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

RANCHERS CATTLEMEN ACTION LEGAL FUND UNITED STOCKGROWERS OF AMERICA,	)	CV-05-06-BLG-RFC
Plaintiff,	)	STATEMENT OF FACTS IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFF S MOTION FOR A PRELIMINARY INJUNCTION
vs.	)	
UNITED STATES DEPARTMENT OF AGRICULTURE, et al.,	)	
Defendants.	)	

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The following statement of facts is submitted in support of defendant s opposition to plaintiff s motion for a preliminary injunction.

A. APHIS's Regulation Of Imports To Safeguard Against Bovine Spongiform Encephalopathy (BSE) Under the Animal Health Protection Act

1. The Animal Health Protection Act, 7 U.S.C. §§ 8301 et seq., gives the Secretary of the United States Department of Agriculture (USDA) broad discretion to regulate the importation of animals and animal products when he determines it to be 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). Congress also found that the prevention of disease was essential to protect, not only animal and human health, but also the economic interests of the livestock and related industries, and foreign commerce. 7 U.S.C. § 8301(1)(C), (E). It further found that regulation by the Secretary and cooperation by the Secretary with foreign countries . . . are necessary . . . to prevent and eliminate burdens on . . . foreign commerce. 7 U.S.C. § 8301(5)(B)(i). Thus, the Secretary must exercise his discretion in observance of these factors.

2. 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) 8044-8045.

1. The BSE Outbreak in Europe and the Species Barrier to BSE s Human Counterpart

3. BSE is a progressive and fatal neurological disorder of cattle. AR 8045. BSE is believed to be transmitted through an abnormal form of a protein called a cellular prion protein. AR 8045. It is spread to cattle primarily through the consumption of animal feed containing protein from

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[1/] Citations are to the Administrative Record filed on February 22, 2005.

ruminants[2/] infected with BSE. AR 8045.

4. 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. AR 8045. However, over 95 percent of all BSE cases have occurred in the United Kingdom, where the epidemic peaked in 1992/1993. AR 8045. As a result of actions taken in the United Kingdom to mitigate BSE, the annual incidence has fallen dramatically, i.e., by 90 percent between 1992 and 1997. AR 8045, 8334. Those mitigation measures include banning mammalian meat-and-bone meal in feed, excluding animals more than 30 months of age from the animal and human food chains, and destroying all animals showing signs of BSE or at high risk of developing it. AR 8045.

5. Only a few cases of BSE have been found in animals less than 30 months of age, and these have occurred primarily in countries with significant levels of circulating infectivity. AR 8329. The incubation period for BSE appears to be linked to the infectious dose received, i.e., the larger the dose, the younger the age at which the cow develops BSE. AR 8329. In the United Kingdom, BSE was found in animals less than 30 months of age primarily in the late 1980s and early 1990s, when BSE was present in feed, although the number was still small. AR 8329. From 1988 to 1996, only 19 cases were confirmed in cattle under 30 months of age. The youngest case of BSE was confirmed in a 20-month-old animal in 1992, and the last case in an animal aged 30 months or less was in 1996. AR 8329. Of all the cattle that developed BSE in the United Kingdom epidemic, only 0.01 percent were under 30 months of age. AR 8330. BSE in young animals would most likely be the result of either no feed controls or an ineffective feed

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

ban. AR 8331.

6 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. Approximately 150 cases have been identified worldwide since 1986. AR 8046. Approximately 95% were linked to exposure in the United Kingdom, 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 specified risk materials (SRMs). AR 8046. 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. In fact, to become infected, humans may need exposure to about 10,000 times the level of infective tissues necessary to infect cattle. Declaration of Daniel L. Engeljohn (Engeljohn Dec.) ¶ 15; Declaration of Lisa A. Ferguson (Ferguson Dec.) ¶ 6.[3/]

2. Classification of Canada as a Minimal-Risk Region To Allow Imports of Cattle Under 30 Months of Age and Beef From Such Cattle

7. 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. As of 2000, all such imports were prohibited from regions in two categories: those with cases of BSE, and those presenting an undue risk of BSE because of insufficiently restrictive import requirements or inadequate

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[3/] All Declarations cited herein are attached as exhibits to Defendant s Opposition to Plaintiff s Motion for a Preliminary Injunction.

surveillance. AR 8046.

8. 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 added Canada to the list of countries affected with BSE and effectively prohibited imports of Canadian cattle and most Canadian beef. AR 8512; see 9 C.F.R. 94.18; 95.4. In August 2003, after evaluating the risk, APHIS announced that it would issue permits to allow the importation of certain low-risk beef products from Canada. AR 8319. As a result of this action, beef products such as bovine liver and boneless beef from Canadian cattle under 30 months of age were eligible for importation. AR 3627, 8319. Those products have been continuously imported to the present and would continue to be imported after the new rule goes into effect on March 7.

9. APHIS then completed a risk analysis regarding the possibility of a more comprehensive resumption of Canadian beef imports. Upon its completion, in a November 2003 proposed rule, APHIS proposed to establish an additional classification of regions with regard to BSE the BSE minimal risk region that would present a minimal risk of introducing BSE into the United States via live ruminants and ruminant products. AR 94, 8046-47. APHIS also proposed adding Canada to this category. The proposed rule would permit imports from minimal-risk regions of cattle less than 30 months of age, AR 100, and meat from such cattle, provided, inter alia, that tissues designated as "specified risk materials" (SRMs) were removed at slaughter and the cow had not been fed ruminant protein, AR 102; see 9 C.F.R. §§ 93.436, 94.19.

10. To qualify as a BSE minimal-risk region, as defined under proposed 9 C.F.R. § 94.0; see AR 96, first, the region must maintain risk mitigation measures to prevent widespread exposure

and/or establishment of the disease, including import restrictions on animals, animal products and feed; surveillance for BSE at levels recommended by the Office International des Epizooties (OIE, also referred to as the World Organisation for Animal Health)[4]; and an effective ban on feeding ruminant protein to ruminants. AR 8047. Second, in regions where BSE has been detected, the regions must have conducted an epidemiological investigation to confirm the adequacy of measures to prevent the further introduction or spread of BSE. AR 8047. Third, in regions where BSE has been detected, the region must take additional risk mitigation measures, as necessary, based on risk analysis of the outbreak. AR 8047. APHIS uses these standards as a combined and integrated evaluation tool, basing a BSE minimal-risk classification on the overall effectiveness of control mechanisms in place (e.g., surveillance, import controls, and a feed ban). AR 8047.

3. The Rationale for the Rule

a. Canada s Compliance with the Minimal-Risk Standard

11. In designating Canada as a minimal-risk region, APHIS determined that measures taken in Canada in response to the BSE outbreak comported with the minimal-risk standards set forth in the rule, AR 96; 9 C.F.R. § 94.0.

i. Canada s pre-existing risk mitigation measures

12. Canada had implemented effective risk mitigation measures prior to its first detection of BSE in May 2003. Canada began restricting imports in 1990, when it prohibited the importation

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[4] OIE is recognized by the World Trade Organization as the international organization responsible for development 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; Declaration of David Wilson (Wilson Dec.) ¶ 2. The OIE guidelines on BSE are detailed in the Terrestrial Animal Health Code. AR 8047; Wilson Dec. ¶ 2.

of live cattle from the United Kingdom and Ireland. AR 8051. By 1996, it had expanded those restrictions to include live ruminants from any country that had not been recognized as free of BSE following a comprehensive risk assessment. AR 8051. Of the total of 182 cattle imported from the United Kingdom between 1982 and 1990, Canada traced and killed those remaining in 1993. AR 8051. Canada had, in fact, restricted the importation of ruminant products since 1978 and has imported no meat-and-bone meal for livestock feed except from the United States, Australia, and New Zealand. AR 8051.

13. Canada also implemented a feed ban in 1997 that prohibits the feeding of mammalian protein to ruminants. AR 8051. The feed ban is equivalent to that in place in the United States, with certain additions. AR 8051. Canada's statistics on compliance demonstrate the effectiveness of the feed ban in the rendering, feed manufacturing, and livestock raising industries. AR 8051. Few cattle born before the 1997 feed ban are alive today. AR 8051. Infected animals typically exhibit clinical signs of BSE 4 to 6 years after infection, and 95 percent do so by the seventh year. AR 8052. Since cattle born before the feed ban would now be at least 7 years old, any remaining infected cattle would likely be showing clinical signs that would be detected through Canada's BSE surveillance system. AR 8052.

14. Canadian authorities inspect rendering facilities annually, and routinely inspect feed manufacturers and feed retailers to ensure compliance with the feed ban. AR 8052. These inspections show a high level of compliance. AR 8052. The rendering sector has consistently achieved full compliance. AR 8052. Noncompliance in the Canadian commercial feed industry occurred in fewer than 2 percent of cases during 2003-2004. AR 8052. Those instances were dealt with immediately and include a lack of appropriate written procedures, records, or product

labeling by feed manufacturers. AR 8052.

15. Canada has met or exceeded the OIE recommended level of BSE surveillance for the past 7 years. AR 8052. For purposes of surveillance, the current OIE Code defines adult cattle as those older than 30 months and recommends annually examining at least 300 samples from high-risk animals within an adult cattle population of 5 million. AR 8052. Canada's adult cattle population consists of approximately 5.5 million cattle older than 24 months of age. AR 8052. From this broader pool, Canada began targeted surveillance in 1992, sampling 225 high-risk cattle, and increasing its surveillance to more than 15,800 per year in 2004. AR 8052. It has announced a goal of testing at least 30,000 cattle in 2005. AR 8053. Canada's surveillance continues to target high-risk adult animals. AR 8052. BSE has been detected in only four Canadian-origin cattle in May and December 2003, and two in January 2005. AR 8052; Ferguson Dec. ¶ 7.

ii. Canada s epidemiological investigations

16. The Canadian Food Inspection Agency (CFIA) reported a case of BSE in a cow in Alberta in May 2003, and in December 2003 another case appeared in a Canadian-origin cow in Washington State. AR 8052. Canada and the United States conducted a rigorous epidemiological investigation of both occurrences and concluded that the animals were born before the implementation of the feed ban in 1997, with exposure most likely occurring before or near that time. AR 8052-53. The most likely source of infection was contamination of the feed supply from an infected animal imported from the United Kingdom between 1982 and 1989. AR 8052-53.

18. In addition, the investigations tracked down feed potentially derived from the carcasses of the infected cows, but only about one percent of the 1800 sites surveyed experienced any possible exposure from the May 2003 incident. AR 8052-53. Those herds, as well as cattle potentially exposed from the December 2003 incident, were destroyed and tested. AR 8052-53. Test results yielded no further evidence of infection. AR 8052-53.

iii. Canada s additional risk mitigation measures

19. An international review team of animal disease experts assessed CFIA s investigation of the May 2003 case of BSE and recommended additional safety enhancements. AR 8052. Among other suggestions, it recommended a requirement that SRMs be removed from cattle at slaughter. There is a solid scientific consensus that BSE infectivity in cattle occurs in certain specified tissues, primarily central nervous system tissues, which have been designated as SRMs. Engeljohn Dec. ¶ 13; Ferguson Dec. ¶ 13. As the infected animal ages, greater levels of infectivity accumulate in the central nervous system tissues. AR 8333; Engeljohn Dec. ¶¶ 5-6. At the end stages of the disease, the brain and spinal cord contain 90 percent of the total infectivity, and the remaining portion is found in other specified risk tissues, i.e., the dorsal root ganglia, trigeminal ganglia, distal ileum, spleen, and eyes. AR 8331, 8333. The removal of SRMs effectively mitigates the BSE risk to humans associated with cattle that otherwise appear healthy and therefore pass both ante-mortem and post-mortem inspections. AR 3839, 8049; Engeljohn Dec. ¶¶ 5, 7; Ferguson Dec. ¶ 13.

20. In July 2003, responding to the recommendations of the international review team, Canada implemented a requirement that SRMs be removed from cattle at slaughter. AR 8052. Canada also implemented enhanced measures for identification and for tracking and tracing, as

well as for increased BSE surveillance and testing. AR 8052. In January 2004 the Canadian Government announced that it would increase its level of BSE testing even further. AR 8053.

b. Domestic Barriers to Transmission of BSE

21 A number of domestic risk mitigation measures reduce the likelihood of tissue from a BSE-infected animal entering the food or feed supply. These measures also contributed to the basis for the rule creating a BSE-minimal risk category and including Canada in that category. They are based on a solid scientific consensus as to the cattle tissues that contain BSE infectivity as well as the modes of transmission of that infectivity, and on the best available science known to effectively minimize risks to animal and public health. Engeljohn Dec. ¶¶ 7, 13.

i. Slaughter controls

22. In three rules effective in January 2004, USDA s Food Safety and Inspection Service FSIS implemented slaughter controls to prevent the BSE agent from entering the human food supply. AR 8050. First, as Canada had done in July 2003, FSIS designated certain cattle tissues as SRMs and prohibited their use in human food. AR 8050, 9958; Engeljohn Dec. ¶ 7. Specifically, it designated as SRMs the brain, skull, eyes, trigeminal ganglia, spinal cord, parts of the vertebral column, and dorsal root ganglia of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle. AR 8050, 9958. To ensure that SRMs from cattle 30 months of age or older are effectively segregated from edible materials, FSIS developed procedures to verify the appropriate age of cattle that are slaughtered. AR 8050, 9958. Additionally, FSIS prohibited all non-ambulatory disabled cattle for use as human food. AR 8049.

23. The second rule placed restrictions on the machinery used to separate meat from bone. AR 8050, 9971-72. These restrictions prevent the final meat product from being contaminated with central nervous system tissue originally connected to the bone. AR 8050; see also Engeljohn Dec. ¶ 3.

24 In the third rule, FSIS prohibited the use of captive bolt stunning devices that result in fragments of central nervous system tissue entering the circulatory system of stunned cattle and becoming lodged in edible tissues. AR 8050, 9983-84.

25. The Food and Drug Administration of the Department of Health and Human Services (FDA) took similar actions and prohibited the use of certain cattle material in human food, pharmaceuticals, and cosmetics. AR 8338. Prohibited materials include SRMs, small intestines of all cattle, material from nonambulatory cattle, materials from cattle not inspected and passed for human consumption, and mechanically separated beef. AR 8338. These food safety measures have been implemented to protect human health and apply to all meat products for human consumption in U.S. commerce, including those of Canadian origin. AR 8338.

ii. Feed manufacture controls

26. In 1997, FDA prohibited the use of all mammalian protein (with limited exceptions) in the manufacture of cattle and other ruminant feeds. AR 8340. Because BSE is spread to cattle primarily through the consumption of animal feed containing protein from ruminants infected with BSE, this measure ensures that U.S. cattle will not be exposed to feed contaminated with protein from Canadian BSE-infected cattle. AR 96-97; Engeljohn Dec. ¶ 13; Ferguson Dec. ¶¶ 6, 9, 10-12. Firms must keep specified records on feed manufacture, prevent the commingling of ruminant feed with contaminated non-ruminant feed, and ensure that non-ruminant feed

containing prohibited materials bears a conspicuous label stating: Do not feed to cattle and other ruminants. AR 8340.

27. FDA continues to conduct compliance inspections of domestic feed mills, renderers, and protein blenders to prevent the recycling of potentially infectious cattle tissue through ruminant feed. AR 8050. Compliance with the feed ban is currently very high. AR 8050. As of July 2004, conditions or practices warranting regulatory sanctions had been found in less than 1 percent of inspected facilities. AR 8050; Ferguson Dec. ¶ 14. APHIS s risk analysis took into account the fact that there would be less than 100% compliance with the feed ban. Ferguson Dec. ¶ 14.

iii. Controls on the diversion of imported animals

28. The minimal-risk rule allows live cattle imported from a minimal risk country to enter the United States only for immediate slaughter or for feeding prior to slaughter. AR 8343; 9 C.F.R. § 93.436. Movement of these imported cattle is carefully controlled by requiring each animal to have permanent identification that indicates its country of origin, and imported cattle must only move to slaughter facilities, or to feedlots with a special permit that inventories all cattle consigned to a particular destination. AR 8343; 9 C.F.R.. § 93.436(a)(4); (b)(4).

c. Risk Assessments by Harvard-Tuskegee and CFIA

29. In April 1998, USDA commissioned the Harvard Center for Risk Analysis and the Center of Computational Epidemiology at Tuskegee University to conduct a comprehensive investigation of BSE risk in the United States. AR 8050-51. The Harvard-Tuskegee Study consists of approximately 1000 pages of analysis and data, developed by some of the world's foremost experts in risk analysis and computational epidemiology. This independent Study

reviewed available scientific information related to BSE, assessed pathways by which BSE could potentially occur in the United States, and identified measures that could be taken to protect human and animal health in the United States. AR 8051. The Study concluded that the United States is highly resistant to any amplification of BSE, and that measures taken by the government and industry make the United States robust against the spread of BSE to animals or humans. AR 8051. The Study incorporated into its assumptions and design the types of information and data contained in RCALF s comments on the rule regarding developments in the science of BSE and epidemiological data. Engeljohn Dec. ¶¶ 9-10.

30. The Study concluded that the most effective measures for preventing the potential spread of BSE are (1) the ban placed by APHIS on the importation of live ruminants and ruminant meat-and-bone meal from the United Kingdom since 1989 and all of Europe since 1997; and (2) the feed ban instituted in 1997 by FDA. AR 8051. It concluded that these would have minimized exposure and worked to eliminate BSE if it had been introduced via importation of live animals from the United Kingdom before 1989. AR 8051.

31. After the May 2003 BSE incident, USDA and the Harvard Center for Risk Analysis evaluated the implications of a then-hypothetical introduction of BSE into the United States from Canada. AR 8051. This assessment confirmed the conclusions of the earlier Harvard-Tuskegee Study, namely that there is a very low risk of BSE becoming established or spreading should it be introduced into the United States. AR 8051.

32. Following the receipt of public comments on the November 2003 proposed rule, APHIS obtained a response from the Harvard Center for Risk Analysis to comments pertaining to the Harvard-Tuskegee Study, including comments submitted by plaintiff's declarant, Dr. Cox, on

behalf of RCALF. AR 8051, 8408. The response, reported to APHIS in a June 18, 2004 memorandum ("Cohen and Gray Memorandum"), updates the Study with new data from FDA addressing the "worst case" assumptions with respect to two critical parameters, i.e., mislabeling and contamination. AR 8408. Even assuming a higher misfeeding rate than in the earlier Study, the Cohen and Gray Memorandum confirmed the conclusions of the Harvard-Tuskegee Study that there was a very low risk of BSE becoming established or spreading. AR 8051, 8416.

33. In December 2002, CFIA issued an assessment of the risk of BSE in Canada. Its assessment indicated a low potential for cumulative introduction of infectivity into Canada via cattle imported from Europe between 1979 and 1997, when Canada implemented the feed ban. AR 8052. The analysis further suggested that the likelihood of the spread and establishment of BSE in Canada, both before and after the 1997 feed ban, was negligible. AR 8052.

4. The Unlikelihood of Infectivity from the December 2003 Case of BSE

34. As explained above, a second case of Canadian origin BSE was reported in the United States in December 2003, shortly before the January 5, 2004 close of the comment period on the November 2003 proposed rule classifying Canada as a minimal-risk region. AR 8049, 8319. In an explanatory note made available in March 2004, APHIS explained why the detection of a second BSE case would not affect the conclusions of the original risk analysis, which found that compliance with the feed ban minimized the likelihood that BSE would be spread by animals infected before implementation of the feed ban in 1997. AR 8049, 8329.

35. APHIS explained that the epidemiological investigation and DNA test results indicated that the December 2003 cow was most likely infected before the implementation of the feed ban. AR 8049. Both animals diagnosed with BSE (in May 2003 and December 2003) were more than

30 months old, and the December 2003 cow was imported into the United States when it was more than 30 months old. AR 8049. Thus, neither cow would have been allowed into the United States under the rule, which prohibits the importation of cattle 30 months or older. AR 8049. Moreover, Canada s incidence rate of two infected cattle in 2003, out of a population of 5.5 million cattle over 24 months of age (0.4 per million head of cattle), was well below OIE s recommendation regarding incidence in minimal-risk regions. AR 8048. OIE s guidelines for minimal-risk regions recommends less than two infected cattle per million during each of the last four consecutive 12-month periods from all cattle over 24 months of age. AR 8048.

36. In view of the BSE episode in December 2003, however, USDA reopened and extended the comment period until April 7, 2004. AR 3837, 8048.

5. The Proposal to Allow Imports of Beef From Cattle 30 Months of Age or Older

37. On March 8, 2004, APHIS also proposed to allow the import of beef from Canadian cattle over 30 months of age, provided SRMs are removed at slaughter. AR 3837. (As explained previously, the original November 2003 proposed rule would have required the beef to come from cattle that were less than 30 months of age at the time of slaughter. AR 8049.) APHIS stated as follows:

> 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.

38. APHIS explained that the change stemmed from new FSIS requirements in January 2004 regarding, inter alia, the removal of SRMs at slaughter and their exclusion from human food, and from the fact that Canada had implemented equivalent safeguards in July 2003. AR 3839, 8049. These measures effectively mitigated any BSE risk to humans. AR 3839, 8049. Additionally, as discussed above, 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 cattle 30 months of age and older, provided the exporting region takes equivalent and other necessary risk mitigation measures (e.g., controls to prevent cross-contamination). AR 3839, 8049.

6. The Final Minimal-Risk Region Rule

39. USDA received a total of 3,379 public comments on the proposed rule by the close of the comment period on April 7, 2004. AR 8049. The final rule published on January 4, 2005, considered and responded to all of them, and explained USDA s reasoning and the basis for its conclusions with respect to each significant issue raised, including those submitted by RCALF. See AR 8049-8119; Engeljohn Dec. ¶¶ 9-10. The rule was the result of collaboration by scores of experts at USDA, including Ph.D. economists in APHIS; scientists at APHIS holding advanced degrees in veterinary medicine, microbiology, economics, and statistics; scientists from other parts of USDA with advanced degrees in a range of disciplines including veterinary medicine, zoology, microbiology, and public health; and members of the Office of the Chief Economist who have Ph.D. s in economics, ecology, energy management and environmental policy, and statistics. Declaration of Kevin Shea (Shea Dec.) ¶¶ 4-11. APHIS also consulted with the Director for the Center for Animal Health and Food Safety at the University of

Minnesota. Id. ¶ 9. The rule was also reviewed by career specialists at the Office of Management and Budget (OMB) who have been conducting similar reviews for the past 20 years. Id. ¶ 12. The staff at OMB analyzing the minimal risk rule is headed by the founder of the Harvard Center for Risk Analysis who has a Ph.D. and ran the Center for over 10 years. Id.

40. USDA s risk analysis drew on a number of sources of information, including previous analyses of risk conducted by APHIS; scientific literature; results of epidemiological investigations; data provided by the Canadian Government; a quantitative analysis of the risk of BSE in Canada; quantitative analyses of the consequences of BSE being introduced into the United States; measures implemented by FSIS and FDA to further reduce the risk of human exposure to the BSE agent in the United States; reports by international review teams; and the BSE guidelines adopted by the OIE. Ferguson Dec. ¶ 5. As a result, the determination to allow imports of certain Canadian ruminants and ruminant products was based on a comprehensive and thorough evaluation of the BSE risk in Canada; the potential for BSE infectivity to be introduced into the United States from live ruminants and ruminant products and byproducts; the potential spread of BSE in cattle and possible human exposure if BSE infectivity was introduced into the United States, the likelihood that BSE could become established in the United States, and which mitigation measures would be (1) necessary to prevent BSE from being either introduced into the United States or spreading within the United States, and (2) necessary to prevent BSE infectivity from entering the animal feed chain or the human food supply. Id.

7. The Two January 2005 Cases of BSE and the Secretary s Delay of the Effective Date for Beef Imports from Cattle 30 Months of Age and Older

41. The January 4, 2005 final rule defines a minimal risk region and provides for the

importation of live cattle less than 30 months of age and the importation of meat products from cattle of any age, provided that certain conditions are met. AR 8132-8135. On January 2, and 11, 2005, two additional BSE-infected cows were confirmed in Alberta, Canada. CFIA s investigation confirmed that the cow discovered on January 2nd was born in 1996 and most likely was exposed to feed produced prior to Canada s August 1997 ban. CFIA s investigation of the January 11 positive animal disclosed that the cow was born in 1997 and is likely to have consumed feed produced prior to the August 1997 ban or shortly thereafter.[5/] APHIS is also conducting a review of the most recent detections in Canada.

42. On February 9, 2005, the Secretary announced that he was delaying the implementation of the portion of the rule regarding meat from animals 30 months of age or older. See Statement by Agriculture Secretary Mike Johanns, Feb. 9, 2005 (attached). The Secretary took this action, in part, because ongoing investigations into the recent finds of BSE in Canada in animals over 30 months are not complete. Id. The Secretary directed officials to move forward in consideration and development of a plan to allow imports of animals 30 months and older for slaughter as well as beef from over 30-month animals as the next step in resuming full trade with Canada. Id. While the final rule with respect to meat products from cattle 30 months and older has been delayed, the remainder of the final rule concerning cattle under 30 months of age and beef from such cattle is scheduled to go into effect on March 7, 2005. AR 8044.

B. APHIS s Environmental Assessment

43. APHIS issued a draft Environmental Assessment for public comment in October 2003,

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[5/] The ages of the four Canadian-origin cows with BSE are 70 months (discovered May 20, 2003), 80 months (discovered December 23, 2003), 98 months (discovered January 2, 2005), and 81 months (discovered January 11, 2005).

regarding the proposed rule which was published on November 4, 2003. AR 94. On January 4, 2005, APHIS issued a Final Rule and a Final Environmental Assessment, with a thirty day comment period on the Final Environmental Assessment. AR 8251. On January 21, 2005, APHIS issued a Notice of Extension of Comment Period of Final Environmental Assessment until February 17, 2005, because APHIS had inadvertently cited the Risk Analysis incorrectly in the Final Environmental Assessment. AR 8286.

Dated: Feb. 22, 2005

Respectfully submitted,

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CERTIFICATE OF SERVICE

_____I certify that on February 22, 2005, a copy of the Statement of Facts in Support of Defendants' Opposition to Plaintiff s Motion for a Preliminary Injunction was served upon plaintiff's counsel by hand-delivery as follows:

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