

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

RANCHERS CATTLEMEN ACTION LEGAL )  
FUND, UNITED STOCKGROWERS )  
OF AMERICA, )  
 )  
 ) Plaintiff, ) Cause No. CV-05060-BLG-RFC  
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 v )  
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 )  
 UNITED STATES DEPARTMENT OF )  
 AGRICULTURE, ANIMAL AND PLANT )  
 HEALTH INSPECTION SERVICE, et al., )  
 )  
 ) Defendants )  
 )  
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Third Declaration of Lisa A. Ferguson, D.V.M.

I, Dr. Lisa A. Ferguson, declare and state the following:

1. I have reviewed the declaration of Gary Weaver, D.V.M., Ph.D., Esq., included as Exhibit 9 to Plaintiff's Reply Memorandum in Support of its Motion for Summary Judgment.
2. In May, 2005, the World Organization for Animal Health (OIE) revised the provisions of the Terrestrial Animal Health Code Chapter relating to BSE. Like the old BSE Chapter (see, David Wilson Declaration ¶ 5), the new BSE chapter begins with a list of commodities which can be safely traded without requiring any BSE related mitigation measures, regardless of the BSE risk status of the cattle population of the exporting country or region. Significantly, boneless beef from cattle under 30 months of age has been added to the list, provided that the cattle were not subjected to certain stunning techniques, were subject to ante-

- mortem and post-mortem inspection, and the meat was not contaminated with specified risk materials. Blood and blood by-products were also added to the list provided that the cattle were not subjected to certain stunning techniques.
3. The new chapter also describes how to determine the BSE status of the cattle population of an exporting country. Like the old version (see, David Wilson Declaration ¶ 5), the new Chapter recommends that the importing country consider the following factors: 1) the outcome of a risk assessment identifying all potential factors for BSE occurrence and their historic perspective; 2) ongoing awareness program for veterinarians, farmers and workers; 3) compulsory notification and investigation of all cattle showing clinical signs consistent with BSE; and 4) an approved laboratory system to examine tissues collected. Under the revised Chapter, the recommended level of surveillance depends on the outcome of the risk assessment. Countries classified as “negligible risk” should conduct surveillance at a level to determine BSE prevalence in one case per 50,000 in the adult cattle population at a confidence level of 95%. It is recommended that all other countries conduct surveillance at a level to determine BSE prevalence in one case in 100,000 in the adult cattle population at a confidence level of 95%.
  4. The Chapter then describes the OIE criteria for specific BSE status classifications. The number of specific status classifications has been reduced from five (see, David Wilson Declaration ¶ 6) to three: Negligible BSE risk; Controlled BSE Risk; and Undetermined BSE Risk. The OIE expects importing countries to identify and evaluate through a risk assessment all of the potential risk factors for

BSE occurrence and management, and their historic perspective, in the exporting country. The OIE “would not consider it appropriate for the importing country to apply each criterion as an item on a checklist and conclude that the exporting country fails to qualify for a particular risk status merely because it does not meet a listed criterion within that particular status.” (See, David Wilson Declaration ¶ 7).

5. Dr. Weaver has incorrectly described Canada’s risk status under the new OIE BSE chapter by continuing to use this inappropriate “checklist” approach to reach his desired outcome. For example, Dr. Weaver contends that Canada does not qualify as a controlled risk region because it failed to permanently identify, control and destroy all the cattle born in the same herd as, and within 12 months of, the birth of each of the four indigenous BSE cases detected in Canada. Such an outcome is not at all intended by the OIE guidelines. If the OIE guidelines and recommendations were literally interpreted, as Dr. Weaver suggests, no country in the world with an indigenous case of BSE, including the United States, would ever qualify as a negligible or controlled risk country. The proper interpretation and application of this recommendation is that a country that routinely conducts effective epidemiological investigations of each case of BSE, such as Canada and the United States, and makes every effort to find the birth cohorts, meets this criterion, even if there are some cattle that cannot be successfully traced.
6. Finally, it should be noted that the final BSE minimal risk region rule establishes APHIS’ standards for BSE minimal risk regions. These requirements, while consistent with OIE recommendations, are not exactly the same as either the

previous or the current OIE chapter. They do, however, in combination with the import restrictions outlined in the final rule, provide equivalent risk mitigation measures.

7. In addition to the declaration, I have also carefully reviewed Attachment B entitled “Canada’s BSE Risk Profile is Inherently Higher than that of the United States”. Dr. Weaver is incorrect. He has gone to great lengths to create what he claims to be a list of factors that would distinguish the risk levels of the United States and Canada. While the factors identified by Dr. Weaver, including import restrictions, surveillance and reporting of BSE, are important risk profile factors, the differences in those factors identified do not bear significantly on the respective BSE risk status of the United States and Canada. For example, the date on which the United States and Canada made BSE a reportable disease, 1986 and 1990 respectively, does not contribute today to differences in risk profiles of the two countries. As to import restrictions, both the United States and Canada imported cattle from BSE countries, and both allowed those cattle to be rendered and used in ruminant feed prior to August, 1997, when both countries simultaneously implemented virtually identical feed bans. While both countries made every effort to trace and destroy all remaining imported cattle, neither country was able to locate and destroy all of them. Finally, contrary to Dr. Weaver’s thesis, both Canada and the United States have had solid surveillance programs and both have implemented enhanced surveillance programs in the last 12-18 months, which are comparable in scope and intensity, given the relative size of the herds and the targeted population in the two countries. As previously

mentioned, both countries put their feed bans in place in 1997 and both have worked to ensure compliance with those bans. Dr. Weaver's attempt to describe an inherently higher risk in Canada than the United States is wrong and is designed to artificially bolster the notion that Canada is not a minimal risk region for BSE.

8. Dr. Weaver's attempt to compare the responses to the 1993 positive BSE cow from a UK import found in Canada to the 2003 positive BSE cow from a Canadian import found in the United States is equally inapposite. The 1993 BSE case found in Canada occurred in a small, known group of imported cattle that were being monitored by Canada and the animal was excluded from the Canadian food and feed chain. Canada immediately took steps to remove any remaining UK imports in that country, a step that the United States did not follow. Under these circumstances, there was no scientifically supportable reason to increase BSE surveillance in Canada's native cattle population in response to finding BSE in an imported cow. In contrast, the 2003 BSE Canadian-origin positive BSE cow found in the United States was discovered after decades of substantial trade in cattle and other ruminant products, including rendered protein, between the United States and Canada. Given these circumstances, APHIS was unable to make a distinction in the risk profiles between the native cattle population of the United States and cattle imported into the United States from Canada. Therefore, the United States decided to substantially increase its surveillance and monitoring program and Canada did the same. Dr. Weaver's comparison also fails to

acknowledge the vast advances in the scientific knowledge and understanding of BSE made between 1993 and 2003.

9. I have also reviewed the Declaration of Gail Charnley, Ph.D., included as Exhibit 5 to Plaintiff's Reply Memorandum in Support of its Motion for Summary Judgment.
10. Dr. Charnley clearly has a demonstrated bias in favor of quantitative risk assessments, perhaps growing out of her work as a principal of a firm named HealthRisk Strategies. While asserting that qualitative risk assessments provide an inadequate basis for the agency's minimal risk region rule, Dr. Charnley never states that she has reviewed the administrative record for this rule and it is clear from her entirely conclusory declaration that she has not even looked at that record. The risk analyses conducted in support of this rule were done in accordance with internationally recognized scientific standards and relied on a multitude of sources, including: a quantitative risk analysis of the risk of BSE in Canada; a quantitative risk analysis conducted by the Harvard Center for Risk Analysis and Tuskegee University; a vast amount of empirical data provided by the Canadian government; results of extensive epidemiological investigations; the OIE guidelines; and an exhaustive review of the scientific literature. A review of the administrative record reveals that the risk analyses were conducted in an open, transparent manner and fully disclosed all of the underlying assumptions and facts upon which the agency relied. The findings and conclusions reached in this rulemaking are supported by objective, empirical data and scientific fact.

11. Dr. Charnley further states that if a quantitative estimate of risk cannot be supported, the risk should be “maintained at zero” until the needed data are collected. First, it should be noted that any implication that a regulatory prohibition is capable of maintaining zero risk is fallacious, as no regulatory provision is 100% effective 100% of the time. Further, such a result is not mandated by the Animal Health Protection Act, the statute pursuant to which this rule was promulgated, nor is it practically achievable in the real world. The Animal Health Protection Act provides that “...the Secretary may prohibit or restrict—(1) the importation or entry of any animal, article, or means of conveyance ...if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock.” There is thus no requirement that the Secretary conduct a quantitative risk assessment under the circumstances of the minimal risk region rule. Nor is there any requirement in the statute that the Secretary apply a “zero risk” standard. APHIS has never interpreted the statute as requiring a “zero risk” standard, which is virtually, if not completely, impossible to achieve. As APHIS pointed out in connection with this rulemaking, if trade were to be made dependent on zero risk, foreign, as well as interstate, trade in animals and animal products would cease to exist. (AR 8118) As the following statements from previous Federal Register documents illustrate, APHIS has routinely permitted the importation or interstate movement of animals and animal products under circumstances in which the risk of introduction or dissemination

of a livestock pest or disease is reduced to an insignificant or negligible level—  
but not to “zero”—

- a. “We believe these measures will mitigate the risk of introducing HPAI (highly pathogenic avian influenza) subtype H5N1 into the United States.” 69 FR 25821 (May 10, 2004).
- b. “The qualitative risk assessment indicated that such importations would present a negligible risk of introducing hog cholera into the United States. Based on the finding of negligible risk, we proposed to allow the importation of pork and products from Yucatan, Mexico.” 65 FR 1529 (Jan. 11, 2000).
- c. “If the accredited herd has undergone adequate surveillance...to ensure that individual animals moved from that herd present a negligible risk of being infected with tuberculosis, we do not believe it is necessary to subject animals from that herd to movement restrictions that would otherwise apply to the entire State or zone.” 65 FR 11913 (March 7, 2000).
- d. “To minimize the risk of disease introduction from imported horses moving from the port of entry to the permanent facility, we are proposing...” “The movement of horses from the port to the permanent facility poses no significant risk of transmitting communicable diseases of animals to the domestic animal population.” 67 FR 44100 (July 1, 2002).

I declare under penalty of perjury that the foregoing is true and correct.

Executed on July 12, 2005 at Washington, D.C.

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Lisa A. Ferguson, D.V.M.