

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 LOUIS ANTHONY COX, JR., PH.D

Louis Anthony Cox, Jr., Ph.D. certifies and states as follows:

1. I am President of Cox Associates, Incorporated (www.cox-associates.com), an independent applied research company specializing in health risk analysis and operations research modeling. Cox Associates' mathematicians and scientists develop and apply computer simulation and optimization models, statistical and epidemiological risk analyses, and operations research decision models to improve health risk analysis and decision-making for public and private sector clients. I have been retained as an expert by both federal agencies and industry to help improve the statistical and risk modeling basis for effective risk management decision-making. Cox Associates is located at 503 Franklin Street, Denver, Colorado, 80218.

2. I received my Ph.D. in Risk Analysis in June 1986 from the Massachusetts Institute of Technology. I received an S.M. in Operations Research in 1985 from M.I.T.'s

Department of Electrical Engineering and Computer Science. I graduated from Harvard University in 1978 with an A.B., concentrating in mathematical economics. I am also a 1993 graduate of the Stanford University Executive Program.

3. I am currently Honorary Full Professor of Mathematics at the University of Colorado at Denver, where I lecture on topics in computational statistics, biomathematics, artificial intelligence, and quantitative health risk assessment. I am a member of the Faculty of the Center for Computational Mathematics at the University of Colorado at Denver. I have also been Clinical Professor of Preventive Medicine and Biometrics at the University of Colorado Health Sciences Center, where I conducted research on uncertainty analysis of epidemiological studies and mathematical models of disease causation. In addition I am a member of the Advisory Board of the Center for Human Performance and Risk Analysis of the University of Wisconsin

4. I am on the Editorial Board of Risk Analysis: An International Journal, and am a co-founder and Area Editor of the Journal of Heuristics. I am also a Fellow of the Society for Risk Analysis (SRA), a member of the American Statistical Association, and a recipient of the Operations Research Society of America's prestigious ORSA prize (1994) for the best real-world applications of operations research.

5. I have authored or co-authored numerous journal articles and book chapters on advanced aspects of risk analysis and applied statistics. A complete list of my publications is included in my curriculum vitae, which is attached to this Declaration as Attachment A.

6. Prior to founding Cox Associates in 1986, I was employed by Arthur D. Little, Inc., Cambridge, MA from 1980 to 1986 as Manager in the Applied Decision Sciences practice area and as a Senior Consultant in Operations Research. From 1978 until 1979 I was a Senior

Research Associate at the American Institutes for Research in the Social and Behavioral Sciences (AIR) located in Washington, D.C. and Cambridge, MA. In addition, from 1987 through 1996 I served as Senior Director/General Manager, U S West Advanced Technologies (USWAT), Boulder, Colorado.

7. I have reviewed and analyzed the *Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States* (2003) prepared by the Harvard Center for Risk Analysis of the Harvard University School of Public Health and the Center for Computational Epidemiology of the Tuskegee University College of Veterinary Medicine, as well as the documents entitled *Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States* (October 2003), *Explanatory Note. Risk Analysis: BSE Risk from Importation of Designated Ruminanats and Ruminant Products from Canada into the United States* (February 2004), and *Analysis of Risk-Update for Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities* (December 2004), prepared by the Animal and Plant Inspection Service (APHIS) of the United States Department of Agriculture (USDA). I have also reviewed other documents related to USDA's BSE policies and the APHIS rulemaking to establish a "BSE minimal-risk region" standard and designate Canada as a BSE minimal-risk region.

8. In connection with comments on the proposed BSE minimal-risk region rule last April, I prepared an Evaluation of the Adequacy and Appropriateness of Risk Analysis Used by the U.S. Department of Agriculture Animal and Plant Health Inspection Service in Support of Proposal to List Canada as a Bovine Spongiform Encephalopathy Minimal Risk Region. A copy of my evaluation was included as Exhibit B in comments on the proposal submitted by R-CALF USA on April 7, 2004. My evaluation concluded that the information provided by USDA's

Risk Analysis does not provide a reasonable basis from which to make an informed decision on whether to increase the importation of ruminants and ruminant products from Canada. It does not provide the essential technical information needed to inform risk management decision makers about potential risks, including information about exposures, currently estimated true prevalence rates of BSE in Canada, error rates under BSE-prevention safeguards, potential for unusually large or severe adverse consequences of BSE cases under some conditions, and remaining uncertainties.

9. I have reviewed the final rule titled "Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities; Final Rule and Notice," January 4, 2005, 70 Fed. Reg. 460 (the "Final Rule"), as well as other materials that USDA has made available in connection with the publication of the Final Rule. Many of the shortcomings I identified in USDA's assessments of the risks of the proposed rule persist in USDA's risk analysis for the Final Rule. The current USDA Risk Analysis does not contain information needed to understand relevant risks to U.S. cattle and consumers from a decision to relax protections against BSE by reopening the border to Canadian cattle and meat.

10. Although the USDA has claimed (only qualitatively) that it believes the risk of beef imports from Canada to be minimal or low, it has presented no calculations or objective, data-driven, quantitative analyses to support such a claim. Calculations by the Harvard Center for Risk Analysis, cited by USDA in support of its rulemaking to establish a new, "BSE minimal-risk region" standard that would apply to Canada, did not consider the Canadian situation *per se*, nor a situation of ongoing imports of Canadian ruminant products, let alone an expansion of such imports. Moreover, a close reading of that study shows that it allows for the possibility that importing any BSE positive cattle from Canada could spark an epidemic if some

of the "worst-case" -- but not impossible or necessarily highly improbable -- conditions considered in the analysis turn out to be accurate. In fact, subsequent events raise questions about some of the key optimistic assumptions underlying USDA's Risk Analysis.

11. Available data show conclusively that the long-standing previous assumption that Canada has a negligibly "small" risk of BSE in its herds can no longer be maintained. To date, limited testing has resulted in four confirmed cases of BSE-infected Canadian cattle: one found in May 2003 in Alberta; one in December 2003 in Washington State, in a cow that had been imported from Alberta in 2001; one 8-year-old cow in Alberta that tested positive for BSE in December 2004 and was confirmed January 2, 2005; and one 6-year-old cow in Alberta that was confirmed to have BSE on January 11, 2005. While the absolute number of Canadian cattle proven to have BSE is small, the important issue, for risk assessment purposes, is the prevalence rate in Canadian cattle. Testing performed to date suggest that this rate is far from negligible. Additionally, the true prevalence of BSE in various subsets of the Canadian herd (by region, age, etc.) is also unknown.

12. According to the government of Alberta, from 1996 until March 2004 2,769 cattle were tested for BSE in Alberta. One case was confirmed to have BSE. From April 2004 to December 2004, perhaps 4,000 more cattle were tested, and another case was found. By early January 2005, an addition 1,300 cattle had been tested, and yet another case of BSE had been found. If the true prevalence of BSE in Canadian cattle were "minimal" or "very low," one would not expect to be seeing such ratios of cattle tested to BSE cases found. Canada has been testing only cattle believed to have the highest chance of infection with BSE: e.g., animals with obvious signs of potential neurological disorders and those that have died of unexplained causes. Based on the European experience, this targeted set of cattle might have a BSE infection rate as

much as 60 times higher than the rate in non-targeted cattle. If one assumes that the observed incidence rate in testing in Alberta to date, which is around one in 3,000 among tested animals, represents a 60-fold greater incidence of BSE infection than in non-targeted animals, then the test results to date suggest a possible true BSE prevalence rate greater than about 5.5 cases per million head of cattle. This is the same order of magnitude as the BSE incidence rate found in countries considered to have a serious BSE problem, such as France and Germany. Moreover, unlike those countries, there is no historical trend in BSE testing results in Canada to indicate that the rate of BSE infection in the Canadian herd is decreasing.

13. The discovery of a BSE-infected cow in Washington State that had been imported from Canada demonstrates the potential for BSE infection to be brought into the United States from Canada. Based on testing that has been performed on Canadian cattle, it is highly likely that the Final Rule will result in additional BSE-infected cattle being brought into the United States. For example, if, under the Final Rule, imports from Canada return to about 1.7 million head per year, then a true BSE prevalence rate of even three cases per million head of imported cattle would imply a probability greater than 99 percent that at least one BSE-positive animal will be imported into the United States per year. (This ignores geographic or other heterogeneities in the rates for individual cattle, which could increase the probability further.)

14. It has been suggested that, because all but one of the four Canadian-raised cattle that have tested positive for BSE were born before Canada implemented its ban on ruminant protein in ruminant feed (the "Canadian feed ban"), the BSE incidence rate in Canada is likely decreasing as more and more animals are born after the implementation of the Canadian feed ban. This conjecture is only speculative: it does not provide an adequate scientific or statistical basis for allowing importation of Canadian cattle and beef. A much higher level of testing, and

testing of both targeted animals and animals without any outward signs of disease, are needed to determine the true BSE prevalence in the Canadian herd and whether it is decreasing.

(Relatively low levels of testing of targeted animals recommended by the OIE for monitoring *whether* BSE has entered a country are entirely insufficient for determining the incidence of the disease once it is known to be present.)

15. So far, the ages of the animals that have tested positive for BSE do not demonstrate the effectiveness of the Canadian feed ban at all. USDA believes that the median incubation period for BSE in cattle is 4.2 years (70 Fed. Reg. 470). All four cases of BSE in Canadian-raised cattle, however, were found more than 4.2 years after the Canadian feed ban. In fact, the latest two cases were about 7.5 years after the effective date of the Canadian feed ban, and USDA believes that 7.5 years is the 97.5th percentile of the estimated incubation period; i.e., there is a 97.5 percent statistical confidence that a cow will have signs of BSE within 7.5 years after initial infection. If the four Canadian cows known to have BSE contracted it from contaminated feed, the probability is that they consumed that contaminated feed after the effective date of the feed ban. These *facts* demonstrate the inappropriateness of *assuming* that the Canadian feed ban is effective in controlling BSE and that BSE rates in Canada are very low and falling.

16. USDA's conclusion that the human health risk of importing Canadian cattle and meat is "very low" is based on assumptions for which USDA has not demonstrated justification. For example, USDA has assumed that the incidence of BSE in Canadian cattle is very low, which is inconsistent with the discovery of four Canadian cases among the Alberta animals tested. That USDA, almost immediately upon discovery of the third and fourth cases of BSE in Canadian cow, declared that this new information would make no difference in USDA's

conclusion that the risks of the Final Rule to animal and human health demonstrates the inadequacy of USDA's risk analysis in failing to condition upon relevant data. USDA acknowledges that the measures it believes will protect U.S. cattle and consumers — the U.S. and Canadian feed bans, removal of SRMs, etc.— are imperfect. Thus, there is *some* risk associated with importing Canadian cattle or meat if Canadian cattle may have BSE. It is not credible that the *magnitude* of the risk does not depend on how large a portion of Canadian cattle are discovered to have BSE.

17. USDA says that the single most important measure in protecting human health is the removal of Specified Risk Materials (SRMs) such as the brain, skull, eyes, spinal cord, and other neurological materials from cattle 30 months of age and older and the tonsils and distal ileum of the small intestine from all cattle. However, recent scientific data raise questions about the assumption that SRM removal is sufficient to thoroughly protect humans consuming meat from a BSE-infected cow. For example, some studies have now reported accumulation of the prions believed to cause BSE, and similar afflictions in other mammals, in skeletal muscle cells of rodents, sheep, and humans; accumulation in tongues of hamsters; indications that the human analog of BSE is transmitted through blood transfusions; surprisingly high incidence of prions in the appendices of people not known to have vCJD in the U.K.; prion accumulation in kidneys and other non-nervous-system tissue in mice; and identification of more than 20 confirmed cases worldwide of BSE in cattle less than 30 months of age. This information makes it inappropriate to assume that humans will *not* be exposed to the BSE infectious agent just because SRMs are supposed to be removed before meat is taken from the carcass. At a minimum, USDA should explain why its assumption is appropriate, for purposes of assessing the risk of the Final Rule, in light of these developments and should perform a sensitivity analysis and communicate th results

to the public on the potential consequences if USDA's assumption is incorrect. In light of the facts suggesting that SRM removal alone may only reduce but not eliminate the risk of BSE exposure for consumers, allowing additional ruminant-derived products from Canada from animals over 30 months of age appears to be especially imprudent, as multiple studies recognize this is the age group posing the highest risks of BSE contamination.

18. Similarly, USDA's assumption that importation of Canadian cattle presents minimal risk of infection of U.S. cattle is based on the assumptions that: (a) there is minimal risk of BSE infection in the Canadian herd and (b) if a BSE-infected Canadian cow enters the United States it will not transmit BSE to cattle in the United States, because of the U.S. feed ban. The first of these two assumptions, as explained above, appears to be inconsistent with recent BSE testing data from Canada. The second is also questionable. For example, the U.S. feed ban does not prevent use of bovine blood in animal feed, despite evidence that vCJD can be transmitted through blood. The U.S. feed ban does not prevent tallow from rendered cattle from entering animal feed, even though USDA acknowledged that it could not dismiss the possibility of transmission of BSE through ingestion of tallow infected with BSE. The ban does not prevent contamination of animal feed when poultry waste is used in animal feed and ruminant protein has been used in poultry feed. Moreover, it now appears that 2004 data from the Canadian Food Inspection Agency indicate that a large proportion of Canadian feed labeled as containing vegetable material only in fact contained noticeable contamination with mammalian protein. USDA has not quantified the risk that the U.S. feed ban will be ineffective at preventing the transmission of BSE from infected Canadian cattle imported into the United States, and thus has not provided an adequate basis for a public policy decision as to whether that risk is acceptable.

19. Some of USDA's key assumptions and conclusions about risk and about the likely effectiveness of risk mitigation measures do not appear to take available data into account fully and do not appear to be well justified by that data. For example, USDA appears to assume in justifying its current actions that BSE cases do not occur or have negligible probability in cattle below a certain age threshold (such as 30 months) and in certain products derived from cattle (such as meat and organs such as the tongue, heart, kidneys and tripe). Current understanding of the disease itself and recent data (such as the detection of BSE in Japan and Europe in cattle less than 30 months old) demonstrate, however, that such assumptions may be seriously mistaken. They should be updated in order to provide a more responsible, fact-driven, quantitative risk assessment that more fully reflects existing data and that can better inform risk management decisions and policies about the probable bovine and human health consequences in the U.S. of actions such as increasing imports of ruminants or ruminant-derived products from Canada.

20. Past and current surveillance programs indicate that the BSE rate in Canada may be high enough to make importation of BSE-infected cattle or beef products into the U.S. over the next few years a virtual certainty under USDA's recent action. It is also not unlikely that BSE will be detected in cattle 30 months and younger. It is not only plausible, but highly probable that the USDA's current surveillance and enforcement activities, together with a prevalence rate of BSE in Canada that is fully consistent with the data, could allow many instances of BSE-contaminated products to enter the U.S. before any are detected, thus creating a potential health problem that will not be detected until it is too late to prevent.

21. Available data allow a rough order-of-magnitude estimate of the potential adverse human health impacts of allowing imports of Canadian beef products. For example, assume that

approximately 1 billion pounds ($1E9$ lb.) of beef products were to be imported into the U.S. from Canada per year (<http://cnas.tamu.edu/publications/MCOOLBeef.pdf>), and that a small fraction of these pounds were contaminated with BSE. Then the number of BSE-contaminated pounds of Canadian beef products consumed per year in the U.S. might be roughly approximated by multiplying the following factors:

- $3.6E-6$ = estimated fraction of Canadian meat products from BSE-positive cattle
- 1% = fraction of such products with contamination remaining after processing at levels sufficient to cause vCJD in a susceptible consumer (based on an assumed SRM failure rate of 1% (Sugiura K, Ito K, Yokoyama R, Kumagai S, Onodera T., A model to assess the risk of the introduction into Japan of the bovine spongiform encephalopathy agent through imported animals, meat and meat-and-bone meal. Rev Sci Tech. 2003 Dec;22(3):777-94).
- A cattle-man barrier that might be as low as 1, but that is very uncertain (<http://www.mhlw.go.jp/shingi/2003/05/s0530-12j3.html>).
- 1 billion pounds ($= 1E9$) of Canadian beef products imported into U.S. per year

This would give an estimate of 36 pounds per year (or about 72 half-pound servings per year) of imported Canadian beef products that would be expected to be significantly BSE-contaminated. If approximately 40% of U.S. consumers are susceptible to vCJD from eating such contaminated servings, and if 72 servings per year can potentially cause vCJD in such consumers, then the expected number of exposures of susceptible consumers to BSE-contaminated servings that could cause vCJD is about $(0.4) \times (72) = 29$ *potential vCJD-causing exposures per year among U.S. consumers from imported Canadian beef products.* The probability of at least one such exposure per year under these conditions is essentially 1. This compares to a baseline estimate of

little to no expected cases of vCJD per year in the U.S. in the absence of Canadian imports (www.fda.gov/ohrms/dockets/ac/04/slides/4019S1_7.ppt).

22. While I do not consider a widespread health threat in the U.S. to be a highly likely consequence of re-introducing Canadian imports as proposed, it is not sufficiently unlikely to be dismissed or ignored. Simple calculations suggest to me that the probability of catastrophic economic and animal health consequences – with a much smaller risk of human health consequences – from relaxing standards for Canadian imports of cattle may be far too high to be acceptable if the risks were quantified, published, and publicly known. The probable economic and health consequences for the U.S. of increasing imports of ruminant products should be better quantified before a decision to allow such an increase is made.

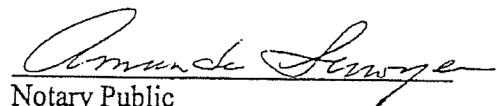
23. I am concerned that vague labels (such as "minimal") do not adequately convey the true risk associated with potential BSE contamination from Canadian ruminants and ruminant products entering the U.S., and thus may lull the public into accepting the re-introductions without understanding the risks involved.

To protect the public interest in the U.S., as well as animal and human health, I believe that it is essential not to weaken the requirements for Canadian beef imports imposed following the detection of BSE, unless and until a thorough, science-based, quantitative estimate of the risks (including uncertainties) of this action has been prepared and subjected to public scrutiny.

Dated: January 28, 2005

Louis Anthony Cox, Jr.
Louis Anthony Cox, Jr., Ph.D.

Sworn and subscribed to before me this 28 day of January 2005.


Notary Public
My commission expires 11-1-2008

