

UNITED STATES DISTRICT COURT
 DISTRICT OF SOUTH DAKOTA
 NORTHERN DIVISION

RANCHERS CATTLEMEN ACTION)
LEGAL FUND, UNITED STOCKGROWERS)
OF AMERICA, <u>et al.</u> ,)
) CIV-07-1023
Plaintiffs,)
) STATEMENT OF FACTS IN
vs.) SUPPORT OF DEFENDANTS’
) OPPOSITION TO PLAINTIFFS’
UNITED STATES DEPARTMENT) MOTION FOR PRELIMINARY
OF AGRICULTURE, <u>et al.</u> ,) INJUNCTION
)
Defendants.)
)

The following statement of facts is submitted in support of defendants’ opposition to plaintiffs’ motion for a preliminary injunction.

I. APHIS’s Regulation of Imports To Safeguard Against Bovine Spongiform Encephalopathy (BSE) Under the Animal Health Protection Act

1. The Animal Health Protection Act (AHPA), 7 U.S.C. §§ 8301 et seq., gives the Secretary of the United States Department of Agriculture (USDA) broad discretion to regulate – or not regulate – the importation of animals and animal products. It states that the Secretary “may” prohibit or restrict such importation “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.” 7 U.S.C. § 8303(a)(1) (emphasis added). The Animal and Plant Health Inspection Service (APHIS) is the agency within USDA that regulates the importation of animals and animal products to guard against the introduction of various animal diseases in the United States. See Administrative Record^{1/} (AR) 8044-45; 72 Fed. Reg. 1102, 1104 (Jan. 9, 2007); 72 Fed.

^{1/} Citations are to the Administrative Record filed in RCALF v. USDA, 359 F. Supp. 2d 1058 (D. Mont. 2005), rev’d, RCALF v. USDA, 415 F.3d 1078 (9th Cir. 2005); see also RCALF v. USDA, 499 F.3d 1108 (9th Cir. 2007) . That Administrative Record will also be part of the Administrative Record in this case and will retain the same pagination once it is available.

Reg. 53,314 (Sept. 18, 2007).

II. The BSE Outbreak in Europe and the Species Barrier to BSE's Human Counterpart, Variant Creutzfeldt-Jakob Disease

2. BSE is a progressive and fatal neurological disorder of cattle. Although the agent that causes BSE has yet to be fully characterized, the theory that is most accepted in the international scientific community is that the agent is an abnormal form of a protein called a cellular prion protein. AR 8045; 72 Fed. Reg. at 1104. BSE is not a contagious disease, and, therefore, is not spread through casual contact between animals. 72 Fed. Reg. at 1104. Scientists believe that the primary route of transmission between cattle requires that cattle ingest feed that has been contaminated with a sufficient amount of infected tissue from another animal. *Id.* This route of transmission can be prevented by excluding potentially contaminated materials, including tissues designated as “specified risk materials” (SRMs), from ruminant^{2/} feed. *Id.*

3. BSE was first diagnosed in the United Kingdom in 1986. AR 8045. There have since been more than 187,000 confirmed cases of BSE in cattle worldwide, from native-born cattle in more than twenty countries. *Id.* However, over 95 percent of all BSE cases have occurred in the United Kingdom, where the epidemic peaked in 1992/1993. *Id.* As a result of actions taken in the United Kingdom to mitigate BSE, including a ban on mammalian meat-and-bone meal in ruminant feed (a so-called “feed ban”), the annual incidence has fallen dramatically, *i.e.*, by 99.4 percent between 1992 and 2005. AR 8045, 8334; 72 Fed. Reg. at 1104-05.

4. Variant Creutzfeldt-Jakob disease (vCJD), a chronic and fatal neurodegenerative human disease, has been linked to exposure to BSE, most likely through consumption of contaminated cattle products. AR 8046; 72 Fed. Reg. at 53,362. Approximately 200 cases have been identified worldwide since 1986. http://www.cdc.gov/ncidod/dvrd/vcjd/factsheet_nvcjd.htm

^{2/} Ruminants are all animals that chew cud, such as cattle. 9 C.F.R. § 93.400.

Approximately 95% of those cases were linked to exposure in the United Kingdom and France; all have been linked to exposure in countries with native cases of BSE; and all are believed to have resulted from the consumption of beef connected to high-risk central nervous system tissues designated as SRMs. AR 8046; 72 Fed. Reg. at 53,335. Some studies estimate that more than one million cattle may have been infected with BSE throughout the epidemic in the United Kingdom. AR 8046. The relatively small number of cases of vCJD suggests a substantial species barrier that may protect humans from widespread illness due to BSE. AR 8046; 72 Fed. Reg. at 53,335. In fact, to become infected, humans may need exposure to as much as 10,000 times the level of infective tissues necessary to infect cattle. 72 Fed. Reg. at 53,335.

III. Gradual Resumption of Canadian Cattle and Beef Imports

A. Initial Temporary Ban on Canadian Imports

5. In response to the discovery of BSE, beginning in 1989, APHIS imposed progressively more restrictive bans on the importation of live ruminants and most ruminant products from regions affected with BSE or presenting a BSE risk. AR 8046. Prior to May 20, 2003, there were no restrictions on imports of Canadian cattle or beef because of BSE. AR 3628. However, following the detection of a BSE-infected cow in Canada in May 2003, APHIS issued an interim rule adding Canada to the list of countries affected with BSE and effectively temporarily prohibiting imports of Canadian cattle and most Canadian beef. AR 8512; 72 Fed. Reg. at 53,315.

B. The November 2003 Proposal to Designate Canada a Minimal Risk Region and to Resume Imports of Under-30-Month Cattle and Beef

6. After issuing the interim rule, APHIS proceeded to complete a risk analysis regarding the possibility of resuming Canadian cattle and beef imports. Upon its completion, in a November 2003 proposed rule, APHIS proposed to designate Canada as a “BSE minimal risk region” – one that would present a minimal risk of introducing BSE into the United States via live ruminants and

ruminant products. AR 94, 8046-47. APHIS based this proposal on Canada's fulfillment of the three requirements for such regions. 9 C.F.R. § 94.0; see AR 96, 8048. First, Canada maintained risk mitigation measures to prevent widespread exposure and/or establishment of BSE, including import restrictions on animals, animal products and feed; conducted surveillance for BSE at levels recommended by the Office International des Epizooties (OIE, also referred to as the World Organisation for Animal Health)^{3/}; and enforced an effective ban on feeding ruminant protein to ruminants. AR 8047. Second, it conducted an epidemiological investigation to confirm the adequacy of measures to prevent the further introduction or spread of BSE. Id. Third, it took additional risk mitigation measures, as necessary, based on risk analysis of the outbreak. Id. APHIS used these criteria as an integrated evaluation tool, basing a BSE minimal-risk classification on the overall effectiveness of control and monitoring mechanisms in place in Canada. Id.

7. The November 2003 proposed rule also proposed to permit imports from Canada of (1) cattle less than 30 months of age, and (2) meat from such cattle, subject to prescribed conditions. AR 100-102. The rationale for this proposal was that because of the nature, incubation period, and progression of BSE infectivity, young cattle exposed to low levels of BSE will accumulate very little BSE infectivity within the first few years of life. AR 8329-31; 72 Fed. Reg. at 1103. Cattle under 30 months of age from a BSE minimal-risk region like Canada are highly unlikely to have accumulated significant amounts of BSE infectivity even if infected. 72 Fed. Reg. at 1103. Therefore, the risk to U.S. livestock presented by the importation of such bovines is very low. Id.

^{3/} The Office International des Epizooties (OIE) is recognized by the World Trade Organization as the international organization responsible for developmental and periodic review of standards, guidelines, and recommendations with respect to animal health and zoonoses (diseases that are transmissible from animals to humans). AR 8047; 72 Fed. Reg. at 53,340, col. 3; id. at 1105; 70 Fed. Reg. 460, 463, col. 2 Jan. 4, 2005); see also RCALF, 415 F.3d at 1088.

C. Federal Agency Responsibilities in Protecting Human and Animal Health and the January 2004 SRM-Removal Rule

8. Because vCJD has been linked via scientific and epidemiological studies to exposure to the BSE agent, most likely through consumption of cattle products contaminated with the BSE agent, APHIS collaborates with other Federal agencies to implement a coordinated U.S. response to BSE. 72 Fed. Reg. at 1104. Protection from the risks of BSE is carried out primarily by APHIS with respect to animal health and USDA's Food Safety and Inspection Service (FSIS) with respect to the food safety of meat and poultry. Id. These entities work in coordination with various offices within the Food and Drug Administration of the U.S. Department of Health and Human Services for the protection of foods other than meat or poultry, blood and blood products, and drugs and medical devices containing bovine material. Id.

9. On January 12, 2004, in response to the December 2003 detection of a BSE-positive cow in Washington State, FSIS issued a series of three interim final rules to minimize human exposure to SRMs scientifically demonstrated to have the potential to contain the BSE agent in infected cattle. One rule designated certain materials from cattle as SRMs, declared that SRMs were inedible, and prohibited the use of SRMs for human food. 69 Fed. Reg. 1862 (Jan. 12, 2004). It required establishments that process and slaughter cattle to develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. Id. This rule also prohibited the slaughter of non-ambulatory disabled cattle for human consumption and prescribed the proper disposition of such cattle. Id. The other rules dealt with requirements for meat produced by advanced meat recovery systems (69 Fed. Reg. 1874 (Jan. 12, 2004)) and a prohibition on the use of air injection stunning methods at slaughter (69 Fed. Reg. 1885 (Jan. 12, 2004)). On July 13, 2007, FSIS finalized the SRM interim final rule with amendments, and affirmed without amendment the air injection stunning interim final rule. 72 Fed. Reg. 38,700, 38,701 (July 13, 2007).

10. In support of FSIS's July 13, 2007, final rule, the agency conducted a risk assessment to develop baseline and mitigation estimates of the potential human exposure to the BSE agent. FSIS used an updated version of the 2001 and 2003 risk assessment models used in a previous human health risk assessment conducted by the Harvard Center for Risk Analysis of the Harvard School of Public Health and the Center for Computational Epidemiology at Tuskegee University. A peer review of the updated model and the resulting assessment was completed in September 2005. In July 2006, FSIS published a notice in the Federal Register announcing the availability of the updated risk assessment and requested public comment. 71 Fed. Reg. 39,282 (July 12, 2006). The notice also announced a public meeting to discuss the updated risk assessment. *Id.* Plaintiff RCALF participated in this process and filed an extensive comment with FSIS regarding the risk assessment and the conclusions drawn therefrom. *See* http://www.fsis.usda.gov/PDF/BSE_Risk_Assess_Response_Public_Comments.pdf. A full and comprehensive discussion of the updated risk assessment is found in FSIS's July 2007 SRM final rule. 72 Fed. Reg. at 38,724-26. FSIS concluded that the results of the 2005 model demonstrate that removal of SRMs almost completely eliminates potential human exposure to the BSE agent and that the regulatory requirements for SRM removal are prudent and appropriate for preventing potential human exposure to the BSE agent. 72 Fed. Reg. at 38,726; *see also* 72 Fed. Reg. at 53,336, cols. 1-2.

D. The March 2004 Proposal to Resume Imports of Beef from Canadian Cattle Thirty Months of Age and Older (OTM)

11. On March 8, 2004, APHIS reopened the comment period on the November 2003 proposed rule and also proposed to allow the import of beef from OTM Canadian cattle, provided SRMs are removed at slaughter. AR 3837. APHIS stated:

The measures taken by FSIS do not restrict the slaughter of cattle in the United States based on the age of the animals — i.e. meat from cattle 30 months of age or older will continue to

be allowed into the human food supply. However, measures are in place to ensure that SRMs from such cattle do not enter the food supply. We now believe it would not be necessary to require that beef imported from BSE minimal-risk regions be derived only from cattle less than 30 months of age, provided equivalent measures are in place to ensure that SRMs are removed when the animals are slaughtered, and that such other measures as are necessary are in place. We believe such measures are already being taken in Canada. We invite comment from the public regarding this change to the provisions we proposed in November 2003 regarding the importation of beef.

AR 3839.

12. These measures effectively mitigated any BSE risk to humans. AR 3839, 8049; 72 Fed. Reg. at 38,700. Additionally, FDA's feed ban prohibits ruminant protein from entering the ruminant feed chain and thereby spreading BSE through feed. AR 3839, 8049. Based on these factors, APHIS concluded that beef imported from BSE minimal-risk regions could safely be derived from OTM cattle, provided the exporting region takes equivalent and other necessary risk mitigation measures. AR 3839, 8049.

E. The January 2005 Final Rule Allowing Imports of Under-30-Month Cattle, and Beef from Cattle of Any Age

13. After evaluating the 3,379 public comments it received, APHIS published a final rule in January 2005 that allowed the importation of cattle under 30 months of age and meat from cattle of any age. Plaintiff RCALF challenged the January 2005 rule and was twice defeated in the United States Court of Appeals for the Ninth Circuit, which reversed the district court's issuance of a preliminary injunction, RCALF v. USDA, 415 F.3d 1078 (9th Cir. 2005), and subsequently affirmed the district court's grant of summary judgment for USDA, RCALF v. USDA, 499 F.3d 1108 (9th Cir. 2007). The Court of Appeals held that the AHPA gives the Secretary "wide discretion . . . over such decisions as whether to close the borders," and "does not impose any requirement on USDA that all of its actions carry no associated increased risk of disease." RCALF, 415 F.3d at 1094; see also RCALF, 499 F.3d at 1115 (same). Examining the rule itself, the Court concluded that "the Secretary had a firm basis for determining that the resumption of ruminant imports from Canada

would not significantly increase the risk of BSE to the American population.” RCALF, 415 F.3d at 1095.

14. The Court “view[ed] the BSE prevention measures currently in place as part of a comprehensive system,” and “evaluat[ed] the cumulative effects of the multiple, interlocking safeguards.” Id.; see also RCALF, 499 F.3d at 1116, 1118. Those measures included the low incidence of BSE in Canadian cattle, Canada’s feed ban and import restrictions, and Canada’s BSE testing and epidemiological investigations. RCALF, 415 F.3d at 1095. The Court also concurred with USDA’s finding that as a result of these mitigations, “Canada’s already low rate of BSE is decreasing.” Id. The Court agreed that measures inside the United States also minimized the risk that BSE would enter the human food supply, such as regulations requiring SRM removal at slaughter. Id. at 1096. It found that the final defense against human BSE infection is possibly “a substantial species barrier that prevents BSE from easily infecting humans.” Id.

15. The Court concluded that “[t]his regulatory system, with its numerous overlapping and complementary safeguards, is designed to minimize the risk of BSE to American livestock and consumers.” Id. It found that “substantial evidence supports USDA’s conclusion that these protections will effectively achieve that goal.” Id. It also cited the findings of the “Harvard-Tuskegee Study,” commissioned by USDA, that even if 10 infected cows were imported into the United States from Canada, the disease was “‘virtually certain’ to be eradicated from the United States within 20 years.” Id.; see also RCALF, 499 F.3d at 1120.

16. Addressing RCALF’s allegations, the Ninth Circuit found that criticisms of Canada’s feed ban are “baseless,” RCALF, 415 F.3d at 1098; that there was “support in the administrative record” for the effectiveness of SRM removal, id. at 1099; and that mandatory testing of Canadian cattle was not an effective food safety measure, id. at 1100. In conclusion, it held that USDA had made a “reasoned determination that the importation of a small number of BSE-infected cattle into

this country would not pose a serious risk to humans or livestock,” and that “USDA necessarily decided that the risks inherent in the uncertainty surrounding current scientific understanding of BSE were insufficiently significant to justify the continued exclusion of Canadian cattle.” Id.; see also RCALF, 499 F.3d at 1121.

F. The Temporary Delay of Implementation of the January 2005 Rule Permitting the Import of OTM Meat

17. On March 11, 2005, APHIS delayed until further notice the applicability of the provisions of the January 2005 final rule as they applied to the importation of OTM beef. AR 12570-71. This temporary delay was “necessary to give Department officials the opportunity for further review and consideration of the specified provisions.” Id. The delay followed the confirmation of BSE in two Canadian cows in January 2005. 72 Fed. Reg. at 1108; 72 Fed. Reg. at 53,316. Ongoing investigations into those cases were not complete, and the Secretary deemed it prudent to delay the effective date for importation of OTM beef. 72 Fed. Reg. at 53,316. Looking beyond the January 2005 final rule allowing importation of live bovines under 30 months of age and beef from cattle of any age, the Secretary stated that USDA would consider and develop a plan – based on the latest scientific information and with the protection of public and animal health as the highest priority – to allow imports of live OTM bovines. Id.

G. The January 2007 Proposal to Resume Imports of OTM Cattle Born After March 1, 1999

18. When USDA reopened the comment period in March 2004 regarding the proposed import of OTM beef, it indicated that it was continuing to evaluate the possible resumption of imports of OTM live cattle. Specifically, it stated that “[w]ith regard to the importation of live animals from BSE minimal-risk regions, APHIS is currently evaluating the appropriate approach regarding such animals and intends to address that issue in a supplemental rulemaking proposal in the Federal Register.” AR 3839.

19. In a proposed rule issued on January 9, 2007, APHIS proposed to allow the import from Canada, under certain conditions, of live bovines born on or after March 1, 1999. 72 Fed. Reg. at 1102. The latter date was determined by APHIS to be the date of effective enforcement of a ruminant-to-ruminant feed ban in Canada. Id. As part of this rulemaking, APHIS conducted an assessment that evaluated the BSE risk to animal health in the United States. 72 Fed. Reg. at 53,315. The assessment concluded that, over the 20 years of the analysis, the BSE risk to the United States is negligible. Id. APHIS made the risk assessment available for public review and comment when it issued the proposed rule. 72 Fed. Reg. at 1102.

20. In addition, APHIS requested an external, formal, independent peer review of the assessment by recognized experts in the field. 72 Fed. Reg. at 53,315. The objective of the peer review was to determine whether the risk assessment was scientifically sound, transparent, and consistent with international standards (i.e., those established by the OIE); the application of external assessments or models was appropriate; and the assumptions were justified, supported, and reasonable. Id. Comments submitted by the public on the proposed rule were submitted to the peer reviewers for their consideration. Id.

21. The reviewers found that the methods used in the risk assessment were scientifically rigorous in terms of using existing literature and models appropriately and making sound assumptions, and that the risk assessment adhered to international risk assessment standards. 72 Fed. Reg. at 53,316. The reviewers also agreed with the conclusion that the likelihood of establishment of BSE in the U.S. cattle population and potential risks from cases that might occur naturally are “negligible.” Id.

H. The September 2007 Final Rule Resuming Imports of OTM Cattle Born After March 1, 1999, and Lifting the Temporary Delay as to OTM Meat

22. APHIS published the final rule on September 18, 2007, adopting the provisions of the

January 2007 proposed rule allowing imports of OTM Canadian cattle born after March 1, 1999. 72 Fed. Reg. 53,314. The final rule also lifted the temporary delay of the January 2005 provisions allowing the import of OTM beef and beef products. Id. at 53,316. APHIS had obtained additional information regarding all aspects of the issues that prompted the delay of applicability and conducted additional analyses in line with its plan. Id.; 72 Fed. Reg. at 1106. Its finding of a negligible risk from the importation of live older cattle gave further support to the conclusion of the risk analysis supporting the January 2005 final rule allowing importation of meat and meat products derived from bovines of any age. Id.

IV. The Rationale for the Rule and the Qualitative and Quantitative Risk Assessment

23. The BSE rules are premised on a series of interlocking, overlapping, and sequential barriers to the introduction and establishment of BSE in the United States. 72 Fed. Reg. at 53,333, col. 3; see also RCALF, 499 F.3d at 1116; RCALF, 415 F.3d at 1095. Each of these interrelated barriers is important, and while no single barrier is itself absolute, each produces a reduction in risk that is compounded by the sequential application of the mitigations. 72 Fed. Reg. at 53,333-34; see also RCALF, 499 F.3d at 1116 (approving of a “holistic approach”); RCALF, 415 F.3d at 1095 (endorsing “the cumulative effects of the multiple, interlocking safeguards”). Together they reduce to a “negligible” level the BSE risk to the United States. 72 Fed. Reg. at 53,334. The requirements of the OTM Rule and the mitigation measures in place in the United States and Canada have proven effective throughout the world and are consistent with the international scientific consensus reflected in the OIE guidelines. Id. at 53,315-16, 53,333, col. 3.

24. The OTM Rule allows the importation of live bovines from BSE minimal-risk regions only if born on or after the date by which the feed ban was being effectively enforced. Id. at 53,314, col. 1. Under this rule, the likelihood of BSE exposure and establishment in the U.S. cattle population as a consequence of infectivity introduced via imports from Canada is “negligible.” Id.

at 53,315, col. 3, 53,316, col. 1, 53,329, cols. 2-3, 53,334, col. 1; id. at 1109. The reasons for this minimal risk are that Canada effectively enforces its feed ban, 72 Fed. Reg. at 53,330, col. 2; id. at 1106; there is a very low level of BSE prevalence in Canada, 72 Fed. Reg. at 53,329, col. 2, 53,334, col. 1; id. at 1108; and the additional, sequential barriers to the transmission of BSE have a multiplicative risk-reduction effect, 72 Fed. Reg. at 53,331, cols. 1-2, 53,333-34, cols. 3, 1; id. at 1109.

A. Very Low Level of BSE Prevalence in Canada

25. APHIS conducted an assessment of the potential BSE risk of importing live bovines from Canada by laying out the series of occurrences necessary for disease to enter and become established, estimating the likelihood of each occurrence, and interpreting its significance in the context of the entire process. 72 Fed. Reg. at 1107. In designating Canada a minimal-risk region, APHIS found that Canada had in place and was maintaining risk mitigation measures adequate to prevent widespread exposure and/or establishment of BSE. Id. at 1107-08; RCALF, 499 F.3d at 1115-16; see also RCALF, 499 F.3d at 1121 (concluding that “the agency considered the relevant factors and articulated a rational connection between the facts found and its decision to designate Canada a minimal-risk country”). Its quantitative estimate of BSE prevalence conducted as part of the risk assessment for the January 2007 proposed rule indicated a very low level of BSE prevalence in Canada. 72 Fed. Reg. at 53,334, col. 1; id. at 1108; see also RCALF, 415 F.3d at 1095 (noting “the low incidence of BSE in Canadian cattle”).

26. It was not unexpected that five of the eleven Canadian-born BSE-infected cattle were born after March 1, 1999, nor did these detections undercut the conclusion that March 1, 1999, should be considered the date of effective enforcement. 72 Fed. Reg. at 53,319, cols. 2-3, 53,330, col. 3, 52,221, col. 1; id. at 1108. Experience worldwide has demonstrated that even in countries with an effective feed ban in place, BSE has occurred in cattle born after it was implemented. 72

Fed. Reg. at 53,328, cols. 2-3; id. at 1108. No regulatory effort can ensure 100 percent compliance. 72 Fed. Reg. at 53,329, col. 3; id. at 1108. Isolated incidents attributable to human error are not epidemiologically significant, nor do they contribute to further spread of BSE, especially when considered in light of the entire risk pathway and its attendant risk mitigations. 72 Fed. Reg. at 53,329, col. 3, 53,331, col. 1; id. at 1108.

27. Based on APHIS's determination that Canada has had in place since March 1, 1999, an effectively enforced feed ban that continues at a robust level, and the demonstrated effectiveness of a feed ban in reducing the likelihood of BSE transmission, APHIS concluded that the prevalence in Canada will continue to decline over the next 20 years from its present minimal level. 72 Fed. Reg. at 53,328, col. 1, 53,334, col. 1; id. at 1108. Such a decline would decrease any possibility of BSE being introduced into the United States by Canadian cattle, and therefore decrease the negligible risk of the spread of BSE to U.S. cattle or consumers. 72 Fed. Reg. at 53,334, col. 1; id. at 1108.

B. Canada's Effective Enforcement of a Feed Ban

28. BSE is not a contagious disease, and oral ingestion of feed contaminated with BSE is the only documented route of field transmission of BSE. 72 Fed. Reg. at 53,347, col. 3; id. at 1104; see also RCALF, 415 F.3d at 1086. In view of this fact, several steps must be taken for BSE to be transmitted to cattle in the United States from a bovine imported live from another country. 72 Fed. Reg. at 53,333, col. 3; id. at 1104, col. 3. A BSE-infected bovine must be imported into the United States; the infected bovine must die or be slaughtered; tissues from that animal that contain the infectious agent must be sent to a rendering facility; the infectivity present in those tissues must survive inactivation in the rendering process; the resulting meat-and-bone meal containing the abnormal prion protein must be incorporated into feed; and this feed must be fed to cattle at a level adequate to infect the cattle. 72 Fed. Reg. at 53,333, col. 3; id. at 1104, col. 3.

29. In order for BSE to be transmitted to cattle in the United States from a BSE-infected bovine imported live into this country from Canada, an infected bovine must actually enter the United States. 72 Fed. Reg. at 53,331, col. 2; id. at 1104. This risk is already very low because of the low prevalence of the disease in Canada and the risk mitigation measures in place there. 9 C.F.R. § 94.19; 72 Fed. Reg. at 53,334, col. 1; id. at 1104. In addition, because of the “extremely low likelihood” that cattle born in Canada on or after March 1, 1999, will have been exposed to BSE, 72 Fed. Reg. at 53,329, col. 3, the OTM Rule ensures that the BSE risk to the United States from the import of OTM cattle remains “negligible,” id. at 53,316, col. 1, 53,346, col. 3.

30. Experience around the world in countries with BSE has demonstrated that feed bans are effective control measures, and that the prevalence of BSE worldwide continues to decline because of them. 72 Fed. Reg. at 53,327, col. 2; id. at 1105; see also RCALF, 415 F.3d at 1087. By eliminating transmission, an effective feed ban reduces the risk of infected animals existing in a given cattle population, which in turn reduces even further the possibility of exposing healthy animals to BSE via subsequent recycling of infectivity. 72 Fed. Reg. at 1105. APHIS bases its determination of whether a region has an effective feed ban on an evaluation of the laws and regulations in place, the adequacy of the infrastructure to implement the regulations, and the evidence of effective implementation and monitoring (i.e., compliance inspections, training, and records). Id. at 1106.

31. USDA has evaluated the feed ban in Canada that prevents the feeding of ruminant proteins to ruminant animals. 72 Fed. Reg. at 53,330, col. 2; id. at 1106. USDA considered the compliance activities reported by the Canadian Food Inspection Agency (CFIA) as well as epidemiological information in concluding that compliance with the feed ban was good, and that the feed ban was effectively enforced. 72 Fed. Reg. at 53,328, col. 1; id. at 1106. In response to the detection of two additional BSE cases in Canada, USDA reassessed the oversight of Canada’s feed

ban in January 2005. 72 Fed. Reg. at 53,327, col. 3; id. at 1106. Based on review of inspection records and on-site observation, USDA confirmed that Canada has a robust inspection program, that overall compliance with the feed ban is good, and that the feed ban is reducing the risk of transmission of BSE in the Canadian cattle population. 72 Fed. Reg. at 53,328, col. 1, 53,330, col. 2, id. at 1106.; see also RCALF, 415 F.3d at 1095, 1098 (noting the effectiveness of Canada's feed ban and finding criticisms of it "baseless"). CFIA conducted its own review in 2005 and concluded that the ban is effectively reducing the BSE risk in Canada to an extremely low level. 72 Fed. Reg. at 1106.

32. Canada's feed ban includes labeling and recordkeeping requirements for verifying compliance with the ban. Id. Its rendering facilities, which serve as control points for the redirection of ruminant protein away from cattle feeds, are subject to annual inspections and permitting. 72 Fed. Reg. at 53,338, col. 1; id. at 1106. In addition, renderers, feed manufacturers, and farmers must take steps to prevent material prohibited under the feed ban from being incorporated into or contaminating ruminant feed, such as establishing dedicated facilities or processing lines that use only prohibited or non-prohibited material. 72 Fed. Reg. at 1106. These measures decrease the likelihood of contamination of ruminant feeds with prohibited material. Id.

33. In determining the date of effective enforcement of a feed ban, APHIS considered the time needed after its regulatory establishment and the practical implementation of the ban. 72 Fed. Reg. at 53,330, col. 2; id. at 1106. It also considered whether additional time was needed to allow most feed products to cycle through the system. 72 Fed. Reg. at 53,330, col. 2; id. at 1106. Although regulations establishing the feed ban in Canada came into force upon publication in August 1997, full implementation and effective enforcement were gradual. 72 Fed. Reg. at 53,330, col. 2; id. at 1107. CFIA recognized that a phase-in period would be required for the exhaustion of prohibited materials already in feed channels and for compliance with labeling and recordkeeping

requirements. 72 Fed. Reg. at 1107. Based on its evaluation of the situation in Canada, APHIS allowed an additional 12 months beyond the estimated 6-month practical implementation period following the August 1997 establishment of the feed ban so that most old feed could cycle out of the system. 72 Fed. Reg. at 53,330, col. 2. Prohibiting the importation of bovines from Canada that were born before March 1, 1999, provided an appropriate additional mitigation to what was already an extremely low risk of introduction of BSE from Canada. 72 Fed. Reg. at 1107.

C. Additional Sequential Barriers to Transmission of BSE and Assessment of Risk to Human Health

34. If an infected bovine from Canada were to be imported into the United States, each in a series of additional mitigations would have to fail or be breached in order for that bovine to infect a U.S. cow or consumer. 72 Fed. Reg. at 53,330, col. 3; *id.* at 1109. Such mitigations include slaughter controls and dead animal disposal requirements, rendering inactivation, feed manufacturing and use controls, and biological limitations to susceptibility. 72 Fed. Reg. at 53,333, col. 3; *id.* at 1109. These mitigations work sequentially and are multiplicative in their risk-reduction effects, so however small the chances that BSE infected material would survive the first barrier, the likelihood of its eventually infecting a U.S. animal would diminish significantly with each subsequent mitigation. 72 Fed. Reg. at 53,333-34, cols. 3-1; *id.* at 1109.

35. The risk assessment for this rule simulated the impact of these mitigations on the likelihood of exposure, establishment, and spread of BSE infectivity in the United States. 72 Fed. Reg. at 1109. Both qualitative and quantitative methods were used, and assuming the most likely scenario that the prevalence of BSE in Canada will continuously decrease, APHIS found a negligible likelihood of BSE exposure and establishment in U.S. cattle or people as a consequence of infectivity in the United States introduced via imports from Canada. *Id.*

36. APHIS also considered the far less likely possibility that BSE prevalence in Canada

will remain constant for the next 20 years. Id. Using this unlikely assumption, the model predicted the importation of approximately 19 infected bovines over a 20-year period under the provisions of the OTM Rule. Id. This model further predicted the consequent infection of 2 U.S. animals during that period. Id. Of the total number of infected animals predicted by the model over the next 20 years (i.e., imported plus U.S. cattle), only a small fraction (numerically, fewer than one) would live long enough to develop clinical signs and be likely to harbor significant levels of infectivity, due to the lengthy incubation period for BSE and the fact that most U.S. cattle are slaughtered before reaching the age when infectivity is manifested in clinical signs. Id. Therefore, even assuming the unlikely event of a constant BSE prevalence rate in Canada over the next 20 years, APHIS's risk assessment model indicates that BSE is highly unlikely to become established in the United States due to implementation of the OTM Rule. Id.

37. The November 2003 proposed rule was based, in part, on a human health risk assessment conducted by the Harvard Center for Risk Analysis of the Harvard School of Public Health and the Center for Computational Epidemiology at Tuskegee University (Harvard-Tuskegee study) and APHIS's analysis of that assessment. APHIS concluded that infectious levels of BSE were unlikely to be introduced into the United States from Canada, and that, even if they were, BSE would be extremely unlikely to enter commercial animal feed and thereby infect U.S. cattle or to result in human exposure to the BSE agent. 70 Fed. Reg. at 505, col. 3. Further, because of the substantial species barrier, USDA found it all the more unlikely that there would be any measurable effects on human health from small amounts of infectivity entering the food chain. Id. at 505, col. 2.

38. Following publication of FSIS's interim final rule relating to SRM removal, FSIS conducted a risk assessment to develop baseline and mitigation estimates of the potential human exposure to the BSE agent which updated the Harvard-Tuskegee study. A peer review of the updated model and the resulting assessment was completed in September 2005. Based on the results

of the 2005 model, FSIS concluded that removal of SRMs almost completely eliminates potential human exposure to the BSE agent, and that the regulatory requirements for SRM removal are prudent and appropriate for preventing potential human exposure to the BSE agent. 72 Fed. Reg. at 38,726, col 1. The results of FSIS's assessment and its conclusions would be applicable for all beef products whether derived from OTM or under thirty month cattle or cattle of U.S. or Canadian origin. 72 Fed. Reg. at 53,336, col. 1-2.

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CERTIFICATE OF SERVICE

I hereby certify that on November 21, 2007, I caused the foregoing Statement of Facts in Support of Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction to be served on plaintiffs by filing it pursuant to this Court's Case Management/Electronic Case Filing Administrative Procedures. Copies were also sent by first-class mail, postage prepaid, to plaintiffs'

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