UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH DAKOTA
NORTHERN DIVISION

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CLERK

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CIV- 07-1023

VERIFIED COMPLAINT FOR DECLATORY AND INJUNCTIVE RELIEF

PUBLIC CITIZEN,
1600 20th Street, N.W.
Washington, DC 20009,

Plaintiffs,

vs.

UNITED STATES DEPARTMENT OF AGRICULTURE,
ANIMAL AND PLANT HEALTH INSPECTION SERVICE,
and CHARLES F. CONNER, IN HIS CAPACITY AS THE
ACTING SECRETARY OF AGRICULTURE,
1400 Independence Avenue, S.W.
Washington, DC 20250,

Defendants.

The Plaintiffs, through their attorneys, bring this action for declaratory and injunctive relief against the United States Department of Agriculture ("USDA"), Animal and Plant Health Inspection Service ("APHIS"), and the Acting Secretary of Agriculture, 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 September 18, 2007, APHIS published a final rule relaxing restrictions on imports of live cattle and edible bovine products from "minimal risk" regions (i.e., Canada), allowing for the first time since May 2003 the importation of cattle for any purpose, provided they were born on or after March 1, 1999, and allowing imports of most edible products from Canadian cattle of any age: "Bovine Spongiform Encephalopathy; Minimal-Risk Regions; Importation of Live Bovines and Products Derived From Bovines; Final Rule" 72 Fed. Reg. 53,314 (Sept. 18, 2007) (the "OTM [over thirty months] Rule"). Unless its implementation is enjoined, the OTM 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 ("R-CALF USA") is a national non-profit cattle association representing over 12,000 U.S. cattle producers on issues concerning international trade and marketing to ensure the profitability and continued viability of independent U.S. cattle producers. R-CALF USA's membership consists of cattle producers, cattle backgrounders, and independent feedlot owners. Its members are located in 46 states, and the organization has 60 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. Its principal place of business is Billings, MT.

2. Plaintiff South Dakota Stockgrowers Association ("SDSGA") is a 120-year-old grassroots, non-profit organization of independent cattle producers dedicated to the continued success and viability of the domestic cattle industry. SDSGA members believe that independent, family owned ranches are the cornerstone to the economic success of the cattle industry and the state of South Dakota. The mission of SDSGA is to promote and protect the South Dakota cattle industry. The South Dakota Stockgrowers Association represents ranchers at the state and national level on trade, marketing, animal identification, animal health, property rights and natural resource use issues. Its principal place of business is in Rapid City, SD.

3. Plaintiffs R-CALF USA and SDSGA have standing to bring this action on behalf of their members. As a result of USDA's action allowing importation of older live Canadian cattle and edible bovine products from older Canadian cattle, the market for R-CALF USA and SDSGA 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 marketability of 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 of older cattle, and beef from older cattle, from Canada. R-CALF USA and SDSGA members will also be adversely affected by the increased risk of disease they face from the beef they consume once beef from Canadian cattle enters and is commingled with the U.S. meat supply, and by the increased risk of disease to their own cattle. Many of their members also live in the areas that will be most affected by the adverse environmental impact of increased truck traffic from Canada and from the importation of infectious BSE prions from Canada. These injuries are caused by USDA's final action allowing importation of Canadian cattle 30 months of age and older and edible bovine meat products from Canadian cattle 30 months of age and older, and these injuries could be mitigated or eliminated by an order declaring that action unlawful and enjoining importation of such Canadian cattle and meat products.

4. Plaintiff Herman R. Schumacher is a member of R-CALF USA and SDSGA. A former member of the Board of Directors of R-CALF USA, he currently is Co-chair of its National

Membership Committee. Schumacher is a former cattle auction market owner and raises cattle and operates a commercial cattle feedlot. He resides in Campbell County, South Dakota.

5. Plaintiff Robert P. Mack is a cow-calf producer and cattle feeder who resides in Codington County, South Dakota. He is a member of R-CALF USA and SDSGA.

6. Plaintiff Ernie J. Mertz is a cow-calf producer who resides in Edmunds County, South Dakota. He is a member of R-CALF USA and SDSGA.

7. Plaintiff Wayne J. Nelson is a cow-calf producer who resides in Marshall County, South Dakota. He is a member of R-CALF USA and SDSGA.

8. Plaintiffs Schumacher, Mack, Mertz, and Nelson have standing to bring this action because their livelihood will be directly adversely affected by the influx of cheap older Canadian cattle and beef from older Canadian cattle that will result from the OTM Rule. In addition, they will be adversely affected by the limitations on U.S. beef exports that will continue to be imposed as a result of commingling of U.S. and Canadian cattle and beef and by the increased risk that BSE-infected bovine protein will enter U.S. feed supplies and infect U.S. cattle. They also live in one of the areas that will be most affected by the adverse environmental impact of increased truck traffic from Canada and from the importation of infectious BSE prions from Canada. These injuries are caused by USDA's final action allowing importation of Canadian cattle 30 months of age and older and edible bovine meat products from Canadian cattle 30 months of age and older, and these injuries could be mitigated or eliminated by an order declaring that action unlawful and enjoining importation of such Canadian cattle and meat products.

9. Plaintiff Center for Food Safety ("CFS") is a non-profit corporation whose principal place of business is in Washington, DC, and that also has offices in San Francisco, CA. Since the organization's founding in 1997, CFS has sought to address the impacts of industrial farming and food production systems on human health, animal welfare, and the environment. CFS seeks to protect human health and the environment by ensuring that all beef is properly inspected and safety-tested for BSE prior to its marketing and sale; that such beef products are tested and regulated in a manner that minimizes any risk of BSE exposure to consumers and the environment; and that beef properly tested and determined to be "BSE- free" is allowed to be appropriately labeled as such. CFS is a membership organization with members in almost every state across the country, including members in states and locations where beef from over-thirty-month-old Canadian cattle will be sold. CFS has standing to bring this action because the interests of CFS and its members are being, and will be, adversely affected by Defendants' actions complained of herein. Defendants' actions ensure that CFS members will be injured by exposure to beef that has a high risk of BSE contamination. In particular, CFS members regularly purchase and consume beef, and Defendants' actions in allowing beef products to be imported and sold derived from cattle over thirty months of age and originating from a BSE positive country will imminently make it more difficult for CFS members to purchase and eat meat that is not at increased risk for BSE contamination. Additionally, CFS members regularly enjoy the environment and visit parks, natural areas, and other habitats and engage in activities such as skiing, canoeing, and hiking that will be impacted by the increased emissions associated with Defendants' action, and their recreational and aesthetic interests will be injured by effects of those emissions on air quality, vegetation, visibility, snowpack, stream flow, and other conditions. CFS members have been injured by Defendants' failure to analyze

the environmental effects of those actions and make that information available to CFS members.

10. Plaintiff Consumer Federation of America ("CFA") is a nonprofit association of 300 pro-consumer groups, representing more than 50 million Americans, that was established in 1968 to advance the consumer interest through research, education, and advocacy. CFA's principal place of business is in Washington, DC, but its member organizations are located across the country. The Food Policy Institute at CFA was established in 1999 to conduct research and advocacy to promote a safer, healthier, and more affordable food supply. The interests of CFA and the members it represents are adversely affected by USDA's decision to place commercial and diplomatic interests above the protection of the U.S. cattle herd and the U.S. meat supply from the expected introduction of BSE from imports of older Canadian cattle and meat from older Canadian cattle. Their interests also have been adversely affected, *inter alia*, by USDA's failure to conduct and provide to the public an accurate, substantive, and comprehensive assessment of the risks to public and animal health and to the environment presented by the OTM Rule. This failure impairs or prevents the ability of CFA and its members to pursue their goals of advocating for wise and safe policy towards importation of cattle and beef from Canada.

11. Plaintiff Creutzfeldt-Jakob Disease Foundation, Inc. is a not-for-profit foundation whose principal place of business is Akron, Ohio, and whose primary mission is to provide emotional and practical support to families of patients with Creutzfeldt-Jakob Disease ("CJD") and other invariably fatal brain disorders that are known as Prion diseases. Prion diseases occur both in humans and certain animals. In humans, the best known of the prion diseases is CJD, which reportedly affects around one person per million per year. Variant Creutzfeldt-Jakob Disease

("vCJD") is acquired through ingestion of BSE-contaminated meat. The CJD Foundation promotes research and the dissemination of research findings; advocates for good quality care for those afflicted with CJD; and actively advocates for the development of sound responses to Prion diseases through public policy. The CJD Foundation has standing to bring this action on behalf of itself, because the OTM Rule conflicts and interferes with the CJD Foundation's mission, and on behalf of its members, because its members will be adversely affected, both physically and emotionally, by the increased risk of vCJD, a risk they are committed to minimizing, in the United States as a result of imports of BSE-infected cattle and potentially BSE-infected beef products under the OTM Rule. These injuries to the CJD Foundation and its members are caused by USDA's final action allowing importation of Canadian cattle 30 months of age and older and edible bovine meat products from Canadian cattle 30 months of age and older, and these injuries could be mitigated or eliminated by an order declaring that action unlawful and enjoining importation of such Canadian cattle and meat products.

12. Plaintiff Food & Water Watch is a non-profit consumer advocacy organization that works to ensure clean water and safe food. Its principal place of business is in Washington, DC. Food & Water Watch has 2500 members who are consumers from across the United States, many of whom consume beef. Food & Water Watch has standing to bring this action on behalf of its members because its members will be adversely affected by an increased risk that they will purchase and consume unsafe beef products, a risk the organization is committed to minimizing. Specifically its members will be adversely affected by an increased risk of vCJD in the United States as a result of BSE-infected cattle and potentially BSE-infected products due to the OTM rule. These injuries are caused by USDA's final action allowing importation of Canadian cattle 30 months of age and older and edible bovine meat products

from Canadian cattle 30 months of age and older, and these injuries could be mitigated or eliminated by an order declaring that action unlawful and enjoining importation of such Canadian cattle and meat products.

13. Plaintiff Public Citizen is a non-profit consumer advocacy organization with approximately 90,000 members nationwide. Since its inception in 1972, Public Citizen has fought for strong food safety protections for consumers. It has promoted this agenda through litigation, congressional advocacy, public education, and input into agency rulemaking processes. Starting in 1991, Public Citizen realized that to fulfill its organizational mission of promoting food safety, it had to become involved in trade issues, as trade deals such as the North American free Trade Agreement (NAFTA) would directly affect food safety standards and inspection policy as between the United States, Canada, and Mexico. Its work regarding Canadian meat import safety started in the early 1990s, with testimony before the House Commerce Committee regarding lax inspection of cross border meat subject to trade under NAFTA rules. Public Citizen has consistently engaged on this issue since then, publishing many of the most detailed reports on safety problems in cross border food trade. Public Citizen and its members have an interest in ensuring that the federal government issues effective regulations to protect humans from unsafe food, including regulations related to diseases such as BSE in cattle that can infect humans who ingest meat and other products produced from cattle. Public Citizen's members will be injured by the USDA's changes to regulations that were intended to prevent BSE-infected cattle and meat from being imported into the United States, as further described below. Public Citizen brings this action on behalf of its members who shop for food for themselves and their families.

14. Defendant 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*., the Animal Disease Risk Assessment, Prevention, and Control Act of 2001, P.L. 107-9, and the Meat Inspection Act, 21 U.S.C. §§ 601 *et seq*. The Animal and Plant Health Inspection Service ("APHIS") is a component service of the United States Department of Agriculture.

15. Defendant Charles F. Conner is Deputy Secretary and currently Acting Secretary of the United States Department of Agriculture. He is sued in his official capacity only.

JURISDICTION AND VENUE

16. 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, 706 (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. §§ 2201-2202.

17. Venue is proper in this Court under 28 U.S.C. § 1391(e) because plaintiffs Herman Schumacher, Robert Mack, Ernie Mertz, and Wayne Nelson reside in the State of South Dakota, within the Northern Division of the District of South Dakota; the South Dakota Stockgrowers Association's principal place of business is in the State of South Dakota; R-CALF USA has substantial membership in South Dakota; and defendants are an agency of the United States and an officer of an agency of the United States.

FACTS GIVING RISE TO THIS ACTION

18. Bovine spongiform encephalopathy ("BSE"), commonly known as "mad cow disease," is an 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.

19. There is no drug that can cure BSE and no medicine can prevent an animal from becoming infected. 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. The only tests available to determine whether cattle are infected with BSE must be performed post-mortem. 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 suggested that consumption of as little as one milligram of tissue containing BSE prions can result in contracting BSE. Studies also indicate that BSE may be spread by maternal transmission from mother to calf. It appears that cattle may also become afflicted, in very rare cases, with spontaneous or atypical BSE that does not appear to come from consuming BSE-contaminated ruminant protein.

20. 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. It is not known how small a dose of BSE-infected bovine protein is sufficient to lead to vCJD in a human. Over 190 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. The majority of vCJD cases have been diagnosed in the United Kingdom, where BSE appears to have affected by far the largest number of cattle, and research attributes over 99 percent of this human BSE exposure to UK cattle over 30 months of age. There have been a number of deaths in the United States and Canada confirmed or suspected to be from vCJD, but it is presumed that these infections were the result of consuming BSE-contaminated meat in the United Kingdom or Saudi Arabia. There are also very rare spontaneous cases of Creutzfeldt-Jakob Disease, referred to as CJD, that occur in small numbers in the United States and elsewhere through an unknown mechanism.

21. 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. Recent testing of tissue samples from healthy-appearing people in the United Kingdom indicates that many more people have infectious prions in their systems than have thus far developed symptoms of vCJD. That may mean that they are less susceptible to the disease and will never develop symptoms, or it may mean that the disease simply has not progressed far enough to produce symptoms and that they may yet become afflicted with vCJD.

22. The scientific consensus is that vCJD can be transmitted between humans through blood transfusions, and that this has already occurred in some cases. BSE has also been transmitted experimentally through blood transfusion in sheep. There is no test currently available to determine whether blood or blood products contains infectious prions that could transmit vCJD. For that reason, the U.S. Food and Drug Administration currently recommends that blood donations not be accepted from people who have spent specified periods of time in the United Kingdom and Europe, where BSE has been most widespread.

23. The BSE epidemic began in the United Kingdom, possibly as early as the 1970s. 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. Although the BSE epidemic in the UK peaked in the early 1990s, a number of countries have detected their first cases of BSE in just the last few years, and it is not yet apparent whether the disease is on the rise or decline in those countries.

24. That is true of Canada, which reported its first case of BSE in a Canadian-born cow on May 20, 2003, in a cow born in Saskatchewan that died in Alberta (shortly after the Canadian Food Inspection Agency ("CFIA") had completed a risk assessment that concluded there was "negligible" risk of BSE infection in the Canadian cattle herd). The carcass of this BSE-infected animal was rendered and entered the animal feed chain in Canada before confirmation of the disease was made, potentially reaching 1800 Canadian farms and ranches. Since then, 10 more cases of BSE have been found in limited testing of Canadian-born cattle, with seven of those discovered just since January 2006. Canada also imported cattle from the UK during a period when large numbers of UK cattle were infected with BSE, including cattle from UK

farms where BSE was found, and some of those cattle were rendered and presumably entered the Canadian feed supply. Canada detected a case of BSE in December 1993 in a cow that had been imported from the UK in 1987. That cow and many of its herdmates were rendered and presumably entered the Canadian feed supply. Canada likely rendered 68 cattle imported from the UK prior to discovering its first case of BSE in 1993. Ten of these cattle were known to originate from BSE-infected farms in the UK, two of which were known also to be herdmates of the BSE-infected cow discovered in 1993.

25. In the year following its first case of BSE, Canada decreased its BSE testing from 645 cattle to 426 cattle. Canada did not make BSE a reportable disease until November 1990; the U.S. made it a reportable disease in 1986, the year it was first confirmed in the UK. Unlike the U.S., which banned imports of ruminants from all BSE countries in 1989, Canada instituted a ban on only live cattle from the UK in 1990, after importing 14 head of cattle and six head of sheep that year. Canada did not institute a ban on cattle from all countries with BSE until 1994, and did not ban the importation of sheep and goats from countries with BSE until 1998. For example, Canada imported four shipments of sheep from Denmark in 1992-94, less than a quarter of which were still alive and could be located and killed when Denmark found its first case of BSE in February 2004.

26. On December 23, 2003, a BSE-positive 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 at about four years of age, 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 most major export markets, with exports, especially to Asia, plummeting at a loss of billions of dollars per year. Major

importers such as Japan and South Korea continue to ban or greatly restrict beef exports from the United States. Where exports from the United States are allowed, in a number of cases they are only allowed from processing facilities that do not intermingle beef from Canadian cattle with that from U.S.-born cattle.

27. Following the discovery of BSE in a Canadian-raised cow in Washington State, USDA greatly increased its testing for BSE, and it has now tested more than 875,000 of the cattle deemed most likely to have BSE. That testing uncovered only two cases of BSE, both in cattle believed to have been born in the early 1990s. In addition, both cases were atypical BSE, the type that might occur spontaneously in rare cases, and so they do not necessarily indicate exposure to BSE-contaminated feed. In contrast, Canada has now tested about 150,000 of the cattle deemed most likely to have BSE, and BSE has been found in 11 cases (including the mature cow that had been exported to Washington State), with only one case over 10 years of age. The U.S. Centers for Disease Control recently concluded that Canadian cattle are 26 times more likely to test positive for BSE than U.S.-born cattle. Also in contrast to the United States, all but one of the cases found in Canada have been of the strain of BSE linked to the BSE epidemic in the UK, while the remaining case, in the cow over 10 years old, was the atypical strain found in the two U.S. cases.

28. USDA has previously acted to protect the United States cattle herd and U.S. consumers from the risk of BSE transmission to domestic cattle and BSE contamination of meat pursuant to the Animal Health Protection Act, 7 U.S.C. §§ 8301 *et seq.* ("AHPA"). This was also the purported authority for the OTM Rule. The AHPA mandates that USDA prevent, detect,

control, and eradicate diseases of livestock.[1] It authorizes the Secretary of Agriculture to "prohibit or restrict...the importation or entry" of animals or products "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." *Id.* at § 8303(a)(3). In addition, the Meat Inspection Act, 21 U.S.C. §§ 601 *et seq.*, authorizes USDA measures to inspect and regulate live cattle, meat and other products, and animal carcasses and 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. Congress also provided an indication of congressional intent with respect to BSE in particular in the Animal Disease Risk Assessment, Prevention, and Control Act of 2001 ("ADRAPCA"), P.L. 107-9, a statute requiring planning and reporting by USDA and other government agencies to coordinate actions to prevent an outbreak of BSE and foot-and-mouth disease in the United States, finding *inter alia* that "the potential introduction of those diseases into the United States would cause devastating financial losses..." (emphasis added).

29. APHIS regulations prohibited the importation of live ruminants (beginning in 1989) and meat and other edible products of ruminants (beginning in 1991) from countries that are listed as regions in which BSE exists, unless the Administrator of APHIS issues a permit in a "specific case." USDA has said that the most likely source of BSE infection in the United States is importation of infected animals or infected animal products, 68 Fed. Reg. 62,386 (Nov. 4, 2003), and has described this prohibition on imports as "the primary firewall"

[1] The AHPA refers throughout to "any pest or disease of livestock." Although BSE has technically been defined as a "pest," this Complaint hereinafter uses the term "disease" to include both pests and diseases, as they are regulated under the AHPA.

preventing BSE infection in the U.S. cattle herd. In the January 2003 report to Congress on measures to prevent the introduction and control the spread of BSE required by ADRAPCA, USDA touted the longstanding policy of prohibiting imports of cattle and meat products from countries known to have BSE.

30. The APHIS regulations list the regions in which BSE exists. Canada was placed on this list in May 2003, immediately after the first case of BSE in native-born Canadian cattle was confirmed. This had the effect of prohibiting all imports of live Canadian cattle and edible bovine products, unless authorized by a specific permit from APHIS.

31. Soon after classifying Canada as a region known to have BSE and therefore prohibiting imports of Canadian cattle and beef, USDA, responding to business interests in maintaining Canadian imports and diplomatic interests in ameliorating Canada's displeasure with the import ban, began extending exemptions to the ban far beyond what had ever been extended to other countries known to have BSE. USDA's actions in effect amended the APHIS BSE regulations without complying with the Administrative Procedure Act, and USDA consented to injunctive relief withdrawing many of those exemptions pending rulemaking, in *Ranchers Cattlemen Action Legal Fund United Stockgrowers of America v. USDA*, D. Mont. No. CV-04-51-BLG-RFC.

32. On December 29, 2004, then-Secretary of Agriculture Ann 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. That 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 "Minimal-Risk

Region Rule"). It authorized for the first time the importation of live cattle from a country known to have BSE (Canada), provided the cattle were 30 months of age or less when slaughtered in the United States. It also authorized imports of beef products from cattle of any age slaughtered in Canada.

33. 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. Then on January 11, 2005, CFIA announced that a fourth cow from Alberta, this one only six years and nine months old, had been confirmed to have BSE. In light of these new discoveries of BSE in Canada, including in a cow that was born after Canada implemented measures that USDA had claimed would virtually eliminate future infections, USDA amended the Minimal-Risk Region Rule on March 11, 2005, 70 Fed. Reg. 12,112, to delay indefinitely imports of edible products from Canadian cattle 30 months of age or older (the group considered most likely to carry infectious levels of BSE prions).

34. Despite these additional cases of BSE in Canada, the Secretary of Agriculture and other USDA officials immediately announced their intention to reopen trade with Canada in cattle and commodities of all ages. Notwithstanding numerous additional cases discovered in 2006, USDA persisted in its course of "normalizing" trade in Canadian cattle and beef, proposing a rule on January 9, 2007, 72 Fed. Reg. 1,002, that would remove the provisions in the Minimal-Risk Region Rule that prevent imports of Canadian cattle, and beef from Canadian cattle, 30 months of age and older. The final OTM Rule, published on September 18, 2007, removed any age restriction on imports of most edible bovine products and allowed imports of Canadian cattle for any use (including breeding) if they were born on or after March 1, 1999.

35. The March 1, 1999 date relates to Canada's "feed ban," a ban on feeding ruminant protein to ruminants, believed to be the primary cause of the spread of BSE. That date is 18 months after Canada imposed such a ban in August 1997, to allow for some phasing-in of compliance and for existing feed manufactured before August 1997 to have been used up. While USDA describes March 1, 1999 as the date on which Canada had a fully effective feed ban, in fact what USDA really means is that Canada had a fully implemented partial feed ban by that date. Experience in the UK and Europe (and in Canada, see below) shows that banning ruminant proteins only from ruminant feed, and allowing it to be used in other types of animal feed, results in continued, although lowered, exposure of cattle to BSE infectivity when cattle feed is contaminated with other animal feed or when other animal feed is intentionally or accidentally consumed by cattle. The United States also has such a partial feed ban, promulgated by the U.S. Food and Drug Administration at about the same time as Canada's. Importantly, the U.S. partial feed ban was implemented over six years before the first case of BSE was discovered in the United States, while Canada's partial feed ban was implemented almost four years after the first case of BSE was discovered in Canada.

36. USDA acknowledges that there is a greater than 99 percent chance that at least some BSE-infected cattle will enter the United States from Canada if the OTM rule goes into effect, predicting between 19 and 105 BSE-infected cattle will enter the United States in the next 20 years. Also, implicitly recognizing the limited protection provided by the partial feed ban in the United States, USDA predicts that U.S.-born cattle will be infected with BSE as well because of the OTM rule. USDA deems this effect to be acceptable or "negligible" because it estimates that, under the most likely scenarios, BSE will not become "established" in the

United States, meaning that it will not continue to spread absent continued introduction of BSE infectivity from exogenous sources.

37. In the spring of 2007, the World Organization for Animal Health (the "OIE") issued a report, "OIE *Ad Hoc* Group for Evaluation of Country Status for Bovine Spongiform Encephalopathy in Accordance with the *Terrestrial Animal Health Code*," which concluded that Canada should be classified as a country with "controlled risk" of BSE, rather than a "negligible risk" country. That report explained that "the absence of a feed ban before 1997, the partial implemented feed ban since 1997, and the absence of a prohibition on the use of specified risk material for animal feed allow the risk of recycling and amplification of the BSE agent within the country." The OIE report also noted that the U.S. partial feed ban presented "the likelihood" of cross-contamination of cattle feed with other animal feed potentially carrying BSE infectivity.

38. From January 2006 to the present, Canada announced confirmed BSE infections in seven additional cattle, including for the first time cattle from the provinces of British Columbia, and Manitoba. Thus, almost two-thirds of the known cases of BSE in Canada have been discovered since the beginning of last year. Most importantly, five of those seven cattle were born after the March 1, 1999 date that USDA claims in the OTM Rule is the date at which Canada had an effective feed ban and after which there should be an "extremely low likelihood that cattle born in Canada... will have been exposed to the BSE agent via feed." 72 Fed. Reg. at 53,371. Put another way, even the limited testing conducted by CFIA has found five animals afflicted with BSE that could have been exported to the United States under the OTM Rule. Canada has now detected more cases of BSE than 9 of the 24 other countries where BSE has been found.

39. In response to the continued discovery of BSE in younger and more geographically diverse cattle, and to its assessment that continuing BSE infection was occurring at least in part due to cross-contamination of cattle feed with other types of animal feed (in which ruminant protein continued to be allowed), CFIA adopted a new, more comprehensive feed ban effective July 2007, which now prohibits the use of ruminant protein in all animal feed. CFIA estimates that this new rule will result in the eradication of BSE from the Canadian herd in about 17 years.

CLAIMS FOR RELIEF

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

40. Plaintiff repeats and realleges paragraphs 1-39.

41. 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, acts inconsistently with prior determinations without providing adequate justification, fails adequately to explain the basis for its action or to respond to important public comments, makes internally inconsistent statements, 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.

42. An agency rulemaking is arbitrary and capricious if it is based on assumptions that are without factual basis. This is especially true when the assumptions are inconsistent with facts available to the agency. The OTM Rule rests on several such assumptions. For example, by USDA's own analysis, it is a virtual certainty that the OTM Rule will result in the importation of Canadian cattle infected with BSE, the meat from which will enter the U.S. food supply. The OTM rule will also result in the importation of billions of pounds of meat from OTM cattle slaughtered in Canada, which almost certainly will include cattle infected with BSE, as well. USDA offers only two measures to mitigate the potential for consumers of such meat to become afflicted with (and therefore die from) vCJD. First, USDA assumes that Canadian cattle that show outward signs of BSE ante-mortem will not be allowed to be slaughtered for human consumption. (No post-mortem inspection occurs that has even the potential to identify BSE-infected cattle.) But (1) USDA acknowledges that extensive BSE infection can occur months before there are any outward signs; (2) actual experience shows that USDA FSIS inspectors often are not even in a position to observe cattle behavior that suggests BSE, and FSIS inspectors in any event could easily miss the subtle signs of BSE infection; (3) countries with universal post-mortem BSE testing have found substantially more cases than were identified from outward signs; and (4) no data exist that demonstrate the extent of BSE contamination in beef that can result in an infectious dose to humans (as USDA acknowledged, and as reinforced by comments R-CALF USA submitted from Dr. Stanley Prusiner, who was awarded the Nobel Prize for discovering the prion proteins that cause BSE and other TSEs), or that suggest that humans can only contract vCJD from consuming meat from cattle with outward signs of BSE. Second, USDA assumes that removal of "specified risk materials" ("SRMs") from the carcass of a BSE-infected Canadian bovine virtually eliminates the

potential for infectious levels of BSE in meat removed from that carcass. But there are no studies that demonstrate that SRM removal prevents levels of BSE in meat that could result in vCJD in humans, either because of cross-contamination or because of BSE prions that have been or may be found in tissues not removed with SRM removal (such as the sciatic nerve and other peripheral nerves). APHIS's risk assessment assumed that the vast majority of cattle in Canada are subject to rendering processes that remove 90+ percent of BSE infectivity, whereas the OIE, based on data submitted by CFIA, concluded in 2007 that only 60 percent of meat-and-bone meal produced for animal feed in Canada is subject to rendering processes that result in any reduction in infectivity. USDA's conclusion that allowing imports of OTM Canadian cattle and meat from OTM Canadian cattle presents an acceptable risk of vCJD for U.S. consumers based on these unsupportable assumptions is therefore arbitrary and capricious.

43. An agency action is arbitrary and capricious if the agency fails to make a reasoned connection between the available facts and the conclusions on which the regulation is based. USDA's attempt to justify the OTM Rule is filled with statements that ignore or are contrary to the facts contained in the administrative record. For example: USDA claims that Canada has had an effective feed ban since March 1, 1999, based on USDA modeling and extrapolation from experience in Europe. But the empirical facts are that Canada's partial feed ban was less comprehensive than the feed bans ultimately adopted in Europe; Canada's partial feed ban did not stop the spread of BSE in Canada, both over time and geographically; CFIA itself concluded that its partial feed ban was not adequate to prevent the continued spread of BSE and adopted a more stringent feed ban in 2007; and the OIE recently found that "the absence of a feed ban before 1997, the partial implemented feed ban since 1997, and the absence of a prohibition on the use of specified risk material for animal feed allow the risk of recycling and

amplification of the BSE agent within the country." APHIS says that its conclusion that Canada's enforcement of its partial feed ban has been effective, despite numerous serious noncompliance incidents noted by commenters, was based in part on its consideration of a February 2004 report to the Secretary by the "International Review Team." In fact, the International Review Team assessed the United States' response to the discovery of BSE in a Canadian-born cow in Washington State, and neither its mission nor its report had anything to do with Canadian feed ban enforcement. APHIS claims its assumption that bison could carry BSE is likely conservative, because, it asserts, "no cases of BSE have been detected in bison," 72 Fed. Reg. at 1103 n.1, yet APHIS acknowledged in 2005 that published information from the UK indicates that BSE has been found in bison. See 70 Fed. Reg. at 479. USDA's inaccurate statements in support of its conclusions about the critical issue of the safety of cattle and meat from a BSE-afflicted country render the OTM Rule arbitrary and capricious and warrant its remand to the agency for further consideration and explanation.

44. Another example of USDA's failure to explain how its conclusions are consistent with the available facts concerns USDA's assertion that the adverse economic effects on the U.S. beef industry from the likely importation of numbers of BSE-infected Canadian cattle under the OTM Rule will be insignificant because BSE is unlikely to become "established" in the U.S. cattle herd, and in fact the economic impact will be favorable because other countries will relax their restrictions on U.S. imports once the U.S. removes the prohibition on importation of OTM Canadian cattle and beef. These conclusions fly in the face of the fact that the U.S. cattle industry suffered billions of dollars in lost exports because of its imports from Canada long before BSE had ever been detected in a single U.S.-born animal, much less "established" in the U.S. And USDA's decision to allow imports of riskier OTM cattle and beef hardly seems

likely to produce less-restrictive requirements for U.S. exports, considering that major export markets like Japan and Korea continue to impose severe restrictions on U.S. beef exports, including requirements that U.S. exports include only U.S.-origin beef processed separately from Canadian-origin beef, at a time when the U.S. is importing only less-risky under-30-month cattle from Canada.

45. An agency action is arbitrary and capricious if it reverses prior conclusions and policy decisions without providing adequate justification for that reversal. Prior to the January 2005 Minimal-Risk Region Rule, USDA determined on numerous occasions that, because of uncertainties about BSE and the difficulty of controlling its spread, prohibition on imports of all ruminants and ruminant products from countries where BSE has been found was "necessary" to prevent the introduction and dissemination of BSE in the United States. In its January 2003 report to Congress made pursuant to the Animal Disease Risk Assessment, Prevention, and Control Act of 2001, USDA committed to Congress that it would protect U.S. livestock and people from the introduction of BSE by preventing its entry at the U.S. border. In January 2005, USDA continued to prohibit imports of OTM cattle, maintaining that this prohibition was necessary, because of the higher likelihood that OTM cattle would carry infectious levels of BSE. Changes in scientific knowledge since 2003 do not justify reversal of USDA's prior conclusions about whether a prohibition on imports of cattle from countries known to have BSE, and of older cattle in particular, is necessary to prevent the introduction and dissemination of BSE in the United States, as required by the AHPA. In fact, more recent developments demonstrate that BSE worldwide is even more widely distributed geographically and chronologically than thought previously, that BSE infection continues in Canada despite USDA's predictions to the contrary, and that Canada's partial feed ban (virtually identical to

the United States') has been insufficient to prevent the continued spread of BSE in Canada. Similarly, more recent data about the distribution of BSE prions within cattle and about the potential for transmission of vCJD among humans through blood transfusions only increase the justification for banning imports of edible bovine products, and especially those from older cattle, from countries known to have BSE.

46. An agency action is arbitrary and capricious when the agency makes inconsistent statements and treats similar situations differently. USDA's action in promulgating the OTM Rule is full of such inconsistencies. For example: In the January 2005 Minimal-Risk Region Rule preamble and supporting documents, USDA stated that the discovery of Canadian cattle afflicted with BSE that were born after Canada's 1997 [partial] feed ban would indicate that the feed ban was either ineffective or inadequately enforced. But in the OTM Rule, USDA now asserts that Canada has had an effective feed ban since March 1, 1999, and therefore there is "an extremely low likelihood" that Canadian cattle born after that date "will have been exposed to the BSE agent via feed," despite the fact that almost half of the BSE cases that have now been found in Canadian-born cattle were born after that date. USDA states that Canadian testing data are insufficient to determine whether BSE prevalence in Canada increased or decreased from 1997 to the present, 72 Fed. Reg. at 53,333, and yet USDA says that Canada's current (even less extensive) BSE surveillance testing is adequate and that restricting imports to cattle born after March 1, 1999 presents a lower risk of importing BSE infectivity than allowing imports of even older animals. USDA places great weight on OIE guidelines when they support its position, but ignores OIE's conclusions that Canada does not fall within the "negligible risk" BSE category, that Canada's partial feed ban has allowed the risk of recycling and amplification of the BSE agent within Canada, and that the United States' partial feed ban

presents "the likelihood" of cross-contamination of cattle feed with other animal feed containing bovine protein and therefore does not provide sufficient protection against the spread of BSE in the U.S. USDA bases the March 1, 1999 cutoff date on the fact that cattle feed generally would be completely used within 12 months after its manufacture, but then disavows this conclusion when responding to comments that this must mean that there were many additional cases of BSE in cattle that were rendered and contaminated animal feed after the March 1, 1999 cutoff date, since BSE has been detected in cattle born during each of the following three years. USDA insists that Canada continues to meet the criteria for a "minimal-risk region," specifically "the standard that the region maintain 'risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease,'" 72 Fed. Reg. at 53,323, when BSE clearly has been "established" in Canada as USDA uses that term in the OTM Rule, meaning that BSE has perpetuated without any evidence of additional, exogenous introductions of the disease into that country. USDA says that BSE in the EU generally cannot be detected until six to seven years after exposure, but then cites, as evidence that the EU's feed ban has been extremely effective, the fact that most of the BSE cases detected in the EU during 2001-2005 were born prior to 1999.

47. Defendant Acting Secretary Conner provided a striking example of such inconsistent statements in a September 24, 2007 letter to R-CALF USA. R-CALF USA had sent a letter to then Secretary of Agriculture Johanns on July 26, 2007, alleging that Canada was not testing BSE-positive birth or feed cohorts (cattle born at the same time as an animal later found to have BSE, or that were exposed to the same feed). Conner's September 24 reply confirms that Canada is not testing cohorts as part of its epidemiological investigations, and he further states that Canada does not need to. The OTM Rule, however states just the opposite when

describing Canada's BSE risk mitigation measures: "As a result of these traces [epidemiological investigations], feed cohorts that remain alive are euthanized and tested for BSE." 72 Fed. Reg. at 53,348. Likewise, Conner's letter claims that CFIA's 2007 expansion of its partial feed ban to prohibit ruminant protein in all animal feed was an "enhancement" that meant that "in fact, Canada has strengthened its BSE risk mitigation measures." The OTM rule, in contrast, rejected comments that older Canadian cattle and beef should only be allowed to enter the U.S. after CFIA's July 2007 enhancements have produced their effect, saying that it is not possible to know whether Canada's 2007 feed ban improvements provide any additional benefit to the feed ban it enacted in 1997. 72 Fed. Reg. at 53,336. When the Acting Secretary of Agriculture is describing Canada's BSE risk mitigation measures in a manner directly contradicting the purported justifications offered for the OTM Rule, the OTM Rule is arbitrary and capricious and must be remanded to USDA for further explanation.

48. An agency is required to conform to its own regulations; promulgating a new regulation that conflicts with a regulation already in force makes the issuance of the new regulation arbitrary and capricious. USDA's Minimal-Risk Region Rule specifies that a BSE minimal-risk region is a region that "maintains, and…had in place prior to the detection of BSE in an indigenous ruminant, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease." 9 C.F.R. § 94.0. The regulation also states that: "Such mitigation measures include the following: …(iii) a ruminant-to-ruminant feed ban that is in place and is effectively enforced." The OTM Rule acknowledges that BSE has become established in Canada, as Canada is now on at least its third generation of the disease. Thus, Canada by definition did not have risk mitigation measures in place prior to the detection of its first case of BSE in native cattle in 2003 that were adequate to prevent establishment of the

disease. USDA's continued treatment of Canada as a minimal-risk region in the OTM Rule, while at the same time acknowledging that Canada does not meet the criteria for minimal-risk regions in 9 C.F.R. § 94.0, renders the OTM Rule arbitrary and capricious.

49. An agency's promulgation of a regulation is arbitrary and capricious if the agency failed to give consideration to an important aspect of the issue. Despite the fact that the OTM rule is expected to result in the importation of dozens of BSE-infected cattle for slaughter and entry into the U.S. beef supply, as well as the importation of billions of pounds of meat from older Canadian cattle slaughtered in Canada, including those born before March 1, 1999 that USDA considers even more likely to carry infectious levels of BSE, USDA by its own admission did not attempt a risk assessment to determine the likelihood of U.S. and foreign consumers consuming BSE-infected beef. Nor, obviously, did USDA conduct a risk assessment to determine the likelihood that those individuals will be afflicted with vCJD, or that the U.S. blood supply will become infected as a result. USDA's cavalier assertion that the exposure will be much less than in the UK, where there have been what it apparently considers to be relatively few (165) cases of this invariably fatal disease, does not supplant an assessment of the risk to U.S. consumers, and especially so when tissue samples from UK residents suggest a much larger group of people infected with BSE prions than those that have so far been confirmed to have vCJD and when testimony by expert prion researcher and Nobel laureate Dr. Stanley Prusiner indicates that it is not possible to make a scientifically sound conclusion that humans have a low susceptibility to vCJD infection from a given level of BSE infection in cattle.

50. It is arbitrary and capricious for an agency to issue a regulation for the protection of public health and welfare without providing for any effective means of enforcement. USDA

believes that cattle born before March 1, 1999 present a higher risk of being infected with BSE, and hence it has prohibited imports of such older cattle. But the OTM Rule gives no guidance on how it is to be determined that an animal was born before that date. Commenters expressed uncertainty about how that would be done. USDA expressed confidence that the requirement would keep most OTM cattle born after March 1, 1999 out of the U.S. as well, because of the difficulty of determining date of birth. But the OTM Rule does not specify a means for making that determination. Similarly, USDA refused to impose a ban on imports of cattle that had consumed the same feed as a BSE-positive animal ("feed cohorts"), based on its assertion that CFIA practice is to euthanize feed cohorts that can be identified in an investigation of a BSE-positive animal. But nothing in the OTM Rule or other U.S. regulation requires that to be done. A regulation whose protection of the health of U.S. cattle, and ultimately U.S. consumers, is founded on a requirement for which there is no specified means of compliance and no practicable means of verifying or enforcing compliance is arbitrary and capricious and should be struck down.

51. USDA's promotion of foreign policy goals and other unauthorized considerations when implementing statutes intended for the protection of U.S. consumers, cattle, and cattle producers, as further described in Count 2 below, and its failure adequately to explain the basis for its action, including especially its failure to respond adequately or at all to important public comments, as described in Count 3 below, also render the OTM Rule arbitrary and capricious and an abuse of discretion under 5 U.S.C. § 706(2)(A). For these and the foregoing reasons, the Court should hold unlawful and set aside the OTM Rule under 5 U.S.C. § 706(2)(A).

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

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 – ...(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;..." 5 U.S.C. § 706(2).

54. 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, detect, control, and eradicate 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.

55. In the OTM Rule USDA, for the expressed purpose of "normalizing" trade with Canada, modified existing prohibitions on the importation from Canada of OTM cattle and beef from OTM cattle, even though USDA acknowledged the virtual certainty that this would mean importing BSE-infected cattle and beef from BSE-infected cattle. USDA attempts to justify this decision with its prediction that BSE would not be "established" in the United States, meaning that the estimated 19-105 BSE-infected cattle that would be imported into the United States over the next 20 years would not result in the infection of sufficient cattle in the U.S. herd to cause BSE to continue to spread in the U.S. herd.

56. By substituting a new standard for regulating imports—restrictions necessary to avoid the establishment of an animal disease in the United States, rather than following Congress' mandate that USDA take action necessary to "prevent" the "introduction into or dissemination within" the United States of animal diseases, and that USDA take the steps necessary to detect, control, and eradicate animal disease, USDA acted outside of its statutory authority. Likewise, USDA acted outside of its statutory authority when it based its restrictions on Canadian imports under the AHPA on a desire to "normalize" trade with Canada and to encourage other countries to lift restrictions on exports of beef from the United States to those countries—objectives that are not authorized under the AHPA.

57. USDA attempted to justify the OTM rule in part on the reduced costs that Canadian producers would realize because of the reduction in paperwork requirements for Canadian cattle exported to the United States and on reduced APHIS and Border Protection and Customs resources needed for inspection of Canadian cattle and beef shipments. By acting to minimize burdens on foreign nationals and U.S. government agencies rather than promoting the interests of the U.S. cattle industry, USDA was acting outside of its statutory authority.

58. Under the OTM Rule, the United States will knowingly import cattle infected with a pernicious, persistent disease that has devastated the cattle industry in other countries (including Canada), and moreover they will be imported into a country that has the least extensive BSE-mitigation measures of any developed country (including Canada). USDA will allow cattle of the age group in which it believes BSE is most likely to be detected (see 72 Fed. Reg. at 53,341) to be imported, even though the United States' measures to prevent the spread of BSE to other cattle are less protective than those in use by other countries, recommended by USDA's own International Review Team, and urged by the OIE. 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 OTM Rule an action in excess of and inconsistent with its statutory authority. For that reason, the OTM Rule is unlawful and should be set aside pursuant to 5 U.S.C. § 706(2)(C).

59. In addition, in a number of respects USDA's claimed justification for the OTM Rule is that it conforms to "OIE guidelines." The OIE has no authority to create standards for the protection of animal and human health for the United States, and USDA acts outside of its statutory authority when it effectively delegates to the OIE responsibility for determining what measures with respect to imports are necessary to prevent the introduction or dissemination of animal diseases into the United States. This derogation of USDA's statutory responsibilities renders the OTM Rule unlawful and requires that it be set aside pursuant to 5 U.S.C. § 706(2)(C).

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

60. Plaintiff repeats and realleges paragraphs 1-59.

61. 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 OTM Rule, including public notice and comment in most circumstances.

62. The OTM rule amends the Minimal-Risk Region Rule by deleting language in 9 C.F.R. §§ 94.19(a), (b), and (f) and 95.4(f) and (g) that prohibited importation of edible bovine

products and certain bovine-derived tallow and gelatin from BSE-minimal-risk regions unless those products came from animals under 30 months of age at slaughter. Imports of edible bovine products and certain bovine-derived tallow and gelatin from cattle 30 months of age and older had been "delayed indefinitely" after the discovery of two additional cases of BSE in Alberta Province, one of which was born months after Canada's partial feed ban became effective. 70 Fed. Reg. 12,112. (March 11, 2005). The 30-month cutoff was based both on the assumption that younger animals, born after Canada enacted its partial feed ban, would not have been exposed to potentially contaminated feed, and on the assumption that, since recognizable symptoms of BSE generally occur a number of years after infection, levels of BSE contamination will be low even in infected cattle under 30 months of age.

63. Defendants never issued a notice of proposed rulemaking, nor did they seek public comments, on the action taken in the final OTM Rule that allows imports of edible products and tallow and gelatin from Canadian cattle that were 30 months of age or older at the time of slaughter. In the January 9, 2007 Notice of Proposed Rulemaking for the OTM Rule, USDA simply made reference to the March 11, 2005 Federal Register notice that amended the regulations to prohibit imports from older Canadian cattle and stated that: "Removal of the delay of applicability, thereby allowing importation of Canadian beef from cattle slaughtered at 30 months or older, is a decision that will be taken at the discretion of the Secretary of the U.S. Department of Agriculture." 72 Fed. Reg. at 1125. In fact, the Notice of Proposed Rulemaking stated that USDA was not proposing to change the 30-month restriction on imports of Canadian beef. 72 Fed. Reg. at 1123. Nor did the January 9, 2007 Notice of Proposed Rulemaking otherwise discuss the safety of beef and other products from Canadian cattle 30 months of age and older, and the APHIS risk assessment prepared to support the

proposed OTM rule deliberately was limited to imports of live cattle, blood and blood products, and small intestines.

64. Section 553 of the APA requires notice-and-comment rulemaking procedures for the removal of a regulation as well as its promulgation. This is especially important where, as here, the removal of a regulation has the effect of authorizing the importation of products that previously had been considered to present an unacceptable risk. While there are certain exemptions in the APA to its notice-and-comment rulemaking procedure requirements, USDA did not attempt to justify its action under any of those exemptions, nor could it. On information and belief, Defendants omitted discussion of importation of beef from the public notice of the proposed OTM Rule and related documents in order to present to the public an inaccurate view that limited the effect of the rulemaking. USDA's promulgation of amendments to 9 C.F.R. §§ 94.19(a), (b), and (f) and 95.4(f) and (g), allowing imports of edible and other bovine products from Canadian cattle 30 months of age and older, without providing notice of the proposed amendments or seeking public comment, renders the OTM Rule unlawful under 5 U.S.C. § 706(2)(D).

65. Additionally, USDA never presented for public comment, even in the rulemaking for the January 4, 2005 Minimal-Risk Region Rule, an assessment of the risks of consuming imported beef from Canadian cattle that were 30 months of age or older at the time of slaughter. The original proposal for the Minimal-Risk Region Rule did not allow such imports, and a 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. 10,633, 10,635. The "Harvard Risk Assessment" and the APHIS Risk Analysis on which USDA relied

in promulgating the Minimal-Risk Region Rule did not contain an assessment of the risk of vCJD from consuming Canadian beef, other than subjective conclusions that it will be "low" or "very low." Moreover, the risk assessments available to the public in conjunction with the proposed Minimal-Risk Region Rule all assumed that Canadian beef imports would be limited to those from cattle under 30 months of age at slaughter. Thus, the public has never had an opportunity to review and comment upon USDA's conclusion that the risk to the public of dying from vCJD as a result of consuming beef products from older Canadian cattle is acceptable (nor that the risk to others from blood transfusions from individuals who may become infected with BSE prions from consuming such products is acceptable).

66. Some of the plaintiffs 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 United States' current incomplete ban on animal protein in cattle feed, and to allow consumers the opportunity to protect themselves against such risks. USDA failed to provide a meaningful response to many of those substantive comments. Likewise, USDA failed to respond in a meaningful way to comments that the Finding of No Significant Impact under the National Environmental Policy Act could not be based on a conclusion that the environmental impacts would be insignificant when compared with the total environmental impacts from all other activities not covered by the OTM Rule, rather than assessing the environmental impacts of the OTM Rule itself. USDA also failed to respond to comments that its Regulatory Impact Analysis should have considered the effect that alternatives, e.g. requiring labeling of

Canadian-origin beef and allowing or requiring U.S. slaughter facilities to test Canadian cattle for BSE, would have on the economic effect of the OTM Rule on small businesses and others, and that the fact that rendered cattle can be used in animal feed in the United States but not in Canada would create a strong financial incentive for Canadians to export older cattle to the United States.

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

Count 4 – National Environmental Policy Act

68. Plaintiff repeats and realleges paragraphs 1-67.

69. 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.

70. The Environmental Assessment and Finding of No Significant Impact APHIS prepared in connection with the OTM Rule did not contain an adequate evaluation of the environmental

impacts that would result from the additional importation of millions of head of cattle from Canada as a result of the OTM Rule. For example, USDA declined to estimate the increased emissions of air pollutants and greenhouse gases associated with those additional imports, on the grounds that it would be difficult to accurately estimate those emissions and that they would not be significant compared to the emissions from the transportation of all goods from Canada.

71. NEPA does not allow an agency to decline to assess the environmental impacts of a proposed action on the basis that they will be small compared to the totality of other environmental impacts, nor on the basis that the environmental impacts are uncertain or difficult to estimate. In so doing, APHIS lacked a meaningful basis for its conclusion that the OTM Rule would not have a significant adverse environmental impact. Just as importantly, decisionmakers and the public have been deprived of an opportunity to form a judgment about whether that environmental impact is acceptable and justified by the purported benefits of the OTM Rule—an opportunity that NEPA is designed to provide. Thus, USDA failed to comply with its obligations under NEPA, and NEPA requires a stay of the OTM Rule until the required analysis can be completed.

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

72. Plaintiff repeats and realleges paragraphs 1-71.

73. USDA admits that the OTM 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.

74. 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 OTM 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. Nor did USDA gives adequate consideration to the mitigation of adverse effects on small businesses that could have been achieved by authorizing small businesses to test the cattle they slaughter for BSE, to address foreign and domestic customers' concerns and to prevent entry of BSE into the U.S. food supply and animal feed supply through the slaughter of asymptomatic BSE-infected cattle.

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court:

a) Enter judgment declaring that USDA's final action entitled "Bovine Spongiform Encephalopathy; Minimal-Risk Regions; Importation of Live Bovines and Products Derived From Bovines; Final Rule," 72 Fed. Reg. 53,314 (Sept. 18, 2007) 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 30 months of age or older and all edible bovine meat products derived from cattle of Canadian origin that were 30 months of age or older at slaughter;

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 November 19, 2007;

d) Award Plaintiffs their costs and reasonable attorneys' fees in this action, pursuant to 28 U.S.C. § 2412 and any other applicable authority; and

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

Dated: October 24, 2007

Respectfully submitted,

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