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ATTORNEYS FOR CANADIAN CATTLEMEN'S ASSOCIATION

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

\_\_\_\_\_  
RANCHERS CATTLEMEN ACTION LEGAL FUND )  
UNITED STOCKGROWERS OF AMERICA, )

Plaintiff, )

v. )

UNITED STATES DEPARTMENT OF AGRICULTURE, )  
ANIMAL AND PLANT HEALTH INSPECTION )  
SERVICE, et al., )

Defendants )  
\_\_\_\_\_ )

) Cause No. CV-05-06-BLG-RFC

) **BRIEF AMICUS CURIAE**  
) **OF THE CANADIAN**  
) **CATTLEMEN'S**  
) **ASSOCIATION IN**  
) **OPPOSITION TO**  
) **PLAINTIFF'S MOTION FOR**  
) **SUMMARY JUDGMENT**

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## INTEREST OF THE *AMICUS CURIAE*

The Canadian Cattlemen's Association is a national federation that encompasses eight provincial organizations and represents the interests of Canada's more than 90,000 beef producers. The Association and those who join it (collectively "CCA")<sup>1</sup> support the United States Department of Agriculture Animal and Plant Health Inspection Service ("USDA/APHIS") in its opposition to the motion for summary judgment filed by the Plaintiff, Ranchers Cattlemen Action Legal Defense Fund ("R-CALF") seeking to prevent implementation of a final rule published by USDA/APHIS that would allow U.S. importation of certain Canadian cattle and beef products ("Final Rule").<sup>2</sup>

The CCA submits this *amicus curiae* brief to provide a viewpoint not otherwise before this Court—the perspective of the producers of the very cattle that are the subject of this litigation. The producers represented by these associations all have an economic interest in this case that is not otherwise represented. The accompanying Motion for Leave to File this *amicus* brief sets forth the CCA's interest in this case and the CCA's efforts to obtain the consent of the parties for the filing of this brief.

This case is R-CALF's latest effort to create barriers to trade in Canadian cattle and beef for its own economic benefit. Indeed, R-CALF was created in 1998 to "file three trade cases on

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<sup>1</sup> The CCA is joined in this submission by B.C. Cattlemen's Association, Canadian Beef Breeds Council, Fédération des producteurs de bovins du Québec, Manitoba Cattle Producers' Association, New Brunswick Cattle Producers, Nova Scotia Cattlemen's Association; Ontario Cattlemen's Association, P.E.I. Cattlemen's Association and Saskatchewan Stock Growers' Association.

<sup>2</sup> The Final Rule is entitled "Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities," 70 Fed. Reg. 460 (Jan. 4, 2005). See Administrative Record ("AR") 8043-8136. Specifically, the Final Rule establishes minimal risk regions for the transmission of Bovine Spongiform Encephalopathy ("BSE") and designates Canada as such a minimal risk region.

behalf of the U.S. cattle industry,”<sup>3</sup> and its current mission is “to represent the U.S. cattle industry in national and international trade and marketing issues to ensure the continued profitability of and viability of U.S. cattle producers.”<sup>4</sup> Consistent with its own goals and objectives, CCA seeks to prevent the establishment of trade barriers, disguised as health measures, that are motivated by parochial economic interests of organizations such as R-CALF.

CCA’s members have a profound interest in how the U.S. structures and implements its BSE regulations. As the U.S. and Canadian beef and cattle markets are viewed globally as largely integrated, the policy decisions and standards established in either country have an impact on the industries of both in their ability to trade internationally. CCA’s interests have been seriously harmed by the Court’s entry of the preliminary injunction in this matter and the CCA continues to have a vital interest in the final remedy, if any, in this matter.

CCA filed a motion to intervene in this action, along with Alberta Beef Producers (ABP). This Court denied CCA and ABP’s motion to intervene by order dated May 17, 2005. On June 2, CCA and ABP appealed that order. The CCA now seeks leave to file this *amicus* brief.

## INTRODUCTION

R-CALF’s motion for summary judgment would have this Court reject the voluminous and

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<sup>3</sup> Not surprisingly, two of those cases were brought against cattle from Canada, one seeking antidumping duties, the other countervailing duties. *See Live Cattle From Canada and Mexico*, USITC Pub. 3255, Inv. Nos. 701-TA-386, 731-TA-812-813 (Final)(Nov. 1999). Ultimately both failed, as did the third case against Mexico, after the Canadian cattle industry incurred significant costs in defending them.

<sup>4</sup> Ranchers Cattlemen Action Legal Fund United Stockgrowers of America, “R-CALF USA Frequently Asked Questions,” *available at* <http://www.r-calfusa.com/News%20Releases/faq.htm> (last visited June 9, 2005).

scientifically supported record relied on by USDA/APHIS in the drafting of the Final Rule.<sup>5</sup> Only by failing to accord appropriate deference to USDA/APHIS' thorough and well-substantiated Final Rule can this Court find in favor of R-CALF. The legal standards and the undisputed facts require a finding by this Court that implementation of the Final Rule should proceed.

In this brief CCA defers to USDA/APHIS to address the applicable legal standards with respect to the deference that should be given to an agency's decisionmaking in a matter of agency expertise, and addresses instead certain specific issues raised by R-CALF. In particular, CCA analyzes R-CALF's misapplication of the guidelines published by the World Animal Health Organization ("OIE") and reviews R-CALF's misleading comparison of the BSE experience in North America with that in Japan and European Union countries, including the United Kingdom. Additionally, this brief considers R-CALF's efforts to turn its complaints regarding USDA/APHIS' procedural obligations under the Regulatory Flexibility Act ("RFA") into a "substantive" economic argument for enjoining the Final Rule. In support of their misguided RFA argument, R-CALF's economic expert not only misrepresents the nature of

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<sup>5</sup> This rulemaking was not based on preconceived intentions to rush to reopen the border or any inappropriate considerations. The rulemaking commenced in November 2003 and included consideration of more than three thousand comments (70 Fed. Reg. at 465 (AR 8049)). When a cow in Washington State (of Canadian origin) was discovered to have BSE, USDA/APHIS reopened and extended the comment period on the rule. The comment period, initially scheduled to close on January 5, 2004, was extended until April 7, 2004. 70 Fed. Reg. at 460 (AR 8044). After another almost eight months of further consideration, including the updating of the risk and economic analyses, the Final Rule was published by USDA/APHIS on January 5, 2005. After the discovery of the two most recent BSE cases in Canada, even though such additional cases were already taken into account by the risk analysis done for the rulemaking, USDA/APHIS undertook to delay for further review the portion of the Final Rule allowing importation of certain Canadian beef products from cattle older than 30 months. See "Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities; Partial Delay of Applicability," 70 Fed. Reg. 12,112 (Mar. 11, 2005).

access to various U.S. and Canadian export markets, but offers an opinion on the potential impact of additional discoveries of BSE cases on consumer demand that is without the support he cites. A careful review of these issues, as well as others raised by USDA/APHIS, shows that R-CALF's motion for summary judgment should be denied.

## **BACKGROUND**

BSE presents no credible human health risk in North America. There has never been a native case of the human variant of BSE – known as variant Creutzfeld-Jakob Disease (“vCJD”) – in either Canada or the U.S., and the probability of such a native case occurring approaches zero. R-CALF has conceded this point in related appellate proceedings before the Ninth Circuit Court of Appeals, stating “R-CALF never argued that there was a great risk to human health from resumed imports of cattle and beef from Canada.” Answering Brief of R-CALF at 44, *National Meat Assoc. v. U.S. Dept. of Agric.* (9<sup>th</sup> Cir. Mar. 29, 2005) (No. 05-35214). Furthermore, any potential animal health risk that may exist by virtue of a lingering low-level of BSE infectivity in older cattle in North America has been effectively mitigated. The USDA/APHIS correctly reached these same conclusions in their exhaustive 18-month, 12,500-page rulemaking, for several reasons:

- BSE is not contagious – people do not “catch” BSE from cattle, nor do cattle “catch” it from each other. The only scientifically established mode of BSE transmission is through the ingestion of infective material.
- People are protected from infection by the removal of potentially infective material from the human food supply, which is accomplished significantly by the ban on SRMs (“Specified Risk Materials”) in food.
- Animals are protected by the removal of potentially infective material from their feed supply, which is accomplished in large part by the ruminant-to-ruminant feed ban.
- The Final Rule is limited to the importation of cattle under 30 months of age, a class of animals in which BSE is virtually never found, and in which it has never

been found in countries like the U.S. and Canada, where established mitigation measures have been in place for a sufficient number of years.

#### BSE Presents No Credible Risk to Humans in North America

BSE is not a human disease; it is an animal disease that has been identified to date in just four North American cattle. Variant CJD<sup>6</sup> is a neurological disease that the current scientific evidence indicates is transmitted to humans through consumption of BSE-infected material.<sup>7</sup> Extensive research shows that BSE is found in certain tissues identified as Specified Risk Materials (“SRM”),<sup>8</sup> but not in beef muscle meat (*i.e.*, steak, roasts, etc.). See USDA/APHIS Analysis of Risk – Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities (“Updated Risk Analysis”) (Dec. 2004) at 14-15 (AR 8332-8333)(“BSE infectivity has never been demonstrated in the muscle tissue of cattle...”). Thus, the most effective means of ensuring human health is the removal of SRMs from human food. In July 2003, Canada implemented a regulation requiring the removal of SRMs from the human food supply, and the U.S. followed Canada’s lead in January 2004. 70 Fed. Reg. at 465 (AR8049). Canada and the U.S. have virtually identical policies and procedures in place to implement this safeguard. *Id.* (describing Canada’s SRM removal procedures as

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<sup>6</sup> Variant CJD should not be confused with the classic form of CJD. Classic CJD is a rare neurological disease, similar to BSE, that occurs in humans. Classic CJD is endemic throughout the world, including the U.S. See Centers for Disease Control and Prevention, National Center for Infectious Diseases, “Fact Sheet: New Variant Creutzfeld-Jakob Disease,” available at [http://www.cdc.gov/ncidod/diseases/cjd/cjd\\_fact\\_sheet.htm](http://www.cdc.gov/ncidod/diseases/cjd/cjd_fact_sheet.htm) (last visited June 9, 2005).

<sup>7</sup> 70 Fed. Reg. at 462 (AR 8046)(Variant CJD “has been linked via scientific and epidemiological studies to exposure to the BSE agent, most likely through consumption of cattle products contaminated with the BSE agent.”).

<sup>8</sup> SRMs include the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse process of the thoracic and lumbar vertebrae, and the wings of the sacrum) and dorsal root ganglia of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle. See 70 Fed. Reg. at 465 (AR 8049).

“equivalent safeguards”). Thus, any beef produced in either a U.S. or Canadian packing plant is safe for human consumption.

#### Animal Health is Protected by the Ruminant-to-Ruminant Feed Ban in North America

As noted, BSE is not a contagious disease. All evidence demonstrates that its transmission from animal to animal is caused by the consumption of one animal’s infected material by another. *See* 70 Fed. Reg. at 461 (AR 8045). The risk of BSE transmission via the feeding of infective material to cattle has been mitigated by banning the feeding of ruminant material to other ruminants. Canada has had a ruminant to ruminant feed ban in place since mid-1997, as has the U.S. *See, e.g.,* 70 Fed. Reg. at 467, 476 (AR 8051, 8060). Canada’s feed ban has materially retarded, and perhaps eliminated any spread and amplification of BSE in Canada and the U.S. *See* 70 Fed. Reg. at 476, 515 (AR 8060, 8099)(Canada has “effectively enforced its feed ban”; Canada established “that the necessary...measures are in place to...eradicate the disease.”).

As evidenced by the U.K.’s experience (*see infra* note 15), a feed ban does not require 100 percent compliance in order to reduce the incidence of BSE. The greater the level of compliance with the feed ban, the more quickly any BSE will be eliminated from the herd. Thus the overall high levels of compliance achieved in both the U.S. and Canada will result in the eventual eradication of BSE in North America. *See* 70 Fed. Reg. at 515 (AR 8099).

Consequently any BSE outbreak in North America that even remotely compares to that experienced in Europe a decade ago is simply not possible, as the already small risk of BSE in North America is becoming smaller and smaller. Further, as noted, both Canada and the U.S. remove SRMs from all cattle for human consumption. Therefore, if an animal with BSE were to

go undetected on either side of the border, the potentially BSE infective tissue of that animal would be removed, and thus prevented from entering the human food supply.

#### The Final Rule Limits Importation to Cattle Under 30 Months of Age

The Final Rule only allows importation of cattle to be slaughtered at under 30 months of age, thus further reducing the already minimal risk.<sup>9</sup> Scientific studies show that the risk of BSE among cattle under 30 months of age is extremely low. *See* 70 Fed. Reg. at 483 (AR 8067).

While rare cases of BSE may be found in cattle under 30 months,<sup>10</sup> these have occurred in countries with high levels of circulating infectivity. *Id.* The larger the infectious dose received by an animal, the shorter the incubation period of the disease. The fact that the Canadian BSE cases have been in cattle of ages far greater than 30 months is itself evidence of a very low level of infectivity. *See* Updated Risk Analysis at 17 (AR 8335) (“[A]s feed bans became increasingly effective, the total exposure decreased and the average incubation periods lengthened.”). While the CCA believes that, with an effective feed ban and SRM removal procedures in place, this 30-month age limitation is not necessary to ensure either human or animal health, USDA/APHIS’ adoption of this conservative policy makes an already remote risk of transmission of BSE even less likely.

### ARGUMENT

#### **I. The OIE Guidelines Support the Final Rule**

##### **A. The Final Rule is Not an Exception to OIE Standards.**

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<sup>9</sup> Under the Final Rule, cattle imported from Canada must be immediately slaughtered or transported to a feedlot for slaughter. In either instance, the cattle must be less than 30 months of age when slaughtered. 70 Fed. Reg. at 548-549 (AR 8132-8133).

<sup>10</sup> In the U.K., where infectivity levels of BSE have been higher than anywhere else in the world, only .01 percent of BSE cases were found in animals less than 30 months of age. *See* Updated Risk Analysis at 12 (AR 8330).

R-CALF has repeatedly claimed that the Final Rule is inconsistent with, and less stringent than, the international recommendations promulgated by the OIE. *See, e.g.*, Memorandum of Points and Authorities in Support of Plaintiff's Motion for Summary Judgment ("R-CALF's Memo") at 16 ("USDA rejected [OIE's] international guidelines because the eight-year time period 'may be conservative,' asserting that the incubation period for BSE infection in cattle is usually less than 7 years."). Such claims reflect R-CALF's fundamental misunderstanding of OIE's BSE risk guidelines. The OIE recommendations are meant to provide guideposts to facilitate trade based on science and reason, not a checklist to arbitrarily curtail or disrupt trade longer than necessary. Indeed the OIE "has become increasingly concerned about reports of international trade disruptions involving the misinterpretation of OIE standards."<sup>11</sup>

Contrary to R-CALF's position, the Final Rule comports with OIE guidelines. In this case, David Wilson, Head of the International Trade Department of the OIE, stated that "OIE would not consider it appropriate for the importing country to apply each criterion as an item on a checklist and to conclude that the exporting country fails to qualify for a particular risk status merely because it does not meet a listed criteria with that particular status." Declaration of David Wilson at ¶7, attached as Exhibit 5 to USDA/APHIS' Opposition to R-CALF's Motion for Preliminary Injunction (Feb. 22, 2005). Going directly to the heart of R-CALF's argument, Dr. Wilson specifically notes that "a deficiency in the length of time a feed ban has been effectively applied could be addressed through restrictions on the age of the live cattle imported." *Id.* at ¶7.

As Dr. Wilson's declaration makes clear, USDA/APHIS' Final Rule is not a departure from the OIE's standards, rather it reflects those standards. Indeed, recent revisions to

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<sup>11</sup> OIE, "The OIE Standards on BSE: A Guide for Understanding and Proper Implementation," available at [http://oie.int/eng/press/en\\_040109.htm](http://oie.int/eng/press/en_040109.htm) (last visited June 9, 2005).

the BSE recommendations adopted by the OIE further validate the regulatory framework established by the Final Rule. R-CALF's arguments regarding differences between the Final Rule and OIE recommendations, while hollow before, are shown by these developments to have been rooted in their basic misapprehension of the OIE process and the nature of OIE guidelines.

B. Recent Revisions to the OIE Standards Further Validate the Framework Established by the Final Rule.

The 167 countries that participate in the OIE recently adopted revisions to the OIE's BSE recommendations to incorporate the increased body of knowledge that has developed regarding the evolution and management of BSE threats. While these revisions were not in effect at the time that USDA/APHIS developed and adopted the Final Rule, they provide further evidence that the Final Rule is not the result of arbitrary and capricious action on the part of the agency. To the contrary, the revised recommendations reflect the same principles advanced by the Final Rule—science based guidelines that acknowledge the low animal and human health risks associated with BSE when effective risk mitigation measures are in place.

The OIE streamlined its system for classifying countries according to relative risk for BSE, reducing the number of "risk" categories from five to three. The new classification system assesses whether the risk of BSE incidence is "negligible," "controlled," or "undetermined." See OIE Terrestrial Animal Health Code, Chapter 2.3.13.1, Bovine Spongiform Encephalopathy (2005). The new system is premised on the actual risk of BSE, giving greater weight to risk management and control than to estimated prevalence rates. Likewise, USDA/APHIS in the preamble to the Final Rule noted that "[w]hile there are many unanswered questions, both research studies and field epidemiological experience have demonstrated effective control measures to prevent spread of this disease.... Continued monitoring and surveillance in Europe – where the exposure is assumed to be the highest – have demonstrated the effectiveness of

control measures that have been enacted, such as feed bans that prevent the recycling of the agent. This increased body of knowledge provides a sound and compelling scientific basis for more focused regulatory restrictions with regard to BSE than those we have been operating under.” See 70 Fed. Reg. at 463 (AR 8047).

In addition, the OIE added boneless beef to the list of products that it recommends should be traded *without regard to a country’s BSE risk status*. Specifically, under the new guidelines, OIE recommends that:

- 1) When authorizing import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from cattle, *Veterinary Administrations* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the exporting country, zone or compartment:....
  - (g) deboned skeletal muscle meat (excluding mechanically separated meat) from cattle 30 months of age or less, which were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, and which were subject to ante- and post-mortem inspection and were not suspect or confirmed BSE cases; and which has been prepared in a manner to avoid contamination with tissues listed in Article 2.3.13.13...

OIE Terrestrial Animal Health Code, Chapter 2.3.13.1, Bovine Spongiform Encephalopathy (2005) (*italics in original text*). As noted, this recommendation applies to trade from all countries without regard to BSE risk status, let alone from a country like Canada with significant risk mitigations in place. Thus R-CALF’s request, made for the first time in its summary judgment motion, that this Court enjoin the importation from Canada of currently traded beef products flies in the face of the latest scientific consensus on the issue.

C. Canada Meets or Exceeds OIE Guidelines.

Canada meets or exceeds the recommendations established by the OIE, both as they existed at the time the Final Rule was adopted and as recently revised.

Feed Ban. As discussed in greater detail below, different countries and regions have faced different BSE challenges and have taken varied courses in mitigating risk, a reality that R-CALF ignores. While the feed ban in Canada has been in place for slightly less than the eight years recommended by the OIE (7 years and 9 months), it was implemented nearly 6 years before a case of BSE was ever identified in an animal native to North America. This preventive aspect of the feed ban is itself a significant safeguard against a BSE outbreak in North America, and creates an important distinction between the experiences and potential risks in North America and in Europe, where feed bans were adopted only after BSE was found and an epidemic was under way.

Surveillance. Canada has an effective surveillance system in place. While animal surveillance does not have a direct impact on human or animal health, it does provide insight into the status and incidence rate of BSE. Since 1996, Canada has exceeded the level of animal surveillance recommended by the OIE and tests an equivalent number of animals to the U.S. Where OIE guidelines recommend testing about 300 cattle each year, Canada tested 23,500 last year, and nearly 23,000 (22,883) in the first four months of 2005 alone. *See* Canadian Food Inspection Agency, "BSE Enhanced Surveillance Program," *available at* <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/surv/surve.shtml> (last visited June 9, 2005). Taking into account that Canada's annual kill is much smaller than that of the U.S. (Canada's 2004 slaughter was 3.9 million animals compared to the U.S. kill of 31.9 million), comparable U.S. testing would have examined about 180,000 animals in the first four months of 2005, while the actual number tested was 164,802. *See* APHIS, "USDA's BSE Test Results," *available at* [http://www.aphis.usda.gov/lpa/issues/bse\\_testing/test\\_results.html](http://www.aphis.usda.gov/lpa/issues/bse_testing/test_results.html) (last visited June 9, 2005).

Specified Risk Material Removal. SRMs are those materials most likely to be infected with the disease in an animal exposed to BSE. As in the U.S. and as recommended by the OIE for minimal risk countries, Canada removes the brain, eyes, spinal cord, skull and vertebral column from all animals over 30 months of age at the time of slaughter. Canada, like the U.S., also removes the tonsils and distal ileum from cattle of all ages.

Since most cattle slaughtered for human consumption in Canada are between 19-22 months of age, and since the average incubation period of BSE is at least 4-5 years, the likelihood of Canadian cattle at slaughter having developed BSE is very remote.<sup>12</sup> The removal of SRMs is an overlapping, and likely redundant, safeguard in the protection of human health.

## **II. R-CALF's Comparisons of BSE Experiences in North America with the Experiences of Other Countries is Not Meaningful**

R-CALF compares mitigation measures adopted in North America with those in place in the European Union and Japan (*See Exhibit 10 to R-CALF's Memo*) without recognizing the very different BSE experiences in these regions. The European Union (principally the United Kingdom) has had significantly more BSE cases than any other region in the world, in numbers far exceeding those in North America. Those numbers combined with the fact that feed bans were not implemented until after BSE cases started to appear, created an epidemic dynamic that is not present in North America. While Japan has had fewer BSE cases than Europe (although significantly more than North America), the Japanese mishandled their initial BSE outbreak,

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<sup>12</sup> *See Updated Risk Analysis at 13 (AR 8331)* ("Young cattle exposed to low levels of BSE will accumulate very little BSE infectivity within the first few years of life, suggesting that Canadian cattle under 30 months of age are highly unlikely to have accumulated significant BSE infectivity, even if exposed."). Studies in the U.K. demonstrate a longer incubation period as exposure doses become smaller (*Updated Risk Analysis at 13 (AR 8331)*), therefore in Canada (with far less BSE exposure than the U.K.) the incubation period will likely be longer than the mean of 4.2 years in the U.K. *See Declaration of Lisa Ferguson, Senior Staff Veterinarian for Veterinary Services, APHIS, attached as Ex. 2 to USDA/APHIS' Opp. to Plaintiff's Motion for Preliminary Injunction (Feb. 22, 2005) at ¶15.*

thereby creating consumer concern, and have subsequently allowed the adoption of mitigation measures to be driven by political concerns, not science.

A. United Kingdom/European Union

Comparing the European BSE experience and the mitigation measures adopted there with the BSE situation in North America is simply not valid. Not only do the more than 180,000 BSE cases in the U.K.<sup>13</sup> and other European countries dwarf the four cases in North America, but the knowledge accumulated about the disease and its containment and prevention has grown tremendously since these other countries experienced their outbreaks. *See* Declaration of Frank Fillo, Assistant Chief and Supervisory Economist of the Policy Analysis and Development staff of APHIS (“Fillo Dec.”) at ¶11 (attached as Ex. 3 to USDA/APHIS’ Opp. to Plaintiff’s Motion for a Preliminary Injunction). R-CALF’s comparison of the U.K./European BSE experience with conditions in North America is contrary to the record evidence.

To fully understand the singularity of the U.K. experience, one has to appreciate that at the time of the U.K. outbreak BSE was an unknown disease – neither its origin nor transmission was understood. It was only with the evolution of the disease in the U.K. that its transmission route came to be understood, and, with that understanding, the importance of a ruminant-to-ruminant feed ban became apparent. As the unhappy pioneer in BSE control, the U.K. instituted a feed ban in July 1988, two years after the identification of its first BSE case in 1986. *See* 70 Fed. Reg. at 461-462 (AR 8045-8046). However, due to the long incubation period of BSE (U.K. data reflect a mean of 4.2 years (70 Fed. Reg. at 470 (AR 8054)), even after the advent of the feed ban, the numbers of identified cases of BSE continued to increase as cattle infected prior

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<sup>13</sup> As of January 1, 2005, the U.K. had 180,687 confirmed cases of BSE, representing 95 percent of all BSE cases worldwide. Declaration of Frank Fillo, at ¶11.

to the feed ban reached the end of their incubation periods.<sup>14</sup> Not until the cattle infected prior to the feed ban worked their way through the system did the annual numbers of infected cattle decrease.<sup>15</sup>

Having observed the U.K.'s epidemic experience, the U.S. and Canada had the foresight to implement a preventive feed ban in 1997, well before the identification of any BSE case native to North America.<sup>16</sup> The importance of this proactive implementation of the feed ban, almost six years prior to the first occurrence of a North American BSE case in May 2003, cannot be overstated – it effectively prevents the replication here of the spike in post-feed ban cases seen in the U.K. This is because the feed ban here does not have to “catch-up” with the lag created by the incubation period, as it did in the U.K. While there may be a small number of isolated cases yet to be identified in North America, the early implementation of the feed ban explains why the epidemic experienced in the U.K. has not, and will not, occur here. *See Updated Risk Analysis at 24-25 (AR 8342-8343).*

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<sup>14</sup> Following implementation of the feed ban in the United Kingdom, 12,739 cases of BSE were reported among cattle born in 1989; 2,104 in 1994; 9 in 1999; and 1 in 2000. *See 70 Fed. Reg. at 462 (AR 8046); Updated Risk Analysis at 16-17 (AR 8334-8335).*

<sup>15</sup> R-CALF tries to make much of the fact that in the U.K. cases of BSE occurred in many cattle born after the implementation of the feed ban. *See F-CALF's Memo at 17.* R-CALF ignores, however, the reason for such cases and the unique complexity of the U.K.'s situation. In the early stages of BSE understanding, it was not appreciated that BSE was being contracted through cross-contamination of cattle feed with pig and poultry feed. In 1994, the issue of cross-contamination and the continuing infection that it caused was fully realized and acted on. The number of BSE cases dropped significantly as a result. *See Committee of the BSE Inquiry, United Kingdom, "The BSE Inquiry: Inquiry Into BSE and Variant CJD in the United Kingdom (Oct. 2000) available at <http://www.bseinquiry.gov.uk/report/volume1/chapte35.htm> (last visited April 19, 2005).* Importantly, in spite of these now-recognized early deficiencies, the feed ban still dramatically decreased the incidence of BSE in the U.K. among all animals.

<sup>16</sup> One BSE positive animal was discovered in Canada in 1993. This animal was imported from the U.K. and was not native to North America. *See 70 Fed. Reg. at 467 (AR8051).*

B. Japan.

R-CALF's comparisons with Japan – a country that has unjustifiably closed its market to U.S. exports – are more puzzling than its comparisons with Europe. While Canada and the U.S. carefully observed events in the U.K. and applied the lessons learned there to construct BSE firewalls in North America, Japan did nothing of the sort, failing to even adopt a complete feed ban until October 2001, after its first case of BSE was found. With three BSE cases that year and no effective feed ban in place, Japanese consumers lost confidence in the safety of their beef. *See* Washington State University College of Agricultural Human and Natural Resource Sciences, “Consumers Key to Ending Meat Crisis” (Jan. 5, 2004), *available at* <http://cahenews.wsu.edu/RELEASES/2004/04001.htm> (because of loss of consumer confidence in Japanese government, beef consumption fell to half of customary levels). Like Europe, and unlike Canada and the U.S., Japan fell behind the BSE incidence lag created by the disease's long incubation period. Thus Japan had two more BSE cases in 2002; four in 2003; five in 2004; and four so far in 2005. *See* OIE, Number of Reported Cases of Bovine Spongiform Encephalopathy (BSE) in Farmed Cattle Worldwide, *available at* [http://www.oie.int/eng/info/en\\_esbmonde.htm](http://www.oie.int/eng/info/en_esbmonde.htm) (last visited June 7, 2005).

In a misguided and scientifically baseless effort to restore consumer confidence, Japanese food safety officials implemented a mandatory 100 percent testing regime in October 2001.<sup>17</sup> *See* Final Report, Japan – United States Working Group (July 22, 2004) at 9 (AR 1626). In so doing, Japan became the poster child for how not to respond to an outbreak. Unfortunately U.S.

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<sup>17</sup> Indeed, Japan is in the process of revising its policy of testing all cattle. *See* The Food Safety Commission, The Prion Expert Committee, “Outline of Report (Excerpts from Conclusion): Food Safety Risk Assessment Related to Measures Against Bovine Spongiform Encephalopathy (BSE) in Japan” (May 6, 2005) at 1, *available at* <http://www.fsc.go.jp/sonota/outlinereport170419.pdf>.

and Canadian exporters are paying the price for these unscientific requirements, with Japan only recently indicating a willingness to move away from their 100 percent testing requirements, possibly opening the door to resuming beef trade with both the U.S. and Canada. Unlike in Japan, as a result of the preventive measures implemented by the U.S. and Canada, North American consumers have remained confident in their consumption of North American beef, even following the announced discoveries of BSE cases.<sup>18</sup>

To follow a course set by Japan would be to irresponsibly abandon all of the knowledge of BSE and its management gained over the last decade.<sup>19</sup> As USDA has observed, the current testing methodology cannot accurately test for BSE until approximately three months prior to an animal exhibiting clinical signs of BSE. *See* Ferguson Dec. at ¶14. Thus R-CALF's suggested imposition on North American consumers and producers of the unnecessary and significant costs<sup>20</sup> to conduct BSE testing of all Canadian cattle is particularly disturbing. *See* Van Sickle Dec. at ¶9 (stating that if Europe and Japan test healthy cattle at slaughter to promote consumer

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<sup>18</sup> *See* Fillo Dec. at ¶4 (“USDA data indicate that consumer demand for beef has remained strong in both Canada and the United States since the 2003 discovery of BSE in North America. Canadian per capita beef consumption increased by 1.1 kg in 2003 and U.S. demand in 2004 is estimated to have increased 7-8% over 2003 levels.”).

<sup>19</sup> In addition to its non-science based test policies, it should be noted that Japan was one of very few countries that voted against the updated OIE guidelines. *See* Grand Forks Herald, “OIE Adopts New Standards on Anti-BSE Measures” (May 30, 2005), *available at* <http://www.grandforks.com/mld/agweek/business/industries/agriculture/11772005.htm>.

<sup>20</sup> Testing is estimated to be \$30 per animal. *See* National Cattlemen's Beef Association, “Large Cost to U.S. Cattle Producers of 100 Percent BSE Testing Cited” (April 21, 2004), *available at* <http://www.beefusa.org/newslargecosttouscattleproducersof100percentbsetestingcited20136.aspx> (NCBA economist “says tests would cost \$30 per animal or more when all costs, such as the kits, labor, shipping, holding, laboratory facilities and others, are included.”). To have cattle producers expend enormous amounts of money testing all cattle, even though such a course is scientifically unsupported, does far greater long term harm to the health of the industry than taking the time and effort now to educate the public about the minimal risk of BSE, the protective safeguards that are in place, and the fact that cattle are tested for BSE, not for safety but to determine the prevalence of the disease. The testing of young animals is particularly wasteful – because of the long incubation period for BSE, they never test positive. Such consumer education will ensure that public reaction is tempered, even in the face of future BSE cases that could arise.

confidence, then such testing by the U.S. should it import Canadian cattle “would tend to reduce consumer fears about BSE-contaminated meat entering the food supply.”). As USDA has observed, the limitation of the current testing methodology could not accurately test for BSE in an animal until approximately three months prior to an animal exhibiting clinical signs of BSE. *See Ferguson Dec.* at ¶14. Clearly the only purpose that would be served by adopting such a policy would be the creation of an economic advantage for R-CALF’s members.

### III. USDA’s Rulemaking Satisfied the Regulatory Flexibility Act

R-CALF contends that USDA/APHIS failed to comply with the Regulatory Flexibility Act (“RFA”), and that consequently the Final Rule should be remanded to the agency to perfect such compliance. No such remand is warranted. Here, R-CALF compounds its misinterpretation of the essentially procedural requirements of the RFA<sup>21</sup> with faulty economic analysis.

In this context, R-CALF’s reliance on the declaration of Dr. John VanSickle is particularly misplaced. For example, Dr. Van Sickle contends that subsequent discoveries of multiple BSE cases could have a “significant” impact on consumer demand, and cites as support for that statement an economic study by Coffey and Schroeder. *See Van Sickle Dec.* at ¶ 6. However, Dr. Van Sickle fails to bring to the Court’s attention the study’s caveat that “given the various biases to which survey responses are subject, and efforts related to how those questions are framed, our results cannot be interpreted with any confidence to predict a significant reduction in beef demand if new cases of BSE are found.” *See Coffey, et al., Kansas State*

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<sup>21</sup> *See Environmental Defense Center v. EPA*, 344 F.3d 832, 879 (9<sup>th</sup> Cir. 2003) (“[T]he analyses required by the RFA are essentially procedural hurdles; after considering the relevant impacts and alternatives, an administrative agency remains free to regulate as it sees fit.”).

University, "The Economic Impact of BSE on the U.S. Beef Industry: Product Value Losses, Regulatory Costs, and Consumer Reactions" (April 2005) at 51.

Likewise, Dr. Van Sickle's attempt to turn the reopening of export markets such as Egypt and Taiwan to U.S. beef into a Canadian induced burden on the U.S. industry is unpersuasive. *See* Van Sickle Dec. at ¶8. The closure of these and other export markets to U.S. beef was in response to a finding of BSE in Washington State in December 2003. The continued closures of various export markets are due to subsequent evaluations of U.S. (not Canadian) safeguards and BSE preventive measures. *See, e.g.*, USDA Press Release No. qa0465.04, "Questions and Answers Concerning U.S.-Japan Beef Trade Agreement" (Oct. 24, 2004) *available at* <http://www.usda.gov> (discussing age verification methods and international review of BSE situation in Japan and U.S.); *see also* USDA Press Release No. 0131.04, "Statement by Agriculture Secretary Ann M. Veneman and U.S. Trade Representative Robert B. Zoellick Regarding Beef Trade with Japan," (Apr. 1, 2004), *available at* <http://www.usda.gov/Newsroom/0131.04.html> (discussing USDA disagreement with Japan regarding testing of all animals).

Both the U.S. and Canada have been working to expand market access for North American beef products and cattle. In some instances, like Hong Kong and Cuba, the markets have reopened first to Canada; in others like Taiwan and Egypt, the markets have reopened first to the U.S. In no instance where the U.S. or Canada has separately succeeded in regaining market access, have officials of the country in question suggested a particular concern regarding the safety of beef products from the other country. Canada has had on-going negotiations with both Taiwan and Egypt and expects to regain access to those markets, as well as others worldwide. *See, e.g.*, Canadian Beef Export Federation, "Inside the Export Marketplace" (April 30, 2005) at 5, *available at* [http://www.cbef.com/PDF/Inside\\_Export\\_2005-04.pdf](http://www.cbef.com/PDF/Inside_Export_2005-04.pdf) (noting that

Council of Agricultural Affairs Deputy Minister Dr. Lee Jen-Chyuan believes that Taiwan will soon re-open to Canadian beef).

USDA's view that Japan and other trading partners consider the U.S. and Canadian beef and cattle markets as integrated and will recommence trade with both at the same time, is almost certainly correct. In this regard the USDA's position is consistent with the international view that Canada and the U.S. have the same BSE risk. The European Union's BSE risk rating tool, the Geographic Risk Assessment ("GBR"), placed the U.S. and Canada in the same geographical risk assessment, both before and after the detection of BSE, and the International Review Team charged with assessing the U.S. response to the BSE case discovered in Washington State in December 2003 stated that "the first case of BSE in the U.S. cannot be considered in isolation from the whole cattle production system in North America" or "dismissed by considering it an 'imported case.'" "Report on the Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States," Feb. 2, 2004, at 4 (AR 8025).

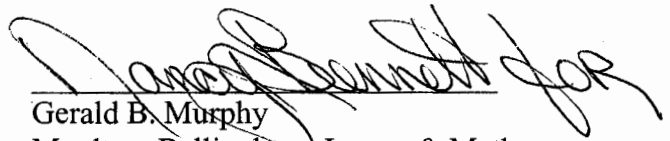
### **CONCLUSION**

In the penultimate paragraph of its "Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States," (Feb. 2, 2004) at 10 (AR 8031)), the International Review Panel recommended "that the U.S. 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." USDA/APHIS has demonstrated precisely this type of leadership in promulgating the Final Rule. In so doing, USDA/APHIS created the template necessary to open export markets based on sound science, rather than to see those markets remain closed based on irrational fear and economic self-interest. The United States and Canada have been working together to successfully construct a North American system governed by science so that in the event that any

further BSE cases are discovered in any part of North America, decision-making can be based on science, not baseless speculation. Both the United States and Canada have been working with Japan and other countries that impose trade restrictions, masquerading as safety standards, well beyond anything recommended by the OIE or having a basis in sound science, to achieve a rational and sustainable trade policy for cattle and beef. R-CALF's version of the "facts" is not undisputed. The USDA/APHIS record supports the Final Rule, is not based on arbitrary and capricious determinations and should therefore be upheld by this Court. R-CALF's motion for summary judgment should be denied.

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Respectfully submitted,



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I hereby certify that I caused a true and accurate copy of the foregoing brief *amicus curiae* of the Canadian Cattlemen's Association in Opposition to R-CALF's Motion for Summary Judgment was sent via Federal Express overnight mail (postage prepaid) and via electronic mail to the following:

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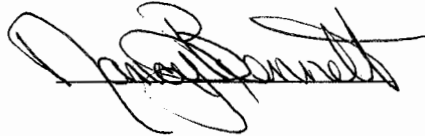
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A handwritten signature in black ink, appearing to read "Scott G. Gratton", written over a horizontal line.