

A. Clifford Edwards  
Taylor S. Cook  
Edwards, Frickle, Anner-Hughes, Cook & Culver  
1601 Lewis Avenue, Suite 206, P.O. Box 20039  
Billings, MT 59104  
(406) 256-8155  
Fax: (406) 256-8159  
Email: [edwardslaw@edwardslawfirm.org](mailto:edwardslaw@edwardslawfirm.org)

Russell S. Frye\*  
Collier Shannon Scott, PLLC  
3050 K Street, N.W., Suite 400  
Washington, DC 20007  
(202) 342-8878  
Fax: (202) 342-8451  
Email: [rfrye@colliershannon.com](mailto:rfrye@colliershannon.com)

William L. Miller\*  
The William Miller Group, PLLC  
3050 K Street, NW  
Fourth Floor  
Washington, DC 20007  
(202) 342-8416  
Email: [wmiller@radix.net](mailto:wmiller@radix.net)

Attorneys for Plaintiff

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

\_\_\_\_\_  
RANCHERS CATTLEMEN ACTION LEGAL FUND )  
UNITED STOCKGROWERS OF AMERICA, )  
P.O. Box 30715 )  
Billings, MT 59107 )

Plaintiff, )

vs. )

UNITED STATES DEPARTMENT OF AGRICULTURE, )  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE, )  
and ANN M. VENEMAN, IN HER CAPACITY AS THE )  
SECRETARY OF AGRICULTURE, )  
14th Street and Independence Avenue, S.W. )

Cause No. \_\_\_\_\_

**VERIFIED COMPLAINT  
FOR DECLATORY AND  
INJUNCTIVE RELIEF**

Washington, DC 20250 )  
 )  
 Defendants. )  
 )  
\_\_\_\_\_ )

The Plaintiff, Ranchers Cattlemen Action Legal Fund United Stockgrowers of America (“R-CALF USA”), through its attorneys, brings this action for declaratory and injunctive relief against the United States Department of Agriculture (“USDA”), Animal and Plant Health Inspection Service (“APHIS”), to prevent implementation of a decision that creates an unjustified and unnecessary increased risk of infection of the U.S. cattle herd with bovine spongiform encephalopathy (“BSE”) and of importing meat contaminated with BSE into the United States. On January 4, 2005, APHIS published a final rule relaxing restrictions on imports of live cattle and edible bovine products from countries known to have cases of BSE and allowing, subject to certain restrictions, the importation of cattle under 30 months of age from Canada and the importation of edible bovine products from Canada regardless of the animal’s age. “Bovine Spongiform Encephalopathy, Minimal-Risk Regions and Importation of Commodities; Final Rule and Notice,” 70 Fed. Reg. 460 (the “Final Rule”). Unless its implementation is enjoined, the Final Rule will expose U.S. consumers to increased risk of an invariably fatal disease associated with consumption of BSE-contaminated meat, will increase the risk of invariably fatal BSE infection in cattle in the United States, and will expose U.S. cattle producers to severe economic hardship.

PARTIES

1. Plaintiff Ranchers Cattlemen Action Legal Fund United Stockgrowers of America is a non-profit cattle association representing over 12,000 U.S. cattle producers on issues concerning

international trade and marketing. R-CALF USA's membership consists of cattle producers, cattle backgrounders, and independent feedlot owners. Its members are located in 44 states, and the organization has 49 local and state cattle and farm association affiliates representing several thousand more cattle producers in 20 states. R-CALF USA's purposes include representing its members' interest before agencies of the federal government and in court.

2. R-CALF USA has standing to bring this action on behalf of its members. As a result of USDA's action allowing importation of live cattle and edible bovine products from Canada, the market for R-CALF USA members' cattle will be adversely affected by the increased risk of BSE-contaminated meat being introduced into the United States; by the increased risk of BSE-infected live cattle being introduced into the United States; by the increased risk of contaminating U.S. cattle feeds with BSE resulting from the use of Canadian cattle products, e.g., blood, in the manufacture of cattle feeds; by the reduced export market for U.S. beef as a result of intermingling with potentially contaminated beef of Canadian origin, and by the increased supply of cattle and beef in the U.S. resulting from resumption of imports from Canada. Even by USDA's estimation, the Final Rule will have dramatic economic effects on U.S. cattle producers, with a present-value estimated cost of the Final Rule ranging from \$2 to \$3 billion. R-CALF USA members will also be adversely affected by the increased risk of disease they face when Canadian beef enters the U.S. meat supply. These injuries are caused by USDA's final action allowing importation of Canadian cattle under 30 months of age and edible bovine meat products from Canada, and these injuries could be mitigated or eliminated by an order declaring that action unlawful and enjoining importation of Canadian cattle and meat products.

3. The United States Department of Agriculture is an agency of the United States Government. It is responsible, *inter alia*, for implementing statutes enacted for the promotion of domestic agriculture and for the protection of humans and animals in the United States from the risk of disease. Those statutes include, *inter alia*, the Animal Health Protection Act, 7 U.S.C. §§ 8301 *et seq.* and the Meat Inspection Act, 21 U.S.C. §§ 601 *et seq.*

4. The Animal and Plant Health Inspection Service is a component service of the United States Department of Agriculture.

5. Ann M. Veneman is Secretary of the United States Department of Agriculture. She is sued in her official capacity only.

#### JURISDICTION AND VENUE

6. This Court has jurisdiction over this action under 28 U.S.C. § 1331 (federal question jurisdiction), § 1346 (United States as Defendant), 5 U.S.C. §§ 702-704 (Administrative Procedure Act), and 5 U.S.C. § 611(a) (Regulatory Flexibility Act), and it may issue a declaratory judgment under 28 U.S.C. §§ 2201-02.

7. Venue is proper in this Court under 28 U.S.C. § 1391(e) because the Plaintiff resides in the State of Montana, the Plaintiff's principal place of business is in Montana, and Defendant USDA is an agency of the United States.

#### FACTS GIVING RISE TO THIS ACTION

8. Bovine spongiform encephalopathy ("BSE"), commonly known as "mad cow disease," is a invariably fatal, progressive, irreversible, neurodegenerative disease that causes progressive

degeneration of the brain and central nervous system of cattle. BSE is a member of a notorious family of diseases, known as transmissible spongiform encephalopathies (“TSEs”) that are generally believed to be caused by extremely hardy transmissible agents called prions. Prions are abnormal proteins that seem to cause normal cellular protein to convert to the abnormal form.

9. The agent that transmits BSE does not respond to immunization, and it is extremely resistant to sterilization, remaining infectious even after being heated to 600 degrees C.

Transmission of BSE can occur when cattle consume feed or supplements that contain bovine protein, typically meat and bone meal. While this is believed to be the primary route of BSE transmission in the past, there is no conclusive scientific proof that it is the only route, and it is unknown what other routes of transmission may be available. Studies have shown that consumption of as little as one milligram of tissue containing BSE prions can result in contracting BSE.

10. Scientists generally agree that the agent that causes BSE in cattle may cause a similar condition in humans known as variant Creutzfeldt-Jakob Disease (“vCJD”). Variant CJD is an invariably fatal, progressive, incurable, neurodegenerative disease in humans. Most experts believe that consumption of bovine protein contaminated with the BSE agent is the most likely way humans contract vCJD, though recent studies have shown it also can be transmitted via blood transfusions between humans. Over 150 people have died of confirmed or suspected cases of vCJD, which is always fatal and for which there currently are no cures, treatments, or vaccines. At least one confirmed death from vCJD has occurred in the United States, but presumably as a result of consuming BSE-contaminated meat in the United Kingdom. Because vCJD has a long incubation period of several to many years and there is no test available to

determine whether an individual will develop clinical symptoms of vCJD, the actual number of cases of vCJD infection is unknown.

11. The BSE epidemic began in the United Kingdom, possibly as early as the 1970's. It is theorized that BSE in cattle originated from the disease scrapie in sheep. BSE spread widely in the UK cattle herd, presumably largely through consumption of feed contaminated with BSE-infected animal protein. BSE has spread from the UK to native-born cattle in over 20 other countries, including Canada.

12. The United States has prohibited importation of ruminants, ruminant meat, and other ruminant products from countries known to have BSE since 1989. A feed ban was instituted in the United States in 1997 to prevent the recycling of potentially infectious cattle tissue. In addition, active disease surveillance methods have been put in place to detect BSE. No case of BSE has been found in native U.S. cattle, although over 230,000 animals considered to have a higher likelihood of having BSE have been tested to date. (This is in contrast to Canada, which has tested only about one-tenth as many cattle for BSE, and where three cows testing positive for BSE in the past two years were raised.)

13. APHIS regulations prohibit or restrict the importation of ruminants and of meat and other edible products of ruminants from countries that are listed as regions in which BSE exists, unless the Administrator of APHIS issues a permit in a "specific case." The regulations list the regions in which BSE exists. Canada was placed on this list in May 2003, immediately after a confirmed case of BSE was found in a native-born cow in northern Alberta province. (Canada had a confirmed case of BSE in 1993, but that was in a cow known to have been imported from the United Kingdom.) This had the effect of prohibiting all imports of live Canadian cattle and edible bovine products, unless authorized by a specific permit from APHIS.

14. USDA commissioned the Harvard Center for Risk Analysis and Tuskegee University to determine “the robustness of U.S. measures to prevent the spread of mad cow disease to animals and humans if it were to arise in this country.” The Harvard-Tuskegee analysis was completed in 2001 and revised in 2003. It concluded that the feed ban implemented in the U.S. in 1997 and the 1989 ban on the imports of live ruminants and ruminant meat and bone meal were the most effective measures at reducing the spread of BSE. USDA has assured Congress that the U.S. has robust controls in place to limit the spread of BSE, most notably by way of the USDA’s January 2003 BSE report to Congress, in which USDA touted the longstanding policy of prohibiting imports of cattle and meat products from countries known to have BSE.

15. On August 8, 2003, the Secretary of Agriculture announced that USDA would depart from its longstanding policy with respect to countries where BSE is known to exist and would begin accepting applications for import permits from Canada of boneless bovine meat from cattle under 30 months of age, and that USDA would commence a rulemaking to address imports of cattle and other edible bovine products from Canada.

16. On November 4, 2003, APHIS published notice of its proposal to amend its regulations to recognize a category of regions that present a minimal risk of introducing BSE into the United States via live ruminants and ruminant products, and to add Canada to this category. 68 Fed. Reg. 62,386 (the “Proposed Rule”). This notice represented a significant departure from the U.S. long-standing BSE prevention measures. Comments on the Proposed Rule were to be received by January 5, 2004. The comment period was later extended to April 7, 2004. In the March 8, 2004 notice extending the comment period, APHIS also stated, with little explanation, that it no longer believed one of the key protections in the Proposed Rule, the requirement that imports of

meat from Canada come from animals less than 30 months of age at time of slaughter, was needed.

17. R-CALF USA and numerous other interested groups, including States, submitted over 3,000 comments, many opposing the new rule. R-CALF USA emphasized that scientific evidence suggested that the regulation would expose the U.S. cattle industry to substantially greater and unnecessary risk that BSE would be introduced into the U.S. cattle herd. In addition, U.S. consumers would be subjected to both greater and unnecessary risk of contracting and dying of vCJD if the United States deviated from its longstanding policy of prohibiting the importation of ruminants and ruminant products from any country known to have BSE.

18. On December 23, 2003, a BSE-positive Holstein cow was found in the State of Washington. An investigation revealed that this animal was born in Canada and most likely was exposed to the BSE agent in Canada. The infected cow entered the United States as part of a shipment of live cattle that arrived in September 2001. The export markets reacted quickly to the discovery of a BSE-infected cow in the United States. United States beef was virtually shut out of all major export markets. Major importers such as Japan and South Korea continue to ban beef exports from the United States.

19. On December 29, 2004, Secretary Veneman announced the issuance of a final rule creating a category of regions with minimal risk of BSE, setting conditions for importation of ruminants and of meat and other ruminant products from such regions, and naming Canada as the sole region with that classification. The final rule, “Bovine Spongiform Encephalopathy, Minimal-Risk Regions and Importation of Commodities; Final Rule and Notice,” was published on January 4, 2005, at 70 Fed. Reg. 460 (the “Final Rule”).

20. Also on December 29, 2004, the Canadian Food Inspection Agency announced publicly that yet another cow in Alberta had been tentatively identified as having BSE. That diagnosis was confirmed on January 2, 2005. Neither the discovery of a BSE-infected Canadian-born cow in Washington State in December 2003 nor the discovery of an additional BSE-infected cow in Canada at the end of 2004 caused USDA to revise or seriously reconsider its determination that opening the border to Canadian cattle and meat would present little risk to U.S. animals, human consumers, and the livestock industry.

### CLAIMS FOR RELIEF

#### Count 1 – Administrative Procedure Act Section 706(2)(A)

21. Plaintiff repeats and realleges paragraphs 1-20.

22. Under the Administrative Procedure Act (“APA”), this Court must “hold unlawful and set aside agency actions, findings, and conclusions found to be – (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law....” 5 U.S.C. § 706(2). An agency acts in a way that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law when it fails to apply criteria for its action contained in relevant statutes, applies criteria for its decision not authorized by its statutory authority, fails to consider relevant information, fails adequately to explain the basis for its action or to respond to important public comments, acts inconsistent with the purpose and intent of the statutes granting it authority, or takes action that is not supported by the administrative record for that action.

23. The Final Rule relaxes APHIS’ longstanding prohibition, contained in 9 C.F.R. § 93.401, of the importation of live cattle and other ruminants from countries where BSE is known to exist.

It also relaxes the existing ban on imports of edible products of ruminants from countries where BSE is known to exist, contained in 9 C.F.R. § 94.18. These import bans were consistent with international practice and were intended to prevent the transmission of BSE to native cattle herds and to prevent potential vCJD in domestic human consumers of ruminant products.

24. There is a presumption against relaxation of animal and human health protections, such as the pre-existing ban on importation of live ruminants and ruminant products from countries where BSE is known to exist. Any relaxation of such an import ban can lawfully be taken only after assessment of the risk that such relaxation poses for the health of domestic animals, human health, and the welfare of the domestic livestock and related industries. Secretary Veneman's own Advisory Committee on Foreign Animal and Poultry Diseases has cautioned against making any relaxation in BSE protections until a thorough and scientific risk assessment is completed. USDA's decision to relax import restrictions for Canada and other countries that satisfy the criteria for a "region of minimal risk for BSE" is founded on USDA's conclusion that importation of live cattle and edible bovine products under the conditions described in the Final Rule presents acceptable risks of BSE infection in the U.S. cattle herd and the U.S. meat supply and acceptable risk of vCJD for U.S. citizens from consumption of BSE-contaminated meat.

25. APHIS justifies the Final Rule with its conclusion that the risk to animals and humans in the United States is "low." APHIS has not conducted a quantitative assessment, or even a supportable qualitative assessment, of that risk, however, nor has it defined what "low" is; i.e., how many head of cattle in the U.S. might be expected to contract BSE, how much of the U.S. meat supply might be contaminated with the BSE infective agent, and how many U.S. consumers may be at risk for contracting vCJD. APHIS' failure to quantitatively assess these risks and to describe with some particularity what "low" risk the United States is accepting as a result of

opening the border to Canadian cattle and meat renders the Final Rule arbitrary and capricious and an abuse of agency discretion.

26. Neither APHIS' December 2004 "Analysis of Risk – Update for the Final Rule" document, nor the Harvard-Tuskegee risk assessment updated in October 2003, the primary documents on which APHIS relies for its conclusion that the risks presented by the Final Rule are acceptable, even purports to assess the risk to human health from consuming BSE-contaminated meat, either imported from Canada or produced in the United States from Canadian cattle. In fact, many of the "barriers to the introduction and establishment of BSE" that APHIS concludes will provide adequate protection are irrelevant to risk from human consumption of BSE-contaminated meat, and especially BSE-contaminated meat allowed to be imported from Canada under the Final Rule. The lack of any scientific assessment of the most important issue for the Final Rule—whether the health of U.S. consumers will be endangered—renders the Final Rule arbitrary and capricious and an abuse of discretion.

27. APHIS' conclusion that the risks presented by the Final Rule are "low" is based upon numerous assumptions that are either unsupported or contrary to scientific evidence. Moreover, in instances where the scientific evidence was equivocal or contradictory, APHIS generally has chosen to assume facts that would suggest a lower risk, rather than the precautionary approach of assuming that the scientific studies or theories presenting the higher risk are correct. In this regard, for example APHIS:

- a) Assumed very low incidence of BSE in the Canadian cattle herd, despite the fact that Canadian testing for BSE to date has been of too small a sample to determine the rate of BSE infection in Canadian cattle, whether born before or after implementation of the Canadian feed ban. APHIS relied on Canadian Food Inspection Agency modeling of

the risk of BSE in the Canadian herd that was completed in 2001, at a time when Canada had conducted only minimal testing for BSE and had not yet identified one, yet alone three, subsequent cases of BSE in native Canadian cattle. In fact, APHIS assumed very low incidence of BSE in the Canadian herd, while available data collected since 2001 would, if representative of the entire native cattle herd, suggest a BSE incidence on the order of that of the most BSE-affected countries in the world. Ignoring these facts, APHIS acts as if Canada is still conducting surveillance testing “to detect the disease *should it exist* in [Canada’s] cattle populations.” 70 Fed. Reg. at 517 (emphasis added).

b) Assumed virtually no risk that BSE-infected cattle or meat will enter the United States, despite the fact that, if the Canadian-born animals tested so far are representative of the Canadian herd (suggesting a true BSE prevalence in the Canadian herd of at least 3-4 cases per million head of cattle), it is highly probable that BSE-infected animals or meat will enter the United States under the Final Rule.

c) Assumed that Canadian rules excluding certain animal protein from ruminant feed (the “Canadian feed ban”) are effective, in the face of, *inter alia*, a 2004 Canadian Food Inspection Agency study showing that 20 of 28 samples (71 percent) of Canadian-manufactured feed labeled as vegetable-only contained undeclared animal protein; Canadian investigations that indicate almost 2000 head of Canadian cattle may have been exposed to BSE-contaminated feed because of the rendering of the BSE-infected animal discovered in Canada in May 2003; a U.S. Government Accounting Office study in 2002 showing inadequate enforcement and significant noncompliance among U.S. feed producers with a similar feed ban in the United States; and the conclusion of USDA’s own International Review Team responding to the discovery of the BSE-

infected cow in Washington State that "...the partial ruminant to ruminant feed ban that is currently in place [in the U.S.] is insufficient to prevent exposure of cattle to the BSE agent." The assumption that the Canadian feed ban is completely effective is also fundamental to the assumption that cattle younger than 30 months are unlikely to have BSE.

d) Assumed that the Canadian feed ban has had and will have the same effect of reducing the incidence of BSE in Canada as the European feed ban has had in Europe, despite the fact that European countries also prohibit the use of ruminant blood products and rendered animal fat in cattle feed, which Canada does not. This distinction is a critical one, given that blood has now been scientifically identified as a vector for transmitting prions such as those that can cause BSE, and given that APHIS has acknowledged that: "Based on scientific evidence currently available, it is not possible to dismiss the possibility that ingestion of tallow infected with BSE creates a risk of the transmission of BSE." 70 Fed. Reg. at 501.

e) Assumed that the Canadian feed ban has prevented and will prevent BSE infection in animals born after Canada promulgated its feed ban in August 1997, based on experience in the UK and Europe, despite the fact that the UK documented over 45,698 cases of BSE (over one-quarter of all BSE cases detected in the UK) in cattle born during the 12 years following the implementation of its 1988 feed ban.

f) Assumed that BSE infectivity resides only in "Specified Risk Materials" ("SRMs") (e.g., brain, eyes, vertebral column) and that SRMs can be completely removed without exposing any of the remaining meat to contamination with the BSE infectious agent, in spite of information that the human form of BSE can be transmitted

through blood and that TSE prions can be found in skeletal muscle cells of hamsters, mice, sheep, and humans, and not just in nerve fibers. In fact, USDA acknowledged the potential of transmission of BSE through blood when it decided that it was necessary to ban importation of fetal blood serum from Canada, and yet USDA ignored the implications of this risk for importing meat and cattle from Canada.

g) Assumed that cattle under 30 months of age do not carry significant accumulations of BSE prions, and that most of the body parts considered SRMs need only be removed from cattle 30 months of age and older, despite more than 20 confirmed cases of BSE worldwide in cattle younger than 30 months and despite requirements in the European Union that SRMs be removed from all cattle over 12 months of age and in Switzerland that some SRMs be removed beginning at six months of age.

h) Assumed that nonambulatory (“downer”) cattle (which USDA believes are more likely to have BSE) in Canada will not be slaughtered for purposes of producing edible products destined for the United States, despite the facts that (a) the Final Rule contains no such restriction on imports and (b) the present Canadian regulations allow nonambulatory cattle to be used for human consumption in Canada and therefore do not provide certainty that nonambulatory cattle will not be used for meat exported to the United States.

i) Assumed that requirements for removal of SRMs from cattle slaughtered in Canada for production of meat or carcasses destined for the United States will be 100% effective, without sufficient information indicating that such measures currently are effective in Canada and in the face of recent information from the union of U.S. food

safety inspectors that USDA Food Safety and Inspection Service requirements for removal of SRMs from animals over 30 months of age often are not being met at U.S. slaughter facilities.

j) Relied, through its reliance on the Harvard-Tuskegee risk assessment, on key assumptions of exceedingly low error rates for sending prohibited material to appropriate rendering plants and feeding cattle properly labeled prohibited feed, without any validation or verification of those assumptions.

k) Asserted that the Final Rule “will continue to protect against the introduction of BSE into the United States” while at the same time acknowledging that it does not know if current regulations have been effective in preventing the introduction of BSE into the United States, and while removing rather than continuing regulatory protections that may have been contributing to keeping BSE out of the United States. Given advancements in the U.S. meat processing and distribution system in recent years, such that meat from one infected animal could be widely distributed in a matter of hours, USDA should have assumed (since it appears to lack any contrary data) that the risk of transmission once a BSE infected animal enters the U.S. is increasing rather than decreasing.

l) Acknowledged that the potential contamination of meat with BSE-causing prions at levels that are undetectable with current technology presents an unknown risk to consumers, and yet assumed that this unknown risk is acceptably low.

m) Stated that “early epidemiological work identified contaminated feed as the *primary* method of spread of the disease between animals” (70 Fed. Reg. at 463 (emphasis added)), but then simply assumed that no transmission between Canadian

cattle imported into the United States and U.S. cattle would occur through any other route. This despite recent scientific research finding TSE prions in the epithelial tissue covering the tongue of infected hamsters, and postulating that normal sloughing of such tissue into the saliva could provide a mechanism for BSE transmission between live cattle.

These and other unsupported or inaccurate assumptions render USDA's conclusion about the low risk of importing Canadian cattle and edible bovine products arbitrary and capricious and unsupported by the administrative record and by sound science.

28. The October 2003 revised Harvard-Tuskegee "Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States," upon which USDA relies extensively, states that the prevalence of BSE in the Canadian herd cannot be determined. In contrast, APHIS asserted in the preamble to the Proposed Rule that the prevalence was low, and in the March 8, 2004 Federal Register Notice and in the Final Rule that the prevalence is "very low," without explaining why the Harvard-Tuskegee conclusion was inaccurate. In fact, APHIS has never presented a meaningful assessment of the likely true incidence of BSE in the Canadian herd, nor has it attempted to evaluate the possibility of "clusters" of BSE infection in the Canadian herd. USDA also has not attempted any rigorous analysis of the ability of Canada to detect BSE in its herds, especially in light of the much lower rate of BSE testing in Canada than in the United States despite the demonstrated BSE infection in some Canadian cattle. More generally, APHIS simply seems unconcerned that the now three confirmed BSE cases in Canadian cattle are completely at odds with its prior assumptions. Each discovery of BSE in an animal raised in Canada increases the statistical probability that BSE-infected animals or meat will be brought

into the United States under the Final Rule, but APHIS has refused to recognize that scientific fact.

29. USDA has asserted that Canada has in place measures to prevent the transmission of BSE comparable to those in the United States, despite, for example, the facts that Canada tests orders of magnitude fewer animals and a substantially lower portion of its cattle herd for BSE, Canada does not exclude nonambulatory cattle generally from the human food supply, and other important distinctions. APHIS recognized in the preamble to the Final Rule and elsewhere that these protections omitted by Canada are important disease mitigation measures.

30. Because of the December 2003 discovery of BSE in a Canadian cow that had been imported into Washington State, 58 beef export markets were closed to United States producers, causing serious and continuing economic injury to major portions of the U.S. cattle industry. No cases of BSE have been found in native U.S. cattle after testing over 230,000 cattle, but commingling of Canadian cattle with the U.S. cattle herd and commingling of Canadian edible bovine products with the U.S. meat supply, especially without some requirement that edible products be identified as to country of origin, will likely interfere with or preclude the resumption of exports of edible bovine products from the United States. USDA failed to assess the economic impact of the Final Rule in terms of diminished exports and the effects that will have on U.S. producers and related sectors. USDA's postulation that the effect of the Final Rule may actually be salutary, by helping "convince other countries of the sanitary safety of both U.S. and Canadian beef," 70 Fed. Reg. at 541, is both speculative and counter-intuitive. USDA also assumed that the Final Rule would result in benefit to U.S. consumers because of the increased supply of feeder cattle in the United States, despite data from USDA's Economic Research

Service contradicting the assumption that a decrease in the price of cattle is likely to result, in the short term, in a decrease in the retail price of beef to the consumer.

31. By concluding that the risk presented by the relaxation of preexisting safety standards by the Final Rule is low, without attempting even a rudimentary credible quantitative assessment of the risk -- and without describing the level of risk that USDA considers to be “low”; by relying on key assumptions that either have no scientific support or are contrary to some or all of the available scientific data; by failing to identify and make available for public comment all of the data and assumptions upon which its risk assessment was based; and by otherwise basing its assessment of the Final Rule’s impacts on unexplained or unexplainable assumptions, USDA has acted in a way that is arbitrary, capricious, an abuse of discretion, and inconsistent with the administrative record and available scientific evidence. For these reasons, the Final Rule is unlawful and should be vacated and enjoined pursuant to 5 U.S.C. § 706(2)(A).

32. In connection with its decision to open the Canada-U.S. border on August 8, 2003 to boneless beef from cattle under 30 months of age, APHIS explained that “whole muscle boneless cuts of beef” are very low risk because they “do not contain the types of nervous system tissues that could carry the BSE infections agent.” Part of the requirements imposed on Canada was that slaughter plants must exclusively process only cattle under 30 months of age to guard against cross-contamination of tissues that could carry BSE (SRMs from older cattle). USDA asserted that bone-in beef is inherently riskier than boneless beef. *See, e.g.*, 69 Fed. Reg. 1862 at 1865, 1867 (Jan. 12, 2004). Because it abandons prior restrictions on imports of bone-in cuts of meat and meat from cattle 30 months of age or older, without adequately explaining why USDA’s prior assumptions were inaccurate or its prior decisions ill-advised, the Final Rule is arbitrary, capricious, and an abuse of discretion.

33. The Final Rule is impermissibly vague and inconsistent with respect to the feed ban requirements. The Final Rule states that meat and edible products from bovines can be imported into the United States only if it is "derived from bovines that have been subject to a ruminant feed ban equivalent to" the U.S. FDA feed ban that applies in the United States. 9 C.F.R. § 94.19(a). Similar language applies to bovine carcasses; meat of sheep and goats; and live bovines, sheep, and goats. *Id.* at §§ 93.419(c), 93.436(a)(2) and (b)(2), and 94.19(b) and (c). It is unclear what is meant by the requirement that the animal "have been subject to" an equivalent feed ban. In some of the preamble discussion, APHIS refers to animals that "were subject to a ruminant feed ban during their lifetime," but even that is unclear. Neither the Final Rule nor the accompanying preamble state explicitly that no animals born before Canada implemented a feed ban equivalent to the FDA rule at 21 C.F.R. § 589.2000 may be imported into the United States or slaughtered in Canada for products destined for the United States. Nor is there any language in the Final Rule that would establish procedures for assuring that the animals were born after the Canadian feed ban was promulgated in August 1997. Thus, it is unclear whether this condition is met merely by virtue of the feed ban having been in place at any time prior to slaughtering for export to the U.S. or transporting cattle across the border, or whether the animal must have been born after August 1997. Because of the vague and ambiguous nature of this portion of the regulation (which addresses what is, according to APHIS' risk analysis, the single most important factor in preventing the spread of BSE), the Final Rule is arbitrary, capricious, and an abuse of discretion.

34. The Final Rule is inadequate to prevent live Canadian cattle slaughtered in the U.S. over 30 months of age from entering the U.S. food supply. The Final Rule does not require live Canadian cattle that are inadvertently slaughtered over 30 months of age to be removed from the

food supply. 70 Fed. Reg. at 484. This stands in inexplicable contrast to the Final Rule's provisions for sheep and goats: If the sheep or goats are not slaughtered at less than 12 months, "the approval of the feedlot will be immediately withdrawn." 9 C.F.R. § 93.419(d)(8)(viii); *see also* 70 Fed. Reg. at 489. USDA's failure to mitigate the risk of human exposure to BSE by promulgating rules that assure animals inadvertently slaughtered at 30 months of age or older are kept out of the human food supply, and its inconsistent inclusion of such a requirement for sheep and goats but not for bovines, renders the final rule arbitrary, capricious, and an abuse of discretion.

35. USDA had an obligation to consider alternatives to the Final Rule that would mitigate its adverse impact on the U.S. cattle market. Commenters suggested that any rule allowing Canadian cattle or beef into the United States should be accompanied by a requirement for labeling that would identify meat derived from Canadian cattle to the ultimate consumer. This would allow consumers to protect themselves against the increased risk (or perceived risk) of exposure to BSE prions in Canadian cattle. APHIS' response to these requests was simply to assert that it was not "necessary" to delay implementation of the Final Rule until a statute requiring mandatory country of origin labeling goes into effect, and to state that the purpose of such statute is "to provide consumers additional information on which to base their purchasing decisions" and it is not "a food safety or animal health measure." 70 Fed. Reg. at 533. The federal country of origin labeling statute referenced by APHIS would not have prevented APHIS from imposing a requirement for labeling of meat derived from Canadian ruminants in connection with reopening the Canada-U.S. border in the Final Rule. Moreover, USDA was statutorily obligated to consider measures to mitigate the adverse economic impacts of the Final Rule on U.S. producers, even if those measures were not food safety or animal health measures

*per se*. Thus, USDA has offered no cogent reason for rejecting these comments or for failing to adopt this measure that would mitigate the adverse impacts to U.S. producers. These shortcomings render the Final Rule arbitrary, capricious, an abuse of discretion, and not according to law.

36. Another provision suggested by commenters that should have been included in the Final Rule is authorization for private companies to test the cattle they slaughter for BSE—a right that USDA thus far has denied to individuals. This would mitigate the adverse impact of the Final Rule on the U.S. cattle market by giving consumers greater confidence that they will not be exposed to the increased risk (or perceived risk) of BSE prions in Canadian cattle, and it could mitigate the adverse effect that allowing imports of Canadian cattle is likely to have on U.S. export markets. Remarkably, APHIS’ response to these requests was to assert that domestic and international confidence in U.S. cattle and beef products would be *greater* if individual companies are prevented from testing cattle they slaughter; i.e., confidence will be greater if BSE testing is less. 70 Fed. Reg. at 534. USDA also claimed a need to “maintain clarity with regard to the purpose of USDA’s BSE testing” (*id.*), even though the request went to private-party voluntary testing and had nothing to do with USDA’s surveillance testing. Thus, USDA has offered no cogent reason for rejecting these comments or for failing to adopt this measure that would help carry out its statutory directive to mitigate the adverse impacts to the market for U.S. cattle and meat products. These shortcomings render the final rule arbitrary, capricious, an abuse of discretion, and not according to law.

37. Commenters pointed out the risk of BSE infection in U.S. cattle if potentially BSE-infected live cattle from Canada are brought into the United States, because current regulations allow bovine protein to be used in poultry feed and for poultry waste to be used in cattle feed (in

addition to the potential for cross-contamination of cattle feed with poultry feed or mis-feeding). USDA did not assert that this risk does not exist, but instead pointed out that FDA, APHIS, and FSIS are considering what improvements are needed to the U.S. ruminant feed ban. 70 Fed. Reg. at 466, 504. USDA's decision to move ahead with allowing importation of Canadian cattle, without first having addressed this important potential route for the spread of BSE within the United States under the Final Rule, renders the Final Rule arbitrary, capricious, and an abuse of discretion.

38. Although the Final Rule is designed to allow other countries with BSE to be designated as minimal risk regions so that they can export cattle and beef to the United States, USDA has not provided any analysis of the health risks and the economic and environmental impacts of granting other countries besides Canada BSE minimal risk status under the rule. On information and belief, at least two other countries, Finland and Norway, which are currently listed by USDA, respectively, as "a country affected with BSE" and "a country with substantial risk associated with BSE," have already petitioned USDA for recognition as "BSE minimal risk" regions. USDA's failure to consider the effect of the Final Rule beyond allowing imports from Canada, when the Final Rule is not limited to Canada, was arbitrary and capricious and an abuse of discretion.

39. USDA said it was assessing economic impact of the proposed action, but failed to give adequate consideration to: the adverse economic impacts on associated industries, as well as employment in those industries; the adverse economic impact from stigma of Canadian beef; the multiplier effects on total economic output; and the already weakened state of U.S. cow/calf producers. Most significantly, the economic impact analysis considers only supply-side effects, assuming that the Final Rule will have no effect on consumer demand (domestic and foreign) for

U.S. beef. This is based in turn on the unsupportable assumption that the importation of cattle and beef from a country with a demonstrated BSE problem will have no effect on real or perceived BSE incidence in the U.S. and no effect on consumer confidence in U.S. beef. In addition, USDA's explanation of the economic impact of the Final Rule in the accompanying preamble is misleading to decisionmakers and the public. The claimed benefit to "consumers" is really a benefit to "fed cattle consumers," i.e. meat packers and supermarkets. Economic impacts actually are predicted to be negative for U.S. beef consumers, i.e. the public. This incomplete, inaccurate, and misleading assessment of the economic impact of the Final Rule renders it arbitrary and capricious and an abuse of discretion.

40. In simply assuming that export markets will be unaffected by the commingling of U.S. cattle and meat with Canadian cattle and meat, USDA has not explained how it expects to convince other countries that its departures from recognized international guidelines for BSE risk mitigation of the Office International des Epizooties (OIE), the World Animal Health Organization. For example, the OIE recommends, for countries that meet Canada's BSE risk characteristics, removal of SRMs from all cattle that are over six months of age at time of slaughter, while the Final Rule only requires removal of most SRMs from cattle 30 months of age or older. The presumption that the Final Rule will not affect the resumption of exports of beef from the U.S., when the Final Rule not only allows commingling of U.S. meat with meat from a country with a demonstrated BSE problem but also departs from OIE recommendations without any indication that other countries will accept these departures, renders the Final Rule arbitrary, capricious, an abuse of discretion, and unsupported by the administrative record.

41. With respect to live cattle, the Final Rule discriminates against producers who are not feedlot owners. Only a feedlot may accept Canadian feeder cattle. Producers who run feeder

cattle on grass/wheat do not qualify. Thus, the benefits of cheaper Canadian cattle will go exclusively to those who own feedlots or feed cattle in feedlots, and to the packers. Given that all live cattle entering the U.S. from Canada will be branded and tagged, there is no apparent reason why feeding such cattle on ranches as opposed to in feedlots would increase the risks presented by the Final Rule. USDA's discrimination against producers who are not feedlot owners and do not feed cattle in feedlots, without sufficient explanation, renders the Final Rule arbitrary, capricious, an abuse of discretion, and unsupported by the administrative record.

42. USDA's promotion of foreign policy goals when implementing statutes intended for the protection of U.S. consumers, cattle, and cattle producers, as further described in Count 2 below, also renders the Final Rule arbitrary and capricious and an abuse of discretion under 5 U.S.C. § 706(2)(A).

Count 2 – Administrative Procedure Act Section 706(2)(C)

43. Plaintiff repeats and realleges paragraphs 1-42.

44. Under the Administrative Procedure Act, this Court must “hold unlawful and set aside agency actions, findings, and conclusions found to be – ... (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;...” 5 U.S.C. § 706(2).

45. The Animal Health Protection Act specifically provides for regulation by the Secretary of Agriculture when necessary “to protect the agriculture, environment, economy, and health and welfare of the people of the United States.” 7 U.S.C. § 8301(5)(B)(iii). That statute was based on the need to prevent and control disease in animals in order to protect “the economic interests of the livestock and related industries *of the United States*;...” 7 U.S.C. § 8301(1)(C) (emphasis added). The Meat Inspection Act, which authorizes USDA measures to inspect and regulate live

cattle, meat and other products, and animal carcasses, is premised on the congressional finding that: “It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged.” 21 U.S.C. § 602.

46. Despite the discovery of BSE-infected cattle in Canada and the subsequent discovery of a BSE-infected cow in Washington State that had been imported from Canada, and in contravention of USDA’s pre-existing policy--consistent with international practice--not to accept cattle or edible bovine products from a country with BSE infection, USDA representatives, up to and including the Secretary of Agriculture, and other Administration officials, up to and including the President of the United States, made numerous statements concerning their intent to reopen the U.S.-Canada border as quickly as possible. Some of those statements were made in advance of any meaningful scientific analysis and many were made prior to completion of the rulemaking leading to the Final Rule. These comments and other information indicate that USDA has based the Final Rule on considerations of relations with the government of Canada and economic impacts of the import ban on ranchers and others in Canada. Such considerations are not appropriate under USDA’s statutory authorities.

47. USDA’s rush to reopen the Canada-U.S. border regardless of uncertainties for human and animal health is apparent, for example, in the preamble to the Final Rule, in which APHIS acknowledged uncertainties regarding BSE infectivity and transmissibility in sheep and goats and that it needs to develop new regulations to protect the U.S. from scrapie and BSE in sheep, but nevertheless stated that: “In order to reestablish trade in low-risk sheep and goat commodities from BSE minimal-risk regions in a timely manner, we are addressing sheep and goats imported

for immediate slaughter and for feeding and then slaughter in this rulemaking.” 70 Fed. Reg.487; *see also id.* at 488.

48. Further indication that USDA’s action is based on these inappropriate considerations and preconceived need to reopen the border, rather than on sound scientific assessment of the impacts on public health and welfare in the United States, can be found in USDA’s response to the announcement of yet another confirmed case of BSE in Canada just prior to publication of the Final Rule. According to a USDA transcript of a December 29, 2004 press conference about the issuance of the Final Rule, Dr. John Clifford, Deputy Administrator for Veterinary Services of APHIS, stated that “if there was an additional case [of BSE] in Canada or elsewhere with regards to consideration for minimal risk regions or countries we would review that information at the time of occurrence and take any appropriate action. The action could be anywhere from continuation of the rule and no revoke [*sic*]. If we did revoke, we would come out with additional rulemaking to revoke that.” However, the following day Dr. Ron DeHaven, Administrator of APHIS, stated that the discovery of an additional case of BSE infection in Canada “would not alter the implementation of the U.S. rule announced yesterday....” On January 2, 2005, Canada confirmed BSE infection in the third Canadian-born cow, and the following day, before the Canadian Food Inspection Agency had completed its investigation of the potential causes and extent of BSE infection related to that case, Dr. DeHaven made a public statement again concluding that there was no need to reconsider the Final Rule. USDA statements downplayed the significance of the third BSE case, asserting that the cow probably was infected with BSE prior to the Canadian feed ban, despite the fact that USDA concluded in the rulemaking that the “incubation period” for BSE is almost always less than the seven years that the Canadian feed ban has been in place.

49. In many instances, USDA's response to numerous comments identifying key deficiencies in its risk analysis has been to challenge the commenters to demonstrate that there is a risk or quantify the risk that USDA failed to attempt to quantify. When the Harvard Center for Risk Analysis concluded it could not assess the risk of BSE entering the United States from Canada, USDA simply assumed that the risk was minimal. When faced with very limited testing for BSE in the Canadian cattle herd, and the fact that three cases of BSE in Canadian-born cattle have already been discovered through such limited BSE testing, USDA chose to assume that the incidence of BSE in the Canadian herd is extremely low; i.e., that if sufficient BSE testing *were* performed in Canada, it would demonstrate a BSE incidence much less than what the limited BSE testing to date has shown. These and similar actions by USDA are wholly inconsistent with the language and intent of the Animal Health Protection Act and the Meat Inspection Act, which emphasize the necessity of assuring that U.S. livestock and U.S. consumers of meat and meat products are not exposed to disease.

50. Despite the emphasis of the Animal Health Protection Act, which APHIS purports to be implementing in the Final Rule, on the protection of U.S. agriculture, APHIS does not even claim any benefit of the Final Rule for U.S. cow/calf producers, for domestic demand for beef, or for foreign demand for U.S. beef, and instead will expose domestic cattle and consumers to increased health risks.

51. USDA's failure to apply the precautionary principles inherent in the legislation it implements and its emphasis of certain economic interests and foreign policy concerns over the health and well-being of U.S. consumers, cattle, and cattle producers makes USDA's issuance of the Final Rule an action in excess of and inconsistent with its statutory authority. For that reason, the Final Rule is unlawful and should be set aside pursuant to 5 U.S.C. § 706(2)(C).

Count 3 – Administrative Procedure Act Section 706(2)(D)

52. Plaintiff repeats and realleges paragraphs 1-51.

53. Under the Administrative Procedure Act, this Court must “hold unlawful and set aside agency actions, findings, and conclusions found to be – ... (D) without observance of procedure required by law;...” 5 U.S.C. § 706(2). *Inter alia*, section 553 of the APA (5 U.S.C. § 553) sets forth procedures required for informal rulemaking such as the promulgation of the Final Rule.

54. The primary agency determination inherent in the Final Rule is USDA’s conclusion that importation of live cattle under 30 months of age from Canada and importation of edible bovine products produced in Canada, under the conditions described in the Final Rule, (1) present a minimal risk of introducing BSE into the United States and (2) present a minimal risk to consumers of contracting vCJD. Those conclusions, however, were based on an APHIS risk analysis that was never subject to public review and comment and that differed substantially from the risk analysis that accompanied the Proposed Rule. In addition, the Final Rule contains fewer risk mitigation provisions than the Proposed Rule. In any event, since USDA offered no explanation of what it means for the risk to be “low” or “very low,” the public had no meaningful opportunity to comment on whether the risk was acceptable. (For example, does “low” risk mean potentially 1 additional case of vCJD a year? Or does it mean 10 new cases a year?) Thus, members of the public were deprived of an opportunity to comment on USDA’s fundamental conclusions about the risk of the Final Rule to human health and animal health, as well as its potential consequences for the U.S. cattle industry.

55. USDA failed to provide adequate notice for its decision to allow importation of edible bovine products from Canada regardless of the age of the animals at the time of slaughter. The November 4, 2003 Proposed Rule would have allowed importation of edible bovine products

from BSE-minimal-risk regions only if those products came from animals under 30 months of age at slaughter (the “30-month restriction”). This restriction was based both on the assumption that younger animals, born after Canada enacted its feed ban, would not have been exposed to potentially contaminated feed, and on the assumption that, since recognizable symptoms of BSE generally occur two to six years after infection, levels of BSE contamination will be low even in infected cattle under 30 months of age. The March 8, 2004 Federal Register Notice did more than reopen the comment period for the proposed rule; it made a significant, substantive change to the proposed rule – it eliminated a key element for human health protection, the 30-month restriction. The March 8, 2004 notice was too vague to allow meaningful public comment, merely stating that APHIS no longer believed the 30-month restriction was necessary, because removal of SRMs and “such other measures as are necessary” were already being taken in Canada. 69 Fed. Reg. at 10,635. There was no explanation to the public of, and thus no opportunity to comment on, the scientific basis for relaxing the 30-month restriction that APHIS had proposed. The entire 2003 Risk Analysis, to the extent it addressed human health risks at all, was predicated on the 30-month restriction.

56. As described more fully in Count 4 below, APHIS prepared a revised Environmental Assessment to reflect new information. That revised Environmental Assessment was not made available for public review and comment, however, until after the Final Rule had been signed (and after USDA and the White House had made public statements suggesting that the Final Rule would not be changed).

57. Plaintiff and other members of the public submitted substantive comments demonstrating the lack of support for or inaccuracy of key assumptions behind APHIS’ tentative conclusion that importation of Canadian cattle and beef would present minimal risk. Comments also were made

about measures that USDA could impose to reduce the risk of importation of Canadian cattle and/or edible bovine products, to reduce the risks created by the current incomplete ban on animal protein in cattle feed, and to allow consumers the opportunity to protect themselves against such risks. APHIS failed to provide a meaningful response to many of those substantive comments. Indeed, in the face of comments that the risk assessment on which APHIS relied failed to address the risk of BSE contaminated cattle and meat entering the United States, but looked only at the risk of the spread of BSE once in the United States, APHIS' response was to cite a statement, by the authors of the Harvard-Tuskegee risk assessment, that their study was never intended to assess the risk of BSE infection in the Canadian herd or the risk that BSE-contaminated cattle and meat will enter the United States under the Final Rule.

58. APHIS' promulgation of the Final Rule without providing sufficient opportunity for public comment on key elements of the Final Rule and key information on which APHIS relied, including but not limited to the Final Risk Assessment, the Final Environmental Assessment, the Final Economic Analysis, and the basis for expanding imports of edible bovine products to those from animals over 30 months of age, as well as APHIS' failure to consider and respond to significant public comments, renders the Final Rule unlawful under 5 U.S.C. § 706(2)(D).

#### Count 4 – National Environmental Policy Act

59. Plaintiff repeats and realleges paragraphs 1-59.

60. The National Environmental Policy Act of 1969 ("NEPA"), 42 U.S.C. §§ 4321 *et seq.*, requires that federal agencies such as USDA prepare an Environmental Impact Statement ("EIS") for any major federal action significantly affecting the quality of the human environment. 42 U.S.C. § 4332(C). NEPA requires an assessment of the effects of an action, both direct and indirect. Council on Environmental Quality and USDA implementing

regulations also provide for the preparation of an “environmental assessment” to support a finding that the proposed action will not have a significant impact on the environment and therefore will not be the subject of an EIS. *See, e.g.*, 40 C.F.R. § 1501.3 and 7 C.F.R. pt. 372.

61. APHIS prepared an environmental assessment in connection with the Proposed Rule, dated October 2003, and then completed a revised environmental assessment in March 2004. Because circumstances subsequently changed, APHIS revised its environmental assessment in December 2004. *See* 70 Fed. Reg. 554 (January 4, 2005). This “Final Environmental Assessment” was not made available to the public for review and comment, however, until after the Final Rule had been signed. *Cf. id. with* 70 Fed. Reg. at 543, 553. Despite public comment requesting that APHIS prepare an EIS, no EIS was prepared.

62. The Final Environmental Assessment relied on an outdated (2003, supplemented with an Explanatory Note in February 2004) risk analysis that fails to take into account subsequent developments and scientific discoveries. It also appears to assume that only meat from cattle under 30 months of age will be imported. Moreover, the outdated risk analysis on which the conclusions in the Final Environmental Assessment are based rests on numerous assumptions that are either unsupported or demonstrably wrong, similar to the shortcomings of the 2004 risk analysis described in Count 1, above. Nor does the risk analysis on which the Final Environmental Assessment relies provide any quantitative assessment of the risk of importing BSE-infected cattle from Canada, transmission of BSE from those cattle to animals in the United States, or infection of humans with vCJD as a result of importation of BSE-infected cattle or meat. Thus, APHIS lacks a meaningful basis for the conclusions in the Final Environmental Assessment that the “consequences with regard to animal health, human health, and the environmental continue to be minimal or low....” Just as importantly, decisionmakers and the

public have been deprived of an opportunity to form a judgment about whether the risk is acceptable—an opportunity that NEPA is designed to provide.

63. APHIS failed to assess numerous direct and indirect effects of allowing importation of Canadian cattle. Millions of head of cattle under 30 months of age are currently being held in Canada because they cannot be exported to the United States (or other countries). Even by USDA's estimation, the Final Rule will result in a flood of 2 million head of cattle from Canada into the U.S. in 2005. APHIS apparently made no attempt to assess the environmental effects of transporting 2 million head of cattle from farms in Canada to feedlots and slaughterhouses in the United States. Nor was there apparently any attempt to assess the environmental impacts of feeding and holding these additional 2 million head of cattle until slaughter. Based on Environmental Protection Agency studies, guidance, and regulations, these environmental impacts could be significant. APHIS also made no real attempt to assess the environmental impacts of disposing of tissues deemed to be of high risk in imported Canadian cattle, e.g., tonsils and intestines.

64. Although the Final Environmental Assessment asserts that it is analyzing the environmental impacts of imports of live cattle and beef from Canada and other countries, in fact the analysis is limited virtually exclusively to the effects of Canadian imports. The risk analysis on which the Final Environmental Assessment relies is limited to risks from Canadian cattle and beef.

65. By failing to prepare an EIS, basing its Final Environmental Assessment on inaccurate or unsupported assumptions and on an outdated and superseded risk analysis, taking final action before its revised environmental assessment was made available to the public for review and comment, and ignoring the potential environmental impacts of imports from countries other than

Canada, USDA failed to comply with its obligations under NEPA. Where an agency has failed to conduct the analysis of the environmental impacts of its proposed action required by NEPA, or when that analysis is based on inaccurate or outdated information and assumptions, NEPA requires a stay of the agency action until the required analysis can be completed.

Count 5 – Regulatory Flexibility Act, 5 U.S.C. §§ 603, 604

66. Plaintiff repeats and realleges paragraphs 1-65.

67. USDA admits that the Final Rule will primarily affect small businesses. Many ranchers, including most R-CALF USA members, are small businesses within the meaning of the Regulatory Flexibility Act, 5 U.S.C. §§ 601-612. USDA estimates that the Final Rule has a present value cost of close to \$3 billion for U.S. producers.

68. The Regulatory Flexibility Act imposes requirements for a regulatory flexibility analysis that have not been met by USDA. For example, on information and belief USDA did not consider adequately the mitigation of adverse effects of the Final Rule on small businesses that could have been achieved through a requirement that edible bovine products derived from Canadian cattle or imported from Canada be labeled so that consumers could choose not to purchase those products.

69. Additionally, USDA's assessment of the impact of the final Rule on small businesses was based on an inadequate and inaccurate assessment of the risks and consequences of the Final Rule, as described in Count 1 above, and therefore did not accurately assess the effects of the Final Rule on small businesses under the Regulatory Flexibility Act.

70. For the foregoing reasons, USDA failed to comply with the Regulatory Flexibility Act and the Final Rule should be remanded to USDA pursuant to 5 U.S.C. § 611(a)(4).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

a) Enter judgment declaring that USDA's final action entitled "Bovine Spongiform Encephalopathy, Minimal-Risk Regions and Importation of Commodities; Final Rule and Notice," 70 Fed. Reg. 460 (January 4, 2004), is arbitrary and capricious, an abuse of discretion, and not in accordance with law and may not lawfully be implemented or enforced;

b) Grant an injunction enjoining implementation of that final action and enjoining the importation into the United States of all live cattle of Canadian origin and all edible bovine meat products derived from cattle of Canadian origin;

c) Set an expedited calendar in this case for any briefs or hearings that may be necessary, so that the Court can act on the requested relief before that final action goes into effect on March 7, 2005;

d) Award Plaintiff its costs and reasonable attorneys' fees in this action; and

e) Grant such other and further relief as the Court deems proper and just under the circumstances.

Dated: January 10, 2005

Respectfully submitted,

---

A. Clifford Edwards  
Taylor S. Cook

Edwards, Frickle, Anner-Hughes, Cook & Culver  
1601 Lewis Avenue, Suite 206, P.O. Box 20039  
Billings, Montana 59104  
(406) 256-8155

---

Russell S. Frye\*  
Collier Shannon Scott, PLLC  
3050 K Street, N.W., Suite 400  
Washington, DC 20007  
(202) 342-8878

---

William L. Miller\*  
The William Miller Group, PLLC  
3050 K Street, NW  
Fourth Floor  
Washington, DC 20007  
(202) 342-8416

Attorneys for Plaintiff  
RANCHERS CATTLEMEN ACTION LEGAL FUND  
UNITED STOCKGROWERS OF AMERICA

\* Motions for admission *pro hac vice* are being submitted.

