmitting BSE because they originated from farms in the United Kingdom that later reported cases of BSE. *See* Canada Report, Exh. A, at 20-22.

first case of BSE in a Canadian cow in May 2003. *See* Canada Report, Exh. A, at 34. Canada's implementation of the feed ban, at a time when the Canadian Government had no evidence that Canadian cattle had been exposed to BSE, has been credited with dramatically reducing the exposure of BSE among Canadian animals and effectively limiting the spread and preventing further amplification of BSE in the Canadian herd. *See id*.; *see also id*. at 14 (explaining that, because of the prolonged incubation period of BSE that averages 4-5 years,[7] the amplification and spread of BSE would have slowly reached its peak in 1996-97, just before Canada implemented the feed ban). As explained *infra*, the circumstances of the four cases of BSE detected in cattle of Canadian origin (three cases in Canada and a fourth in the United States) indicate that the feed ban remains effective in limiting the spread of BSE in North America. *See, e.g., id*. at 32.

3. A national BSE surveillance program, initiated in 1992 to detect BSE-infected animals, that exceeds OIE guidelines. As the USDA recognized in the Final Rule, for over a decade Canada has actively surveyed the national cattle herd for high risk animals showing clinical symptoms of BSE. *See* 70 Fed. Reg. at 514 (finding that Canada's surveillance program provides "sufficient evidence" for USDA to conclude that "Canada's prevention and control measures have been effective"); *see also* CFIA Factsheet, Exh. B, at 3; Canada Report, Exh. A, at 26-29. Moreover, since 1996, Canada has exceeded the level of annual surveillance recommended by OIE. *See* 70 Fed. Reg. at 515 (observing that Canada's "active, targeted surveillance program" has exceeded OIE guidelines for more than the past seven years); *see also*

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[7] A cow's "incubation period" is the interval from the time the cow becomes infected with BSE to when it develops clinical symptoms of the disease. As noted above, the average incubation period of BSE in cattle is 4-5 years. *See* Canada Report, Exh. A, at 14.

Canada Report, Exh. A, at 28 (stating that, in 2002, a year *before* the detection of the first indigenous case of BSE, Canada tested 50% more than the number of animals recommended by OIE). As a result of this intensive testing, since 2003 Canada has detected only three cases of BSE in Canada out of more than 35,000 high risk animals surveyed (not including a fourth case of BSE detected in a Canadian-born cow in the United States). *See* CFIA Factsheet, Exh. B, at 3-4 (stating that this result demonstrates the extremely low level of BSE in Canada). Further, Canada is in the second year of a five-year, Canadian $92 million program to expand the scope of the national surveillance program. *See* Canada Report, Exh. A, at 28-29 (describing additional testing efforts, as well as the public relations campaign launched in 2004 to encourage cattle producers to report cattle for BSE testing); *see also* 70 Fed. Reg. at 469 & 515 (noting that Canada has significantly broadened its national surveillance program).

4. Slaughter practices that detect and eliminate potential BSE cases before they enter the human food system. Because the majority of Canadian cattle are slaughtered for human consumption at less than two years of age, and because the average incubation period of BSE is 4-5 years, the Canadian cattle taken to slaughter are not likely to have developed infective levels of the disease. *See* Canada Report, Exh. A, at 9; *see also* CFIA Factsheet, Exh. B, at 4; 70 Fed. Reg. at 513 (distinguishing Canada from countries with a high prevalence of BSE in the cattle population, such as the United Kingdom, where BSE infection has been found in younger animals). Further, when cattle are taken to slaughter, Canada's rigorous food safety measures provide additional protections to Canadian and United States consumers. *See* CFIA Factsheet, Exh. B, at 3; *see also* Canada Report, Exh. A, at 9-10 & 15. Canada's federally-regulated slaughter establishments produce 100% of the meat exported to the United States. At each of these facilities, federal inspectors carefully inspect animals before and after slaughter for

clinical signs of BSE. The inspectors screen out animals displaying clinical signs of BSE, such as neurological impairment, and only meat approved by the inspectors may be distributed for human consumption. *See* Canada Report, Exh. A, at 9 & 15.[8]

5. The removal of SRMs as the final safeguard to protect humans from BSE. As outlined above, Canada's BSE risk mitigation measures constitute an overlapping network of controls that have minimized the presence of BSE in Canada. Because of the effectiveness of these safety measures, the vast majority of animals entering the human food system in Canada do not pose a significant risk of BSE. *See* CFIA Factsheet, Exh. B, at 4. Nevertheless, to provide the maximum protection to humans from exposure to the BSE agent, Canada implements a final safeguard: the removal of SRM from all animals slaughtered for human consumption. *See* Canada Report, Exh. A, at 11 (explaining that Canada and the United States require the removal of the same SRM). This measure, which eliminates virtually 100% of potential BSE infectivity to which humans might be exposed, is internationally recognized as the most effective way to protect consumers. *See id*. at 8-9; *see also* 70 Fed. Reg. at 465 (acknowledging that Canada's SRM removal procedures are equivalent to the procedures implemented by the United States). Removing SRM ensures that, in the unlikely event that an infected animal enters the slaughter system during the period of early infectivity when BSE is established but not clinically detectable, the meat and meat products from the animal will be virtually free of the tissues where the highest levels of BSE are found. *See* Canada Report, Exh. A, at 10 & 15; *see also* 70 Fed.

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[8] *See also Meat Inspection Regulations, 1990* (SOR/90-288), s. 9, made pursuant to the *Meat Inspection Act* SC 1985 c. 25 (1st Supp).

Reg. at 513 (emphasizing the importance of the SRM removal requirements in both Canada and the United States).

6. Appropriate epidemiological investigations to evaluate any suspected case of BSE and risk mitigation measures to limit its impact. On the rare occasions that BSE has been detected in a cow of Canadian origin, Canada has conducted an exhaustive epidemiological investigation to confirm the adequacy of its existing risk mitigation measures. As USDA has noted, the rigor and transparency of Canada's post-detection investigations reflects yet another layer of protection in Canada's efforts to control BSE. *See* 70 Fed. Reg. at 491 & 513 (describing Canada's investigations into cases of BSE). Canada also implements additional risk mitigation measures when a case of BSE is detected in Canada, including culling those animals' herdmates and offspring to test them for BSE. *See* 70 Fed. Reg. at 515. Most recently, Canada has proposed to require the removal of SRM from all animal feeds. *See* Canada Report, Exh. A, at 37-39. This action will further minimize any residual risks associated with potential cross-contamination in Canada's animal feed production systems or on-farm misuse of animal feed, thus further accelerating the elimination of BSE from the Canadian herd. *See id.*

Finally, in the highly improbable scenario that SRM removal and every other BSE safeguard fails, the chance of a United States citizen contracting vCJD from the consumption of BSE-contaminated Canadian beef remains extremely low because of the species barrier that appears to protect most humans from infection with BSE. *See, e.g.*, 70 Fed. Reg. at 462; Canada Report, Exh. A, at 10.

C. USDA Correctly Found That Canada Poses A Low Risk Of Transmitting BSE Into The United States

Contrary to R-CALF's exaggerated speculation that importation of cattle from Canada presents a "virtual certainty" that BSE-infected cattle will enter the United States

(R-CALF Br. at 13), USDA properly determined that such a risk, considered in the context of the mitigation measures proposed under the Final Rule, was "very low." 70 Fed. Reg. at 511 (further stating that, "even if a small amount of infectivity were introduced into the United States, it would be unlikely to spread and result in the establishment of BSE"). As a result of the BSE controls outlined above, BSE has remained an exceedingly rare disease in the Canadian cattle population. Moreover, as USDA found, the continuing operation of Canada's risk mitigation measures is expected not only to limit the spread of BSE in North America, but ultimately to eradicate the disease in Canada. *See* 70 Fed. Reg. at 511 (noting that "[t]he projected trajectory of the disease is down, because of the downward pressures the measures have shown to exert on the incidence of disease in such a region.") & 515; *see also* CFIA Factsheet, Exh. B, at 5; Canada Report, Exh. A, at 9 & 32.

II. CANADA'S DETECTION OF THE CASES CONFIRMED IN JANUARY 2005 DOES NOT PUT UNITED STATES CITIZENS AT A GREATER RISK OF EXPOSURE TO BSE AND IS CONSISTENT WITH THE FINAL RULE

A. The Detection Of The Cases Confirmed in January 2005 Does Not Mean That The Risk Of BSE Exposure From Canadian Beef Has Increased

As explained above, Canada confirmed two new cases of BSE on January 2 and 11, 2005, respectively, bringing the total number of cases detected by Canada's BSE surveillance program to three (not including a fourth case of BSE detected in a Canadian-born cow in the United States). *See* Canada Report, Exh. A, 14-15. The BSE case confirmed on January 2, 2005, was an 8-year old cow born in October 1996, before Canada implemented its feed ban in August 1997. *See id.* at 15; *see also* CFIA Summary Report Case #2, *available at* http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2005/2investe.shtml (last viewed Feb. 21, 2005); CFIA Questions and Answers Case #2, *available at* http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2005/2queste.shtml (last

viewed Feb. 21, 2005), at 1-2. The BSE case confirmed on January 11, 2005, was a cow born in March 1998 (age 6 years and 9 months) during the first year of Canada's feed ban. *See* Canada Report, Exh. A, at 15; *see also* CFIA Summary Report Case # 3, *available at* http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2005/2investe.shtml (last viewed Feb. 21, 2005); CFIA Questions and Answers Case #3, *available at* http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2005/3queste.shtml (last viewed Feb. 21, 2005), at 1. CFIA has confirmed that all living birth cohorts and offspring of the infected cows tested negative for BSE. *See* CFIA Questions and Answers Case #3, at 2.

Importantly, and contrary to arguments made by R-CALF and *Amici* States of Connecticut, *et al.*, the detection of the January 2005 cases does *not* indicate that the risk of human or animal exposure to BSE has increased. The current testing results from Canada's surveillance system reflect the exposure of Canadian cattle to the BSE agent which occurred in the past, before the feed ban was fully implemented. The two cases were detected *before* they entered either the human food or animal feed systems. *See id.* at 1; *see also* CFIA Factsheet, Exh. B, at 4. Canada's risk mitigation measures, enumerated *supra* at § I(B), thus operated in their normal course to exclude both SRM from the human food supply and animal tissue from the animal feed system. *See, e.g.*, CFIA Questions and Answers Case #3, at 1.

B. The Cases Confirmed in January 2005 Demonstrate That Canada's Surveillance Program Is Working And Results Confirm That Canada's Feed Ban Has Limited The Spread Of BSE

R-CALF suggests that the January 2005 cases undermine USDA's rationale in the Final Rule. In reality, the detection of these two cases is a testament to the success of the national surveillance program, which in turn continues to confirm the effectiveness of Canada's feed ban.

Canada's surveillance program, as noted above, targets the highest risk animals for BSE. *See* CFIA Factsheet, Exh. B, at 3. The discovery of only three cases of BSE in Canada, out of 35,000 high risk animals sampled since 2003, provides further evidence that the level of BSE in Canada is extremely low. *See id*. at 3-4. Moreover, the detection of the January 2005 cases indicates that Canada's surveillance program is functioning effectively, and that it may lead to the detection of a small number of additional cases. *See* Canada Report, Exh. A, at 31. The increased BSE testing undertaken by Canada in 2003 resulted in a more sensitive surveillance system, "capable of detecting even more of the small number of possible BSE cases in the adult cattle population." *Id*. at 30. For this reason as well as others,[9] the January 2005 cases are two of perhaps a few additional cases of BSE that Canada may detect as animals reach the age where any BSE infectivity would manifest itself. *See id*. (explaining that the detection of the two cases confirmed in January 2005 was not unexpected because the diagnosis of BSE in 2003 had indicated the presence of a low level of BSE in older Canadian cattle).

The results from Canada's surveillance program also provide strong evidence that Canada's feed ban has effectively limited the BSE agent from being recycled and prevented its amplification in Canada's animal feed system. *See* CFIA Factsheet, Exh. B, at 4. If the feed ban had allowed BSE to continue to spread through the animal feed system, the number of animals

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[9] Other factors that substantially increased the likelihood that Canada would detect additional cases of BSE, consistent with a very low and declining prevalence of BSE in Canada, include the following: Canada's national surveillance program has targeted more animals in certain risk groups for testing; laboratory techniques continue to use the most sensitive screening and confirmatory tests and procedures available; Canadian governments have established a financial reimbursement program to encourage farmers, veterinarians, and members of the rendering industry to identify animals for surveillance; and older animals have been retained in the national herd as a result of depressed market conditions. *See* Canada Report, Exh. A, at 29-30.

detected within Canada's highly targeted surveillance regime would be much higher. More telling than the small number of cases, however, is the older age of the four cases of BSE in cows of Canadian origin (6-8 years). *See id*. at 4. Research has shown that higher doses of the BSE agent will shorten the incubation period, leading to the development of disease symptoms at an earlier age. The fact that the surveillance program has not detected BSE in younger animals provides further evidence that the feed ban has limited the recycling and prevented further amplification of the BSE agent in the feed system. *See id.*; *see also* Canada Report, Exh. A, at 30 (explaining that the evidence "strongly suggest[s] that the Canadian BSE cases are likely to have been exposed to a very low level of infectivity in their feed early in life with anticipated incubation periods as long as 7.5 years or more").

C. The Cases Confirmed in January 2005 Do Not Alter USDA's Rationale For Listing Canada As A Minimal-Risk Region

1. The Final Rule Contemplates The Discovery Of Additional Cases Of BSE In Canadian Cattle

R-CALF claims that USDA acted arbitrarily and capriciously in attempting to "explain away" the January 11, 2005 case "literally within hours" of its discovery. *See* R-CALF Br. at 13 & 16. That argument mischaracterizes USDA's thorough analysis and treatment of the January 2005 cases, and of the January 11, 2005 case in particular. *See, e.g.*, CFIA Questions and Answers Case #3 at 5 (explaining that USDA sent animal health experts to Canada to gather information about the January 2005 cases and to verify the continuing effectiveness of Canada's feed ban). More fundamentally, R-CALF fosters the misleading impression that the January 2005 cases were somehow a surprise to both CFIA and USDA. *See, e.g.*, R-CALF Br. at 13. While the timing of the cases – coinciding with the publication of the Final Rule – may have been unforeseen, the potential for the discovery of new cases was expressly forecast by USDA

when it stated that "it is possible there may be other asymptomatic BSE-infected animals in Canada."[10] 70 Fed. Reg. at 515.

In the Final Rule, USDA acknowledges the potential for Canada to detect a "small" number of new cases of BSE as its risk mitigation measures operate to eliminate BSE from the Canadian national herd. *See, e.g.*, 70 Fed. Reg. at 514 (stating that "we have confidence that if [additional BSE-infected cattle] do exist [in Canada], the number is small."). Yet that small possibility, when considered in the context of the various mitigation measures implemented by Canada and imposed by the Final Rule, rightly did not preclude USDA from listing Canada as a minimal-risk region:

> We concur that at present ***it is not possible to know whether any additional cows in Canada are infected with BSE***. However, as documented in our risk analysis, we have concluded that the surveillance, prevention, and control measures implemented by Canada, in combination with the restrictions imposed by this rule, ***will comprehensively mitigate the risk of introducing BSE into the United States*** through imported Canadian-origin animals and animal products.

70 Fed. Reg. at 515 (emphasis added); *see also* Canada Report, Exh. A, at 29 (explaining that the detection of the January 2005 cases was not unexpected).

Because the discovery of the January 2005 cases was, in fact, consistent with USDA's analysis in the Final Rule, USDA had no need to "revise or seriously reconsider" its determination that Canada qualified as a minimal-risk region, as R-CALF claims (R-CALF Br. at 5). R-CALF's suggestion that USDA improperly defended the Final Rule following Canada's announcement of the January 2005 cases is therefore wholly without merit.

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[10] Indeed, USDA has acknowledged that it "cannot state with certainty that BSE will never occur in indigenous animals [of United States origin]." 70 Fed. Reg. at 513-14.

2. Canada's BSE Prevalence Rate Remains Below OIE's International Guideline For A Minimal-Risk Region

R-CALF claims that "[t]he discovery, in a relatively short time, of four animals . . . stricken with BSE [*i.e.*, three in Canada and a fourth of Canadian origin detected in the United States] is inconsistent with USDA's assertion that the BSE incidence rate in Canada is 'very low' or 'minimal.'" R-CALF Br. at 13; *see also* Amicus Curiae Brief of the States of Connecticut, *et al*., at 6 (claiming that "[t]hese new BSE cases require reassessment of USDA analyses presuming a 'very low' presence of BSE and conclusions about the 'very low' risks if the border is opened."). R-CALF further argues that Canada's BSE incidence rate (as adjusted by R-CALF) "would [be] on a par with a number of European countries with a BSE problem." R-CALF Br. at 13. These statements are completely at odds with the facts. Even in light of the January 2005 cases, Canada's BSE prevalence rate remains well within the OIE's recommended guideline for a minimal risk region. *See* Canada Report, Exh. A, at 7.

In the Final Rule, USDA concluded that Canada's risk mitigation measures had prevented widespread exposure and establishment of BSE based on its comparison of Canada's annual prevalence rate of two infected cattle in 2003 with the OIE-recommended level of "less than two infected cattle per million during each of the last four consecutive [12 month] periods within the cattle population over 24 months of age." *See* 70 Fed. Reg. at 464; *see also id*. at 512 (explaining that, while "the number of detected cases does not, by itself, allow for a determination of prevalence," the number may be taken as a "strong indication" that mitigation measures are in place and thus "prevalence is likely to be low"). USDA concluded that Canada's incidence rate, calculated by the USDA as 0.4 cases per million head of adult cattle, was well below the OIE recommendation for incidence in minimal-risk regions. *See* 70 Fed. Reg. at 512.

In recalculating the prevalence rate in light of the cases confirmed in January 2005, Canada has determined that, even if the January 11, 2005 case were to be included in the 2004 test results, "the resulting incidence rate (**0.3 [per million head of cattle]**) [correlating to two cases] would still be well ***below*** the two-in-a million threshold for a minimal risk country as defined by the OIE." Canada Report, Exh. A, at 30 (emphasis added); *see also id.* at 7 (providing a table of estimated rates based on OIE's reporting requirements). Further, because Canada expanded its surveillance program in 2003, the detection of a few additional cases does *not* indicate that the prevalence of BSE in Canada is increasing, but rather that Canada is more capable of finding the small number of remaining BSE cases in the adult cattle population. *See id*. at 30-31. In light of the fact that Canada's BSE prevalence rate remains within the OIE's recommended guidelines for a minimal risk region, USDA's rationale for listing Canada as a minimal-risk region on this basis applies with equal force today.[11]

3. Canada's Feed Ban Continues To Provide An Effective Barrier To The Spread Of BSE, Consistent With OIE Guidelines

To sound an alarm about USDA's recognition of Canada as a minimal-risk region, R-CALF calls into question almost every aspect of Canada's feed ban – even though Canada's feed ban is virtually identical to the feed ban simultaneously implemented by the United States in 1997 in response to the same risk factors. R-CALF claims, among other things,

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[11] Furthermore, R-CALF's claim that Canada's national surveillance program is insufficient to "assess accurately" the rate of BSE infection in Canada (R-CALF Br. at 12) is baseless. In the Final Rule, USDA recognized not only that Canada's surveillance program "exceeds the OIE recommended level of testing," but that Canada's "surveillance program for BSE in cattle [is] of high quality because it includes active surveillance for BSE in cattle that is appropriately targeted based on known risk factors." 70 Fed. Reg. at 464; *see also* Canada Report, Exh. A, at 30 (stating that Canada tested 23,500 cattle samples in 2004, easily exceeding OIE's minimum sampling targets).

that USDA acted arbitrarily and capriciously in determining that Canada's feed ban was effective because the feed ban has now been in place for seven years and six months instead of the eight-year standard recommended by OIE. *See* R-CALF Br. at 15. R-CALF further charges that Canada's detection of the January 11, 2005 case, involving a cow born after Canada implemented its feed ban in 1997, indicates that "Canada has had an *effective* feed ban for substantially less than . . . seven years."[12] *Id*. at 16 (emphasis in original).

As a threshold matter, R-CALF's suggestion that Canada's feed ban cannot be trusted to protect public and animal health in the United States is contradicted by the fact that the January 11, 2005 case is the only BSE-infected animal ever identified in North America that was born after Canada and the United States had implemented their feed bans. CFIA determined that the infected animal may have consumed feed manufactured a short time after the feed ban was implemented, and that the feed may have been "cross-contaminated" by exposure to feed that contained prohibited materials. *See* "Report of the Investigation of the Third Case of Bovine Spongiform Encephalopathy (BSE) in Alberta, Canada," CFIA (Feb. 11, 2005), *available at* http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2005/3investe.shtml (last viewed Feb. 21, 2005), at 3 (explaining that "this finding is consistent with the experience of all countries with BSE which have implemented feed bans").

Given the level of complexity in implementing the feed ban across a network of feed mills, retailers, rendering facilities, and farms, it was not possible for Canada or the United

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[12] R-CALF also raised questions about other aspects of Canada's feed ban, including industry compliance with the feed ban and the ban's inability to block the spread of the BSE agent through routes of transmission that do not involve the ingestion of contaminated material, such as through blood or saliva. Those questions are addressed *infra* at § III.

States to eliminate all of the prohibited feed the moment the ban took effect in August 1997, nor was it necessary in order to achieve the ban's objectives. *See* Canada Report, Exh. A, at 34-35; *see also* CFIA Questions and Answers Case #3, at 6. The feed ban, as noted above, was implemented as a proactive precaution, nearly six years before BSE was detected in the Canadian herd. For these reasons, there was a natural transition period following implementation of the ban, as the various sectors of the feed industry changed their practices to comply. *See* Canada Report, Exh. A, at 34-35 (explaining that, because existing feed supplies were not recalled, it is possible that some feed containing ruminant protein was fed to cattle before such supplies were exhausted); *see also id.* at 39-40. Nonetheless, despite any permeability in the feed ban, the evidence shows that Canada's feed ban has proven to be effective in limiting the spread of BSE in North America.[13] *See id.* at 32 & 34-35; *cf.* 70 Fed. Reg. at 510 (noting that the feed ban in the United Kingdom exerted a "substantial" "downward pressure" on the presence of BSE, even though the feed ban was only "partially implemented").

Furthermore, the January 11, 2005 case does not, as R-CALF suggests, indicate that USDA should have denied Canada status as a minimal-risk region because its feed ban has now been in place for approximately seven and a half years, rather than the eight-year period recommended by OIE for a minimal-risk country. Because Canada introduced its feed ban seven

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[13] Although some cows, like the January 11, 2005 case, may have become infected in the transition period after the feed ban was implemented, the potential number of such animals would be far less than the number of potential cases involving cattle infected before the feed ban was implemented. *See* Canada Report, Exh. A, at 32. Contrary to R-CALF's claims, such discoveries would not indicate that Canada's feed ban is inadequate. In fact, the detection of several new cases of BSE in older cattle would be considered epidemiologically unimportant. *See id*. Although such cases may prolong the time required for Canada to eradicate BSE, they would not pose a risk of initiating an outbreak of BSE because the feed ban minimizes the likelihood that they would infect other animals. *See id*.

and a half years ago, in August 1997, the eight-year time period has almost elapsed. More meaningful than a specific duration of time, however, is the intent of OIE's recommendation. Even though Canada's feed ban has not been in place for the full eight years, Canada's feed ban, like that of the United States, assures an equivalent level of protection to the eight-year feed ban recommended by OIE. *See* Canada Report, Exh. A, at 36.

The OIE' s guidelines were developed when BSE was restricted to the United Kingdom and Europe, where thousands of cases of BSE had been detected before the countries introduced feed bans or other control measures. *See id*. Because the feed bans were introduced after cases had been established, widespread exposure within the cattle population had already occurred before the feed bans took hold. In that more extreme situation, and taking into account the incubation period for BSE, OIE determined that it would take approximately eight years before the majority of BSE cases had been removed from those cattle populations. *See id*. That situation is completely different from the case of Canada and the United States, and therefore the same logic does not apply.

In the case of Canada, like the United States and other countries that introduced a preemptive feed ban, the number of animals actually infected with BSE at the time the ban was introduced would have been substantially less. *See id*. Accordingly, the length of time required to reach the same low prevalence level of BSE as the countries (such as the United Kingdom) that introduced a feed ban after detecting actual BSE cases would be less than eight years. *See* Canada Report, Exh. A, at 36; *see also* 70 Fed. Reg. at 470. For this reason, and as USDA rightly concluded, the seven and a half year duration of Canada's feed ban satisfactorily

addresses the expected BSE incubation period in North America.[14] *See*, *e.g.*, 70 Fed. Reg. at 470 ("[w]e determined that the duration of the feed ban in Canada adequately addresses the expected BSE incubation period, taking into consideration all of the actions Canada has taken to prevent the introduction and control the spread of BSE . . . ."); *see also id.* at 471 (stating that "[a]lthough Canada does not precisely meet the OIE guideline for duration of a feed ban, its control measures in other areas (such as surveillance and import restrictions) more than compensate for this"). For all of these reasons, Canada has an epidemiologically effective feed ban under which BSE eventually will be eradicated. *See* Canada Report, Exh. A, at 32.

D. Canada Has Demonstrated Substantial Compliance With The Feed Ban

R-CALF claims that Canada's feed ban has not been sufficiently enforced in the feed industry, which should preclude Canada from exporting cattle and beef products to the United States. *See*, *e.g.*, R-CALF Br. at 16; Decl. of William T. Bullard, Jr., at 7. This argument is contradicted by years of compliance statistics and inspection reports demonstrating that Canada actively enforces the feed ban – a fact that USDA considered in the Final Rule. *See* 70 Fed. Reg. at 467-68 (finding a "high" or "full" level of compliance for various sectors of the feed industry). Over the past three years, for example, the average compliance rate with the Canadian

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[14] Because of the success of the feed ban in minimizing the spread of BSE and the prolonged incubation period of BSE in Canadian cattle, Canada expected the number of BSE cases in Canada to peak approximately six years after the feed ban was implemented, *i.e.*, in 2003-2004. *See* Canada Report, Exh. A, at 32. R-CALF's declarant is therefore wrong in asserting that "the ages of the animals [6 to 8 years old] that have tested positive for BSE do not demonstrate the effectiveness of the Canadian feed ban at all." Decl. of Louis Anthony Cox, Jr., Ph.D., at 7. In fact, the confirmation of two cases in 2003 and the two new cases in January 2005 is consistent with an effective feed ban.

feed ban at the end of a complete inspection cycle has been 95% at commercial feed mills. *See* Canada Report, Exh. A, at 35.

In January 2005, the United States National Cattlemen's Beef Association ("NCBA") evaluated industry compliance with Canada's feed ban in connection with its own investigation into the January 2005 cases. The NCBA has no organizational interest in vouching for the efficacy of Canada's feed ban. NCBA's Canadian Trade Delegation nonetheless issued a report on February 2, 2005, expressing confidence in the Canadian feed industry's compliance with the feed ban based on its review of annual audit reports and its visits to beef operations, feed mills, and rendering facilities in Canada. *See* "NCBA Canadian Trade Delegation Final Report" (Feb. 2, 2005) ("NCBA Report"), *available at* www.beefusa.org/documents/ACF985.pdf (last viewed Feb. 21, 2005) (attached hereto as Exhibit C), at 12; *see also* Canada Report, Exh. A, at 35. On February 16, 2005, in a letter to R-CALF commenting on R-CALF's "recent distortion of the facts" regarding the BSE risks in Canada, NCBA further explained that Canada's "compliance with feed restrictions, especially since 2001, has been well over 90 percent," with any violations of the ban primarily "paperwork" in nature, rather than involving the feeding of prohibited materials to animals. *See* Letter from Bob Smith and Jamie Willrett of NCBA to Leo McDonnell of R-CALF (Feb. 16, 2005) (attached hereto as Exhibit D), at 2 (delineating reasons why "[t]he fact that Canada has detected 4 cases of BSE . . . all born before or shortly after the 1997 feed restrictions went into place, does not alter [Canada's] international standing as a minimal risk country.").

As part of its investigation, NCBA also researched the facts alleged in two newspaper articles appearing in the *Vancouver Sun* in December 2004, which reported that samples of vegetable-based cattle feed analyzed by CFIA in a feed sampling and testing trial

were found to contain animal protein, purportedly in violation of the feed ban. *See* NCBA Report, Exh. C, at 10-11; *see also* Canada Report, Exh. A, at 40-41; *cf.* Cox Decl. at 9 (asserting that "a large proportion" of Canadian feed labeled as containing vegetable material had been contaminated with prohibited mammalian protein). While in Canada, members of NCBA's Canadian Trade Delegation questioned Canada's Chief Veterinarian Officer about the articles. *See* NCBA Report, Exh. C, at 10. The NCBA members subsequently reported that the circumstances of the feed sampling and testing trial were unique, in that CFIA was testing new microscopy technologies for use in determining the presence of foreign matter in feed samples. *See id*. at 10-11 (stating that, of the 110 samples tested, only 65 were Canadian; 90% of the samples contained non-prohibited animal protein, such as insects and feathers, and the remaining 10% of samples were unable to be confirmed); *see also* Canada Report, Exh. A, at 40-41 (discussing the context and conclusions of the feed sampling and testing trial). Weighing these facts, NCBA observed that the *Vancouver Sun* reporting was "sensationalized."[15] NCBA Report, Exh. C, at 11; *see* Canada Report, Exh. A, at 41.

On January 11, 2005, the Honourable Andy Mitchell, the Canadian Minister responsible for the CFIA and Minister of Agriculture and Agri-Food, announced a review of Canada's feed ban. *See* Canada Report, Exh. A, at 35-36 (explaining that the review "is part of the government's on-going efforts to demonstrate to Canadians and our trading partners that the

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[15] Additionally, R-CALF is wrong in stating that, "as recently as 2003 a Canadian cow with BSE made its way into cattle feed to which over 1800 Canadian cattle may have been exposed." R-CALF Br. at 16 (citing Bullard Decl. at 7). After investigating the incident and tracing the animal remains that were rendered, CFIA concluded that Canada's feed ban and other BSE controls were followed. *See* Canada Report at 39-40.

feed ban is effectively limiting the spread of BSE in Canada").[16] But there is no factual basis to expect any findings that would undermine USDA's confidence in the Canadian system. There is, accordingly, no reason to delay implementation of the rule pending release of this report. Regulatory authorities on both sides of the border will inevitably continue to investigate and respond to developments but the facts known today provide compelling support for USDA's conclusion that importation of Canadian cattle and beef products, as authorized under the Final Rule, poses no significant risk to United States citizens or the United States cattle herd. The review is expected to be completed shortly, at which time the Canadian Government will publish the findings and results.

E. Canada's SRM Removal Policy and Feed Ban Represent The Most Effective Means Of Protecting Public and Animal Health

In attempting to persuade this Court to enjoin the Final Rule, R-CALF argues that the United States and Canada cannot rely on feed bans or SRM removal to protect public and animal health if BSE-infected cattle are imported into the United States. *See*, *e.g.*, R-CALF Br. at 14-15; *see also* Cox Decl. at 8. R-CALF asserts that BSE (and even vCJD) may be transmitted through a laundry list of pathways, including via blood, fetal bovine serum, saliva, rendered animal fat in cattle feed, poultry waste, and other unknown routes. *See* R-CALF Br. at 14-15 & 17-18.

As a preliminary matter, R-CALF does not dispute that animal feed containing (or contaminated by) ruminant materials contaminated with the BSE agent is the principal route of

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[16] *Amici* States of Connecticut, *et al.*, are flatly incorrect in stating that "Canada has yet to fully evaluate the ban's effectiveness." Amicus Curiae Brief of the States of Connecticut, *et al.*, at 6. Canada, like the United States, continuously monitors the effectiveness of its feed ban. The feed ban review is merely another step in this on-going process. *See* Canada Report, Exh. A, at 35.

transmission of BSE. *See* R-CALF Br. at 14. Contrary to R-CALF's suggestion (R-CALF Br. at 15 & 17), however, extensive studies have failed to demonstrate that the BSE agent is present in the muscle tissue or blood of cattle. *See* Canada Report, Exh. A, at 37; *see also* 70 Fed. Reg. at 502 (stating that "conclusive science is lacking regarding the risk of BSE transmission by blood and blood products"). In addition, the other routes of transmission identified by R-CALF are either being controlled to the extent possible by BSE control measures in United States and Canada, or they are attenuated pathways of infectivity that do not have conclusive scientific support.

More fundamentally, however, and for the reasons explained *supra* at § I(B), Canada's feed ban and policy of removing SRM from the human food system, along with other risk mitigation measures, provide the most effective barriers to BSE exposure from potential routes of transmission. Because Canada's mitigation measures, like those of the United States, are based on sound science and internationally recognized standards, and because they have proven to be highly successful in controlling the spread of BSE, they provide comprehensive health protection to humans and animals alike. *See, e.g.*, 70 Fed. Reg. at 473. This Court should not be misled by R-CALF's suggestion that any Canadian meat or beef, simply by virtue of being from Canada, poses a threat to public and animal safety.[17]

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[17] Indeed, as noted in a report recently issued by USDA's Inspector General, the United States Food Safety Inspection Service ("FSIS") reviewed Canada's risk mitigation measures in December 2004. FSIS determined that Canada's network of mitigation measures had no deficiencies and thus operated effectively in protecting human and animal health. *See* "Audit Report, Animal & Plant Health Inspection Service Oversight of the Importation of Beef Products from Canada" (Report No. 33601-01-Hy), U.S. Dept. of Agriculture Office of Inspector General (Feb. 2005), at 18.

III. CONSUMERS CONTINUE TO EXPRESS JUSTIFIABLE CONFIDENCE IN CANADIAN BEEF

R-CALF contends that imports of Canadian cattle and beef should continue to be prohibited because "domestic consumers of beef [will] question its safety," R-CALF Br. at 5, and thus "domestic and consumer confidence in the U.S. beef supply" will "diminish," *id*. at 7. That speculation has been conclusively rebutted by the Canadian experience. *See* Canada Report, Exh. A, at 17-18. Canadians are continuing to consume Canadian beef at record levels even though beef prices are at relatively normal levels, and despite extensive and continuing media coverage of the BSE issue that, at times, is factually inaccurate. *See id.* at 17-18 (stating that, in 2003, each Canadian ate on average 5% more beef than the year before). This consumer confidence, which remained strong following the confirmation of the January 11, 2005 case, shows that Canadians are reassured by the safety of the beef supply and Canada's food inspection system. *See id*. For example, 64% of respondents to a January 2004 (EKOS) survey expressed confidence in the food safety system. One year later, soon after the confirmation of the January 11, 2005 case, 73% of respondents to a follow-up survey continued to express confidence in Canada's food safety system, representing an increase of nearly 10 points. *See id*. at 18.

Furthermore, there is no evidence that the BSE issue North America has led to a decline in consumer confidence in the United States. Consumer demand for beef continued to show strength in the first quarter of 2004, with preliminary data showing the Beef Demand Index increased by 10.4% compared to the first quarter of 2003. *See* Canada Report, Exh. A, at 18-19 (citing NCBA data). In addition, a number of countries that had banned imports of Canadian beef after the initial detection of BSE in Canada in May 2003 have subsequently concluded that Canadian beef products are safe and have restored market access. *See id*. at 57 (Annex A)

(showing consumers of Canadian beef products by product class). Their confidence in the safety of Canadian beef has remained robust in light of the January 2005 cases, as it should. *See id*. at 18.

CONCLUSION

For the foregoing reasons, Canada respectfully asks this Court to deny R-CALF's application for a preliminary injunction and to defer to USDA's substantiated expert judgment that Canadian beef is safe and that the public interest would be served by allowing the Final Rule to take effect on March 7, 2005.

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Respectfully submitted,

By: _____

Charles E. Hansberry
HOLLAND & HART LLP
401 North 31st Street, Suite 1500
P. O. Box 639
Billings, Montana 59103-0639
Telephone: (406) 252-2166
Facsimile: (406) 252-1669
Email: chansberry@hollandhart.com

Maureen E. Mahoney
Cassandra Sturkie
LATHAM & WATKINS LLP
555 Eleventh Street, N.W.
Suite 1000
Washington, DC 20004-1304
Telephone: (202) 637-2200
Facsimile: (202) 637-2201
Email: maureen.mahoney@lw.com
Email: cassandra.sturkie@lw.com

Counsel for the Government of Canada

DC\741724.6