

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,) Cause No.CV-05-06-BLG-RFC
ANIMAL AND PLANT HEALTH INSPECTION)
SERVICE, et al.,)
Defendants)

**DECLARATION OF GARY A. WEAVER, D.V.M., Ph.D., Esq, IN SUPPORT OF
MOTION FOR SUMMARY JUDGMENT**

I, Gary A. Weaver, D.V.M., Ph.D., Esq, certify and state as follows:

1. My Qualifications

I am a Senior Fellow at the Center for Food and Nutrition Policy, Virginia Tech in Alexandria, VA. My areas of expertise at Virginia Tech include agroterrorism, bioterrorism, animal health, plus food safety and security.

I worked counterterrorism issues at the Food and Drug Administration after serving as an Intelligence Officer at the Central Intelligence Agency. Earlier in my career, I was a member of the Thomas M. Cooley Law Review before becoming a criminal defense lawyer.

As a veterinary pathologist, I directed the pathology group of the Wisconsin Veterinary Diagnostic Laboratory. While a Research Fellow at the University of Minnesota, I published 20

scientific papers and was admitted to both the veterinary medical honor society Phi Zeta, plus the agriculture honor society Gamma Sigma Delta. My doctoral thesis "Experimental Mycotoxicoses in Food-producing Animals" studied the effects of T-2 mycotoxins in cattle, swine, and poultry. My research was completed about the time the United States began openly speculating that the Soviet Union-backed North Vietnamese were using T-2 mycotoxins as a biological weapon called "Yellow Rain." This was later proven true.

I am a licensed veterinarian and a licensed lawyer. I hold a JD *cum laude* from Thomas M. Cooley Law School in Lansing, MI; an MS and PhD in Veterinary Pathology from the University of Minnesota; a BSVM and DVM from the University of Illinois Urbana-Champaign; and a BS in Zoology from Northern Illinois University.

In my current position, I have been monitoring bovine spongiform encephalopathy (BSE) issues and reviewing current literature on BSE as much as possible. Last year, I hosted a BSE roundtable organized by Virginia Tech's Center for Food and Nutrition Policy.

2. Recent modifications to the BSE guidelines of the Office International des Epizooties (OIE) make it clear that Canada's BSE surveillance data and BSE mitigation measures do not qualify it as a region with negligible risk of BSE.

Recent modifications made to the 2005 Terrestrial Animal Health Code of the Office International des Epizooties (OIE) make it clear that Canada does not qualify as a region with negligible risk of BSE. While Canada's stated BSE risk mitigation measures would presumably allow it to meet the criteria for a region with a controlled risk of BSE, Canada fails to meet two important conditions for that category: First, as discussed in Attachment A, Canada's ongoing BSE surveillance program falls well short of the surveillance levels recommended by the OIE. Second, and as discussed also in Attachment A, Canada does not meet the OIE requirement that all birth cohorts, born within 12 months of each of the four indigenous BSE cases detected in Canada, be destroyed. As a result, Canada meets only the requirement of a region with undetermined BSE risk and must, according to these international guidelines, make substantial

improvements to its BSE mitigation and surveillance measures in order to elevate itself from this OIE category that reflects significant uncertainty for BSE risks. Until Canada implements upgraded measures such as expansion of its present ban on specified risk materials (SRMs) to include a ban on the use of SRMs in animal feed and fertilizer and modification of its SRM removal policy to begin removing such high-risk tissues in animals over the age of 12 months, neither cattle nor beef products traded by Canada meet the criteria even for a controlled risk region of the new OIE guidelines.

3. Numerous historical facts make it more likely that BSE infectivity is circulating in Canadian cattle than in cattle raised in the United States.

Numerous historical facts make it more likely that BSE infectivity is circulating in Canadian cattle than in cattle raised in the United States. Unlike the United States, which acted more decisively in response to the emergence of BSE in the United Kingdom, Canada lagged behind in instituting even rudimentary precautions. As discussed in “Canada’s BSE Risk Profile is Inherently Higher than that of the United States,” Attachment B, Canada lagged behind the U.S. in making BSE a reportable disease, in imposing import restrictions on ruminant and ruminant products from BSE-affected countries, and in implementing a national surveillance program. Even after the discovery of its 1993 case of BSE in a cow imported from the United Kingdom, Canada initially reduced, rather than increased, its BSE surveillance. It did not enact a feed ban until four years later. Evidence suggests that the birth cohorts of the 1993 case were rendered in Canada, and they may well be the source of Canada’s present BSE incidents. Canada’s early and documented exposure to the BSE agent, several years prior to the implementation of the feed bans in both the United States and Canada, suggest that the BSE agent was free to recycle within the Canadian cattle herd years before the feed ban would have begun to arrest such amplification. Only by monitoring the ongoing evolution of the BSE

disease in Canada, by testing sufficient numbers of cattle over time, can the full scope and direction (whether the disease incidence is waning or advancing) of Canada's BSE problem be accurately estimated.

I declare under penalty of perjury that the foregoing is true and correct. Executed on June ____, 2005.

Gary A. Weaver

ATTACHMENT A

The USDA Final Rule, May 2005 Revisions to OIE BSE Guidelines, and Canada

In May 2005, the World Organization for Animal Health (OIE) revised its recommendations for managing the human and animal health risks associated with bovine spongiform encephalopathy (BSE). The revised guidelines are available at http://www.oie.int/downld/SC/2005/bse_2005.pdf.

A. OIE Recognizes Three BSE Risk Categories

The OIE now has three risk categories. In descending order of risk they are: Undetermined BSE Risk (Art. 2.3.13.5), Controlled BSE Risk (Art. 2.3.13.4), and Negligible BSE Risk (Art. 2.3.13.3).

Canada does not meet the lowest risk category

Canada does not meet the criteria for the OIE category of least risk, Negligible BSE Risk, because it has had at least one indigenous case of BSE within the previous 7-year period (Art. 2.3.13.3 (3)), and because it has not “demonstrated, through an appropriate level of control and audit” that ruminant feed has not been fed to ruminants for “at least 8 years.” *Id.*

Canada does not meet the moderate risk category

Based on factors existing in Canada on the date the USDA Final Rule was published, i.e., January 4, 2005, and which factors are clearly identified in the Final Rule or accompanying administrative record, Canada also does not meet the moderate risk category, Controlled BSE Risk. Canada fails to meet the following factors recommended for a region with Controlled Risk:

1. Canada does not meet the recommended surveillance levels of a region with a Controlled BSE Risk. Art. 2.3.13.4 (2). The criterion requires a country with Canada’s demographics to test about 187,000 cattle per year. According to the Final Rule and accompanying record, Canada was testing at a “current” level of only 15,800 cattle per year (AR008052) when the Final Rule was published, and plans to test about 30,000 cattle in 2005. AR008053.
2. According to the Final Rule, Canada has not also met the criteria of permanently identifying, controlling the movements, and, when slaughtered or at death, completely destroying all the cattle born in the same herd as, and within 12 months of, the birth of (referred to as birth cohorts), each of the four indigenous BSE cases detected in Canada between 2003 and 2004. Art. 2.3.13.3 (3)(iii). The administrative record reveals that Canada has only traced and destroyed “the majority of surviving cattle that were birth cohorts of the May 2003 and December 2003 cases of Canadian origin.” AR008328.

Canada also did not identify all birth cohorts of its 3rd BSE case, reporting that “four animals were untraceable because of missing records.” *See:* <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2005/2investe.shtml> (SAR012832-34). Canada also did not identify all birth cohorts of its 4th BSE case, reporting that “three animals were deemed untraceable because of inadequate records.” *See:* <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2005/3investe.shtml> (SAR012901-904).

Canada meets only the highest risk category

Based on Canada’s failure to meet the criteria for either a region of Negligible BSE risk or Controlled BSE risk, Canada meets only the criteria for the highest risk category of the OIE, Undetermined BSE Risk. Art. 2.3.13.5.

B. Risk Mitigation Measures Recommended for Undetermined BSE Risk Countries

The OIE recommends specific risk mitigation measures that increase in intensity as a country’s risk profile increases. Such measures are recommended for both live cattle and beef products. The measures for mitigating the risks from Undetermined BSE Risk countries are the most stringent measures recommended by the OIE. Canada does not presently meet even the minimal criterion recommended for this risk category.

Canada does not meet the minimal risk mitigation measures for live cattle

The Final Rule and the administrative record show that Canada does not meet the minimal OIE recommendations for ensuring the safe trade in live cattle. Canada fails to meet the criterion established by the OIE for the following reasons:

1. Canada does not have an effectively enforced feed ban. Evidence submitted by R-CALF USA and others in the administrative record show significant breeches in the Canadian feed ban as late as 2004 (AR001634-1636), including the rendering of the BSE-positive cow in 2003 into feed and the subsequent exposure to that feed by Canadian cattle. AR009734. (Because exposure was found to have likely occurred in 3 out of 200 farms, then exposure likely occurred on 27 farms total ($3/200 = 27/1800$). But, only 3 were mitigated. Therefore, it is likely that the 24 additional farms were exposed to the rendered cow in 2003, and no mitigation measures were implemented). In addition, the Canadian government stated in 2004 that “assessing non-compliance and the effectiveness of the ban remains difficult. AR009735. In addition, the Canadian BSE-positive cow detected on January 11, 2005, was born March 21, 1998, nearly 8 months after the date of implementation of Canada’s feed ban, providing empirical evidence that Canada’s feed ban was not effective since at least some time after March 1998. See Report of the Investigation of the Third Case of Bovine Spongiform Encephalopathy (BSE) in Alberta, Canada, Feb. 11, 2005, at AR012901. As recently as July 30, 2004, Defendant was informed by the Canadian government that 31 of 416 Canadian feed mills were non-compliant with Canadian BSE regulations in 2002, and 28 of 533 feed mills

remained non-compliant in 2004. Presumably included in these numbers are 10 feed mills found non-compliant involved in situations where direct contamination of ruminant feeds with prohibited materials had occurred during 2003 to 2004. Letter from Canada to U.S. at AR011388 – AR011389. Additionally, as recently as December 2004, Defendant knew that Canada had conducted a pilot feed ban compliance program for cattle feed during January, February, and March of 2004 and found evidence of prohibited meat-and-bone meal in as many as 9 of the 109 samples tested during that period, indicating a failure rate as high as 8 percent. Memo to Administrator at AR011628. In its 2005 assessment of Canada's feed ban, USDA indicates that from 2002 through 2003, 5.8 percent of Canada's feed mills were sufficiently non-compliant with Canada's BSE rules to warrant regulatory sanctions. During 2004 through 2005, there remained 3.8 percent of Canada's feed mills meeting this level of objectionable conditions or practices. Assessment of the Canadian Feed Ban, USDA, February 2005, at AR 012632, see also AR012623-24.

The month following Canada's May 2003 detection of a BSE-positive cow, a Canadian government-sanctioned international scientific review team submitted a report informing the Canadian government of steps needed to adequately address its first indigenous case of BSE. This report suggested the following measures to prevent the further spread of BSE in Canada:

- A ban on specified risk materials (SRMs) in animal feed. Report in Response to BSE, June 26, 2003, at AR009577.
- Implementation of measures to avoid the inclusion of any ruminant-derived meat-and-bone (MBM) meal in ruminant feed. *Id.*
- Eliminate opportunities for possible cross contamination of ruminant feed. *Id.*
- Implementation of a system that avoids cross feeding of rations containing ruminant MBM among multiple species raised on Canadian farms. *Id.* at AR009578.

To date, Canada has failed to adopt these additional measures.

2. Canada did not permanently identify for purposes of ensuring that all cattle born in the same herd as, and within 12 months of the birth of (referred to as birth cohorts), each of the four BSE cases detected in Canada are destroyed. Art. 2.3.13.8 (2)(c). The administrative record states that Canada has only traced and destroyed "the majority of surviving cattle that were birth cohorts of the two May and December 2003 cases of Canadian origin." AR008328. Canada did not also identify all birth cohorts of its 3rd BSE case, reporting that "four animals were untraceable because of missing records." *See:* <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2005/2investe.shtml> (SAR012832-34). Canada did not also identify all birth cohorts of its 4th BSE case, reporting that "three animals were deemed untraceable because of inadequate records." *See:* <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2005/3investe.shtml> (SAR012901-904).

3. The evidence in the administrative record of significant breeches in the Canadian feed ban as late as 2004 demonstrates that Canada does not meet the requirement of limiting its live cattle imports to only those born at least 2 years after the feed ban was “effectively enforced.” Art. 2.3.13.9 (3)(b).

Canada does not meet the minimal risk mitigation measures for beef products

Canada does not meet the minimal risk mitigation measures recommended by the OIE for beef and beef products and the Final Rule does not prescribe comparable measures to achieve the minimal safety level sought by OIE recommendations. The Final Rule is deficient in the following respects:

1. Contrary to the OIE recommendation of prohibiting tonsils and distal ileum from cattle of any age in the preparation of feed and fertilizer (Art. 2.3.13.13 (1)), the Final Rule only prohibits such tissues from the human food chain, thus intensifying the potential for BSE amplification. AR008049, 8050.
2. Contrary to the OIE recommendation that all specified risk materials SRMs, i.e., brains, eyes, spinal cord, skull, vertebral column and derived protein products, be removed from cattle over 12 months of age at the time of slaughter (Art. 2.3.13.11(2)(a); 2.3.13.13(3).), Canada, like the United States, currently removes such tissues only from cattle over 30 months of age under the current USDA permitting process and under the Final Rule, thus exposing consumers to unnecessary and avoidable risks. AR008049, 8050.
3. Contrary to the OIE recommendation that all SRMs described in (2) above from cattle over 12 months of age not be used in preparing feed or fertilizer (*Ibid.*), Canada, like the United States, only prohibits SRMs from the human food supply, thus intensifying the potential for BSE amplification. AR008049.
4. Contrary to the OIE recommendation to ensure that beef or beef products not contain “nervous and lymphatic tissues exposed during the deboning process (Art. 2.3.13.11 (2)(d).), no such restriction is imposed by USDA. The FSIS does not even recognize cerebral fluid and spinal fluid as SRMs (AR009999) and its proposed method of removing “readily identifiable” SRM contamination by knife trimmings (*Ibid.*) appears inadequate in view of the consequences associated with inadvertent exposure to infected tissue.
5. Contrary to the OIE recommendation to prohibit mechanically separated meat from the skull and vertebral column from cattle over 12 months of age (Art. 2.3.13.11(2)(c).), the Final Rule only prohibits such practice for cattle over 30 months of age, thus exposing consumers to unnecessary and avoidable risks. AR008050.

Canada does not meet the minimal risk mitigation measures for gelatin

The OIE does not contemplate trade in gelatin and collagen prepared from bones (either for human food or animal feed) with countries with an Undetermined BSE Risk. Art. 2.3.13.14.

Moreover, even for countries considered a moderate risk, Controlled BSE Risk, the OIE recommends stringent risk mitigation measures that are not required by the Final Rule. With respect to gelatin, the Final Rule states:

In this rule, we are allowing the importation of gelatin from a BSE minimal-risk region only if the gelatin is derived from bovines from which SRMs have been removed in the exporting region, and, further, that the bovines from which the gelatin was derived were subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration. AR008087.

This requirement is orders of magnitude less restrictive than the following OIE recommendations for countries with a Controlled BSE Risk – the more favorable risk category Canada does not meet:

1. Skulls and vertebrae are excluded. Art. 2.3.13.14(2)(a).
2. The bones have been subject to a rigorous procedure that includes pressure washing, sterilization at least at 138 degrees centigrade for at least 4 seconds, and acid demineralization. Art. 2.3.13.14(2)(b)(i-v).

Despite OIE's recommendation that countries with an Undetermined BSE Risk prohibit gelatin from feed, and that countries with a Controlled BSE Risk restrict the use of skulls and vertebrae irrespective of age from gelatin extraction, Canada allows gelatin even in ruminant feed. AR008051. Canada, however, acknowledges the risk associated with this practice and is at least contemplating a ban on the use of gelatin in ruminant feed. AR009738.

C. Surveillance Testing Recommended by the OIE

The OIE has recently clarified the need for greatly expanded BSE surveillance programs in order for countries to ascertain the prevalence of BSE within their herds.

Maintenance testing for countries with no detected cases of BSE

The OIE recommends that countries with no detected cases of BSE and which meet the Negligible BSE Risk category should conduct surveillance at a "maintenance level." Art. 3.8.4.3(2), see also AR010131,AR010132. The OIE more specifically tabulates levels of testing sufficient to allow the detection of BSE prevalence of at least one case per 50,000 in the adult cattle population (i.e., twenty times the one case per million rate that USDA and Canada discuss), at a confidence level of 95 percent. Art. 3.8.4.3(2). Canada, with four confirmed cases of BSE detected within the past two years, does not meet even these criteria for countries using only a "maintenance level" surveillance program.

Nevertheless, applying the two OIE tables contained in the OIE's recommendations for maintenance level surveillance at a country without BSE to Canada's cattle herd size and demographics, Canada would have to test about 94,000 high-risk cattle between the ages of 4 to 7 years of age, and that are non-ambulatory or that are sent for emergency slaughter or

condemned at ante-mortem, in order for Canada to meet the OIE's least aggressive surveillance recommendation. See Table 1 and 2, Art. 3.8.4.4. This minimal international recommendation clearly shows the inadequacy of Canada's testing levels to date reported by Hueston et al. at less than 56,000 total cattle tested since 2003, the year Canada discovered an indigenous case of BSE. Hueston et al. at 31.

More aggressive testing for countries with BSE

As Dr. Tony Cox explains in a second declaration prepared in support of R-CALF USA's Motion for Summary Judgment, the OIE recommends a more intensive testing regime for countries with known cases of BSE in their domestic herds, as a means of determining prevalence and for monitoring the evolution of the disease following its detection. Applying OIE tables 1 and 2 again (to obtain lower-bounds on the required sample sizes, as these tables are developed for countries with no known disease prevalence), Dr. Cox estimates for Canada, "187,500 consecutive targeted cattle (with a BSE risk equal to that in the "Casualty slaughter, age between 4 and 7 years" subpopulation in Table 2), should be tested and found BSE-free to be confident that the BSE prevalence is not more than 1 in 100,000 – even in a country that (unlike Canada) has not identified any BSE cases."

Until and unless Canada increases testing above that recommended by the OIE for countries without known cases of BSE, neither the United States nor any other potential importing country will be able to make an informed decision about the actual risks presented by cattle and beef originating in Canada. Dr. Cox's suggestion that Canada increase testing between 187,000 and 1.9 million cattle is comparable to the testing levels conducted in other regions of the world where, like Canada, multiple cases of BSE have been detected.

OIE persists in encouraging importing countries to test imports from known BSE sources

The OIE includes in its recommendations for targeting subpopulations of cattle likely to harbor BSE the subpopulation of cattle identified as imported from countries not free of BSE. Art. 3.8.4.2, see also AR010077. Commenters, including R-CALF USA have urged USDA to trace, identify, and test all cattle that were imported into the United States from Canada prior to the border closure in 2003 as a means of determining whether or not the BSE agent has entered the U.S. by that route. AR004624, 4626; AR001512, 1513. Such a reasonable, internationally recommended surveillance measure would ensure that any BSE cases detected in the U.S. would be properly attributed to the country of origin of the infected animal. AR000621.

ATTACHMENT B

Canada's BSE Risk Profile Is Inherently Higher than that of the United States

June 26, 2005

- The United States made BSE a reportable disease in 1986 (Harvard 2003 at AR003740), the same year BSE was first detected. Final Rule at AR008045. Canada waited several years, until November 1990 to make BSE a reportable disease. Canada Risk Assessment, 2002, Appendix 1 at AR002665.
- The United States prohibited the importation of ruminants and most ruminant products from all BSE countries in 1989. Harvard 2003 at AR003740, see also Brown et al. at AR011647. Canada instituted a ban on only live cattle from the U.K. in 1990, after importing 14 head of cattle and six head of sheep from the U.K. that year. Canada Risk Assessment, 2002, at AR002558, AR002664, see also Final Rule at AR008051. Canada did not institute a ban on cattle from all countries where BSE had been diagnosed in native cattle until 1994. Canada Risk Assessment, 2002, at AR002665. It was not until 1998 that Canada instituted a ban on the importation of sheep and goats, and it did so at that time in order to harmonize its policies with that of the United States. Canada Risk Assessment, 2002, at AR002666. Canada imported four shipments of sheep from Denmark in 1992-94, less than a quarter of which were still alive and could be located and killed when Denmark found its first case of BSE in Feb. 2004.
- The United States implemented an active BSE surveillance program in 1990. Harvard 2003 at AR003740. Canada did not begin its active surveillance program until 1992. Final Rule at AR008052.
- Canada discovered its first case of BSE in December 1993, in a cow imported from the U.K.. Canada Risk Assessment, 2002, at AR002665. Canada “potentially rendered” 68 cattle imported from the U.K. prior to discovering its first case of BSE. *Id.* at AR002561.

Ten of these cattle were known to originate from BSE-infected farms in the UK, two of which were known also to be herdmates of the BSE-infected cow discovered in 1993. *Id.*

- The Harvard Center for Risk Analysis states that while the United States may have rendered 173 cattle imported from the U.K. prior to 1989, “none came from a birth cohort [same birth farm and year] in which a BSE case is known to have developed.” Harvard Study, 2003, at AR003720.
- As of May 31, 2005, the United States has tested 433,183 cattle in the cattle population considered to be of highest risk for BSE, and while two positive cases have been detected, one was known to have been imported from Canada (December 2003), and the origin of the other is not yet known (June 2005). See generally Hueston et al. Dec. at 31. Canada has tested only 64,788 cattle in its cattle population considered to be of highest risk for BSE, and four BSE-infected cows have been detected in its domestic cattle herd (including the 2003 cow detected within the United States). *Ibid.*
- The year immediately following the United State’s discovery of an imported cow with BSE, the United States increased its BSE testing from 20,543 cattle to over 176,460 cattle. See generally Hueston et al. at 31. The year immediately following Canada’s discovery of an imported cow with BSE, Canada decreased its BSE testing from 645 cattle to 426 cattle. Canada Risk Assessment, 2002, Part B, at AR002622.
- The United States had its feed ban in place for over six years prior to detecting BSE in even an imported animal (August 1997 to December 2003). Canada, however, did not implement its feed ban until over three years after their discovery of BSE in an imported cow (December 1993 to August 1997). Note: The Canadian Risk Assessment, 2002, states that Canada’s August 4, 1997 feed ban was “[i]mplemented in October of 1997.” AR002665.