



Fighting for the U.S. Cattle Producer!

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Docket No. APHIS 2008-0093
Regulatory Analysis and Development, PPD
APHIS, Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

Via Facsimile and Federal Rulemaking Portal: 301-734-8934

Re: R-CALF USA Comments in Docket No. APHIS-2008-0093: Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Meat, Meat Byproducts, and Meat Food Products Derived From Bovines 30 Months of Age or Older

Dear Administrator:

The Ranchers-Cattlemen Action Legal Fund – United Stockgrowers of America (R-CALF USA) appreciates this opportunity to submit its comments regarding the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service's (APHIS's) request for comments published at 73 Fed. Reg., 54083-54089 (APHIS' 2008 Notice) on the removal of the delay of applicability of certain provisions of the rule entitled "Bovine Spongiform Encephalopathy: Minimal-Risk Regions and Importation of Commodities," (Final MMR Rule) published at 70 Fed. Reg., 460-553. The delay of applicability was removed in a final rule entitled "Bovine Spongiform Encephalopathy; Minimal-Risk Regions; Importation of Live Bovines and Products Derived from Bovines," (Final OTM Rule) published at 72 Fed. Reg., 53314-53379.

R-CALF USA is a non-profit cattle-producer association that represents thousands of U.S. cattle producers in 46 states. R-CALF USA's mission is to ensure the continued profitability and viability of independent U.S. cattle producers. The demographics of R-CALF USA's membership are reflective of the demographics of the entire U.S. cattle industry, with membership ranging from the largest of U.S. cattle producers to the smallest. R-CALF USA's membership consists primarily of cow-calf operators, cattle backgrounders, and feedlot owners. Various main street businesses are associate members of R-CALF USA. In addition to being producers of cattle, R-CALF USA members are also beef consumers and responsible stewards of the environment.

I. INTRODUCTION

APHIS' 2008 Notice relates directly to the Final OTM Rule for which R-CALF USA had submitted two separate sets of comments, the first on March 12, 2007 and the second on August 2, 2007. Both sets of comments contained numerous attachments. As a preliminary matter, R-CALF USA is restating those comments herein with the same force and effect as though they were set forth in full herein. The comments are attached hereto as Exhibits 1 and 2, respectively, and the attachments referenced therein are available to APHIS in the Administrative Record.

APHIS asserts in its 2008 Notice that its regulations found at 9 CFR parts 93, 94, 95, and 96 “govern the importation of certain animals . . . meat, [and] other animal products and byproducts . . . into the United States in order to prevent the introduction of various diseases, including bovine spongiform encephalopathy (BSE).” 73 Fed. Reg., 54084, col. 3. Emphasis added. R-CALF USA will demonstrate in its following comments that not only does APHIS' 2008 Notice *not* accomplish this mandate, it actually constitutes a regime to knowingly *allow* the introduction of BSE into the United States from Canada in direct defiance of the agency's mandate.

II. APHIS DID NOT EVALUATE THE RISKS OF CANADIAN BEEF DERIVED FROM CATTLE BORN BEFORE AN EFFECTIVE FEED BAN

A. APHIS Misrepresents its Actions and Intentions Regarding the Removal of the 30-Month Age Restriction on Imported Meat Products.

APHIS' 2008 Notice deceptively states that the agency “proposed to allow the importation of beef derived from cattle of any age” in a document published March 8, 2004. (73 Fed. Reg., 54086, col. 3) (emphasis added). This is not at all what the March 8, 2004 document stated. Instead, the March 8, 2004 document stated that the agency then believed “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 . . . that [] other measures as are necessary are in place.” 69 Fed. Reg., 10635. Emphasis added.

Thus, the document published March 8, 2004 contemplated a different standard than the original 30-month standard to effectively limit the age of cattle from which meat and meat products could be imported into the United States. The different standard was the date when necessary measures were put in place. This is the same standard applied to cattle imports in the Final OTM Rule – the age of cattle continues to be restricted by the date APHIS established as the effective date of Canada's feed ban.

B. APHIS has Not Evaluated the Risks from Beef Derived from Canadian Cattle of Any Age.

The 2008 Notice erroneously states that the Final MMR Rule published by the agency on January 4, 2005 at 70 Fed. Reg., 460-553 likewise “allowed the importation of meat from bovines of any age.” 73 Fed. Reg., 54086, col. 3. This statement is demonstrably false and

misleading as evidenced by APHIS' risk analysis that accompanied its Final MRR Rule. The risk analysis stated:

The risk of introducing BSE infectivity can be reduced by requiring that animals presented for export and animals from which meat or meat products intended for export were derived were subject to a ruminant feed ban. Therefore, the final rule requires that veterinary officials in the country of origin certify that the animals were subject to a ruminant feed ban considered equivalent to that in place in the United States.¹

Emphasis added.

Clearly, the age of animals from which meat or meat products could be exported to the U.S. was effectively restricted in the Final MRR Rule by the effective date of Canada's feed ban, which date APHIS subsequently determined to be March 1, 1999. *See* 72 Fed. Reg., 53333, col. 2, 53377, col. 3, 53378, col. 1. Importantly, APHIS' substitute for the 30-month age restriction, i.e., the requirement that animals be subject to a feed ban, was a requirement that encompassed the entire lifetime of the animal. *See, e.g.,* 70 Fed. Reg. 498, col. 3 (requirement that all meat meeting the FSIS definition of meat in 9 CFR 301.2, including tongues, must be "derived from bovines that were subject to a ruminant feed ban during their lifetime equivalent to the requirements established by FDA.") (Emphasis added.)

Every Canadian bovine and every bovine product derived from Canadian bovines intended for human food that was allowed entry into the United States pursuant to the 2005 Final MRR Rule was subject to APHIS' feed ban requirement.² Thus, every bovine product imported for food under the Final MRR Rule was required to be derived from a bovine whose age was restricted by its birth date, as the animal had to be born *after* the effective date of Canada's feed ban in order to be eligible for importation into the United States.

As is clearly demonstrated above, the Final MMR Rule and the accompanying APHIS risk assessment (which was not even completed until 8 months *after* APHIS closed the comment period for the MMR Rule and, therefore, was never exposed to public refutation³) were predicated on the requirement that all products from cattle intended for human food would be derived only from cattle that were of an age that guaranteed they were subject to a ruminant feed ban during their entire lifetime. Therefore, neither the Final MMR Rule nor the accompanying APHIS risk assessment addressed the risk of BSE contamination in beef from cattle that were born prior to an effective feed ban and exposed to possible BSE-infected feed.

It is clear that APHIS has not conducted any assessment of the risk associated with meat or meat products derived from Canadian cattle that were born before the date of effective

¹ Analysis of Risk – Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, APHIS, December 2004, at 18.

² *See* 70 Fed. Reg., 548, col. 3 (§ 93.436(a)(2)); 549 (§ 93.436(b)(2)); 551 (§ 94.19(a)), (§ 94.19(b)(1)), (§ 94.19(f)); 552 (§ 95.4(g)(1)(iii)).

³ On March 8, 2004, APHIS extended the comment period for the MMR Rule for 30 days, until April 9, 2004. *See* 69 Fed. Reg., 10633-10636. The APHIS risk assessment used to support the Final MMR Rule was completed December 2004, approximately 8 months after the close of the comment period.

enforcement of Canada's feed ban, which APHIS has determined to be March 1, 1999. APHIS, therefore, has no basis to lift its restriction on beef from Canadian cattle that were over 30 months of age at the time of slaughter and the Final OTM Rule should be withdrawn.

C. APHIS Does Not Explain Why It Removed the Requirement that Beef Must be Derived From Cattle That Were at Least Subject to a Feed Ban During their Entire Lifetimes.

As definitively established above, the *only* risk analysis conducted on OTM beef prior to the publication of APHIS' 2005 Final MMR Rule was the December 2004 risk analysis that was completed approximately 8 months *after* the agency closed the comment period for the Final MMR Rule, and which, therefore, was *not* subject to any public review. That 2004 risk analysis, as was also definitively established above, was predicated on the requirement that only beef derived from cattle subject to a feed ban during their entire lifetime (again, APHIS subsequently determined that Canada's feed ban was not effective until March 1, 1999, would be imported into the United States from Canada.

Notwithstanding the impropriety of using a risk analysis that was not made public in these proceedings and, therefore, not "exposed to refutation"⁴ as a basis for agency rulemaking, this *is* the risk analysis relied on in APHIS' 2008 Notice to allow OTM beef into the United States from Canada. APHIS' 2008 Notice confirms this fact by stating:

Therefore, the conclusion of negligible risk [contained in the Final OTM Rule] related to the importation of live older bovines gives further support to the conclusion of the risk analysis conducted for our January 2005 final rule regarding meat and meat products derived from bovines of any age in BSE minimal-risk regions.

73 Fed. Reg., 54088, col. 1. Emphasis added. But, and of paramount importance, APHIS' "conclusion of negligible risk related to the importation of live older bovines" was wholly predicated on the requirement that live bovines be subject to a feed ban during their entire lifetimes.⁵ And, as definitively established above, SO TOO was the risk analysis conducted for APHIS' Final MMR Rule regarding meat and meat products derived from bovines wholly predicated on the requirement that meat and meat products for human consumption be only from cattle subject to a feed ban during their entire lifetimes.⁶

⁴ Memorandum Opinion and Order on Motion for Preliminary Injunction, United States District Court, District of South Dakota, Northern Division (hereafter "Court Order"), July 3, 2008, at 16 (The only risk assessment addressing the risk of importing Canadian beef, and which was made public and exposed to refutation, was the APHIS risk analysis completed October 2003 that accompanied the agencies November 4, 2003 proposed MMR Rule. That risk assessment was predicated on a strict, 30-month age restriction.)

⁵ See 73 Fed. Reg., 54087, col. 2 (discussing the agency's January 9, 2007 proposed OTM Rule that established "conditions for the importation . . . of live bovines . . . born on or after a date determined by APHIS to be the date of effective enforcement of a ruminant-to-ruminant feed ban" (emphasis added)); see also *id.*, fn 4 (justifying the requirement that "live bovines exported to the United States . . . be born after the date of effective enforcement of a ruminant-to-ruminant feed ban").

⁶ See *supra*, at 2, 3.

APHIS does not even know the additional risk associated with Canadian cattle born before the March 1, 1999 date it has established as the effective date of Canada's feed ban,⁷ but it knows the risk is greater than for cattle born after that date because, APHIS states, "of the greater likelihood of cattle born prior to the effective enforcement of a feed ban having been exposed to infectivity." 72 Fed. Reg., 53371, col. 3. Thus, beef from Canadian cattle born before March 1, 1999 would, like the cattle themselves, present a very different, i.e., a much riskier, risk profile than that considered by APHIS in its December 2004 risk analysis. As demonstrated below, however, this March 1, 1999 date is not the date when Canada implemented an effective feed ban as that date is July 2007.

This critical feed ban requirement, however, was simply dropped by APHIS, without any explanation, in its 2007 Final OTM Rule that has allowed the importation of Canadian beef from cattle of any age into the United States since November 19, 2007. *See* 73 Fed. Reg., 54088, col. 1. Thus, since November 19, 2007, APHIS has allowed beef to enter the United States from a country that has now had 16 native cases of BSE, well over half of which were infected with BSE while in Canada between 2000 and 2003,⁸ without ever having conducted a risk assessment or rulemaking that addresses the risk associated with meat and meat products derived from Canadian cattle that were not subject to an effective feed ban. APHIS' 2008 Notice not only fails to explain why the agency has taken such action, it deliberately and deceptively hides this crucial fact from the public.

The foregoing facts show that APHIS' claim that it has assessed the risk associated with its Final OTM Rule that allows the importation of OTM beef from Canada; that its risk analysis specific to the importation of OTM live cattle from Canada can be applied to OTM beef; and, that "the risk is even lower for the importation of meat and meat products than for live bovines" (73 Fed. Reg., 54088, col. 1), is utterly preposterous, baseless, and deceitful.

III. APHIS IS IMPROPERLY ATTEMPTING TO CONVINCING THE PUBLIC THAT THE RISK OF BSE IN OTM U.S. CATTLE IS THE SAME AS THE RISK OF BSE IN OTM CANADIAN CATTLE, DESPITE EVIDENCE TO THE CONTRARY

A. APHIS Has Misrepresented the Purpose of Mitigation Measures Contained in its Earlier Proposed Rule to Restrict Canadian OTM Beef.

In APHIS' 2008 Notice, APHIS claims that, with respect to the importation of meat, the 30-month age restriction contained in its November 4, 2003 proposed rule (2003 Proposed Rule) (*see* 68 Fed. Reg., 62386-62405) was "a measure to guard against the importation of, or contamination of meat through contact with, tissues other than meat that have the potential of containing high levels of BSE infectivity." 73 Fed. Reg., 54086, col. 2. Emphasis added. This claim is demonstrably false and, as discussed below, is directly contradicted by the agency's 2003 Proposed Rule.

⁷ *See* 72 Fed. Reg., 53371, col. 2 ("We [APHIS] do not have a quantitative estimate of the additional risk posed by importation of Canadian cattle born before March 1, 1999.")

⁸ *See* Matrix of BSE Cases, Prepared by Bill Bullard, CEO, R-CALF USA, Revised November 17, 2008, attached hereto as Exhibit 3 (nine of the 16 native cases detected in Canada were born between 2000 and 2003).

With respect to the importation of meat, the 30-month age restriction contained in the 2003 Proposed Rule was a measure used concomitantly with the feed ban requirement to prevent the importation of animal products, both tissues *and* meat, from BSE-infected cattle in Canada that were most likely to harbor infectious levels of BSE, including OTM cattle,⁹ cattle that were born before the implementation of an effective feed ban,¹⁰ and cattle that may have been exposed to contaminated feed.¹¹ These latter concerns were predicated on APHIS' finding, independent of the 30-month restriction, that “[a]nimals, and the products derived from those animals . . . will present a lower risk if the animals were [] born after the implementation of an effective feed ban.” 68 Fed. Reg., 62390, col. 3. Emphasis added. APHIS explained that its concurrent requirements were necessary because “restrictions applicable to age alone may not always be possible or sufficient.” 68 Fed. Reg., 62391, col. 1.

The 2003 Proposed Rule expressly stated that the measure to avoid “contamination of meat from bovines under 30 months of age with materials from older bovines” (68 Fed. Reg., 62394, col. 3) was the requirement that slaughtering facilities in Canada either slaughter only cattle under the age of 30 months (UTM cattle) or comply with an approved segregation process. *See* 68 Fed. Reg., 62394, col. 3). It is clear that APHIS was concerned that not only could high-risk tissues, or meat contaminated by high-risk tissues, be imported directly, but also, APHIS was concerned that meat could be imported that had been contaminated by other meat that itself was contaminated by high-risk tissues, e.g., the 2003 Proposed Rule expressly stated that APHIS would require that ground meat “has not been combined with meat that might contain high-risk tissues from high-risk animals.” 68 Fed. Reg., 62394, col. 3. Emphasis added.

To achieve APHIS' objective of preventing the importation of animal products, both tissues *and* meat, from BSE-infected cattle in Canada that were most likely to harbor infectious levels of BSE, each time the 2003 Proposed Rule imposed the 30-month age restriction on cattle or products derived from cattle, and without exception, it concurrently required that the cattle or products derived from cattle be also subject to a feed ban or not exposed to contaminated feed.¹² This clearly establishes that the purpose of the 30-month age restriction was to ensure that products derived from cattle that were imported into the United States would be derived from cattle that, themselves, were not likely to be exposed to the BSE infectious agent. APHIS confirmed this fundamental fact in its risk assessment that accompanied its Final MMR Rule stating: “The risk of introducing BSE infectivity can be reduced by requiring that animals

⁹ The 2003 Proposed Rule made a bright line distinction between infectious levels above and below 30 months of age: “In summary, infected cattle over 30 months of age . . . may have levels of the abnormal prion in affected tissues that are sufficient to infect other animals fed protein derived from these tissues. Infected animals less than 30 months of age . . . are unlikely to have infectious levels of the prion protein.” 68 Fed. Reg., 62391, col. 2.

¹⁰ This fact is revealed by the requirements contained in the 2003 Proposed Rule that products derived from Canadian cattle, e.g., be from animals under 30 months of age when slaughtered *and* that also “were born after the region of origin implemented an effective feed ban on the feeding of ruminant protein to ruminants.” 68 Fed. Reg., 62405, col. 2 (for importation of bovine tallow).

¹¹ This fact is revealed by the requirements contained in the 2003 Proposed Rule that products derived from Canadian cattle, e.g., be from animals under 30 months of age when slaughtered *and* that also “are not known to have been fed ruminant protein, other than milk protein, during their lifetime.” 68 Fed. Reg., 62404, col. 1 (for importation of fresh meat); 68 Fed. Reg., 62404, col. 1 (for importation of fresh whole or half carcasses); 68 Fed. Reg., 62404, col. 3 (for importation of gelatin).

¹² *See* 68 Fed. Reg., 62402, col. 1 (§ 93.436(a)(1, 2)), (§ 93.436(b)(1, 2)); 68 Fed. Reg., 62403, col.3, 62404, col. 1 (§ 94.19(a)), (§ 94.19(b)(1, 2)); 68 Fed. Reg., 62404, col. 3 (§ 94.19(j)); 68 Fed. Reg., 62405, col. 2 (§ 95.4(f)(3)).

presented for export and animals from which meat or meat products intended for export were derived were subject to a ruminant feed ban.”¹³

APHIS further explained that the 30-month age restriction provided the assurance that Canadian cattle intended for export, as well as Canadian cattle from which meat and meat products were intended for export, were subject to a ruminant feed ban. The agency stated:

In addition, the Canadian cattle less than 30 months of age were born and raised during a time when the Canadian feed ban had been in place for more than five years, and, based on evidence of a high level of compliance with the feed ban, are unlikely to have been exposed to the BSE agent.”¹⁴

APHIS’ treatment of two specific products derived from cattle stand out to further disprove APHIS’ claim regarding the purpose of the 30-month age restriction and to prove that APHIS’ true intention was to prevent the importation of products derived from Canadian cattle that were exposed to BSE infectivity. The 2003 Proposed Rule would have allowed the importation of bovine tongues without imposing the 30-month age restriction, even though APHIS acknowledged that tongues are connected to, and bear the risk of, contamination by tissues that have the potential of containing high levels of BSE infectivity, i.e., tonsils. *See* 68 Fed. Reg., 62395, cols. 2. To mitigate this risk, the 2003 Proposed Rule required that tongues be derived from cattle from which the tonsils were removed at slaughter *and* that “were born after the implementation of an effective feed ban” *and* that “were not known to have been fed ruminant protein, other than milk protein, during their lifetime.” 68 Fed. Reg., 62395, cols. 2. This example demonstrates that the measures used by APHIS in its 2003 Proposed Rule to “guard against the importation of, or contamination of meat through contact with, tissues other than meat that have the potential of containing high levels of BSE infectivity” (73 Fed. Reg., 54086, col. 2.) were other mitigation measures and *not* the 30-month age restriction.

Moreover, the 2003 Proposed Rule would have allowed the importation of liver that, likewise, was not subject to the 30-month age restriction, even though, according to APHIS, it too was susceptible to contamination by tissues that have the potential of containing high levels of BSE infectivity, i.e., brain emboli. *See* 68 Fed. Reg., 62395, col.1. Here, APHIS directly contradicts its instant claim by stating:

In and of itself, the liver is unlikely to contain infectious levels of the BSE agent, so we are not proposing to require that liver be derived from animals less than 30 months of age or not known to have been fed ruminant protein, other than milk protein, during their lifetime.

68 Fed. Reg., 62395, col. 1. To mitigate the potential of liver contamination by the BSE agent, the 2003 Proposed Rule required only that liver be derived from cattle “for which an air-injected stunning process was not used at slaughter.” 68 Fed. Reg., 62404, col. 1. Again, this example

¹³ Analysis of Risk – Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, APHIS, December 2004, at 18.

¹⁴ *Ibid.*

further demonstrates that the measures used by APHIS in its 2003 Proposed Rule to “guard against the importation of, or contamination of meat through contact with, tissues other than meat that have the potential of containing high levels of BSE infectivity” (73 Fed. Reg., 54086, col. 2.) were other mitigation measures and *not* the 30-month age restriction.

Notwithstanding APHIS’ initial proposal to relax safety requirements for liver, the agency’s Final MMR Rule found that the mere prohibition against air-injected stunning for imported liver was insufficient to achieve the agency’s objective to prevent the importation of products that pose a risk of introducing BSE into the United States. *See* 70 Fed. Reg., 500, col. 2. The Final MMR Rule reinstated the same mitigation measures for liver and other offal as set forth for meat, meat byproducts, and meat food products, including the requirement that liver must be derived from bovines that were subject to a ruminant feed ban. *See* 70 Fed. Reg., 500, col. 2; *see also* 70 Fed. Reg., 552, col. 1 (§ 95.1 Definitions); *see also id.*, (§ 95.4(g)(1)(iii)).

The foregoing facts show that despite APHIS’ attempt to mislead the public into believing that the 30-month age restriction was *not* to prevent the importation of meat or meat products from animals that themselves may have been exposed to BSE infectivity in Canada, that is precisely what the 30-month age restriction was designed to accomplish.

B. APHIS Improperly Implies that FSIS Had Evaluated the Reduction of Risk Associated with Restricting the Age of Cattle Eligible for Slaughter *in the United States.*

APHIS’ 2008 Notice improperly implies that the U.S. Food Safety and Inspection Service (FSIS), when it declared SRMs inedible and required their removal from cattle at slaughter, had considered, if not evaluated, a restriction on the age of cattle eligible for slaughter in the United States as among the alternatives it had weighed when it took steps to mitigate the BSE risks to humans *in the United States.* APHIS’ 2008 Notice states:

FSIS did not restrict the age of cattle eligible for slaughter because the removal of SRMs effectively mitigates the BSE risk to humans associated with cattle that pass both ante-mortem and post-mortem inspections (i.e., apparently healthy cattle).

73 Fed. Reg., 54086, col. 3. There is no basis for this implication that appears to be an attempt to saddle the United States with Canada’s higher BSE risk profile. The FSIS’s 2004 Interim Final Rule (2004 IFR) declaring SRMs inedible and requiring their removal from cattle at slaughter did not discuss restricting the age of cattle eligible for slaughter in the United States. *See* 69 Fed. Reg., 1861-1874. Instead, the 2004 IFR provided reassurance that the U.S. had already implemented measures to prevent BSE from entering the United States and to prevent its spread should it be introduced in the United States. *See* 69 Fed. Reg., 1863, col. 2. Further, the 2004 IFR referenced the Harvard study’s conclusion that due to the preventive measures already in place in the U.S., BSE is “extremely unlikely” to become established in the United States and should BSE enter the U.S., “only a small amount of potentially infective tissues would likely reach the human food supply.” 69 Fed. Reg., 1867, col. 1.

The FSIS did, however, evaluate three alternative SRM removal scenarios in 2004, though none included a restriction on the age of cattle eligible for slaughter in the United States.¹⁵ In its 2004 evaluation, FSIS concluded that the scenario depicting the SRM removal policies adopted by the agency “can reduce potential human exposure [to BSE] by 80 percent.”¹⁶

The FSIS’s 2005 amendments to the 2004 IFR likewise did not consider or evaluate a restriction on the age of cattle eligible for slaughter in the U.S. as among the alternatives with which to mitigate the BSE risks to humans in the United States. *See* 70 Fed. Reg., 53043-53050. Thus, when the 2005 Final MMR Rule was published, the expected effectiveness of FSIS’ SRM removal requirements was no more than an 80 percent reduction in potential human exposure to BSE and APHIS believed this was sufficient to mitigate the BSE risk in cattle *slaughtered in the United States*.

C. APHIS Has Inappropriately Applied Study Results to Canada that Were Predicated on Factors Specific Only to the United States in Order to Justify Importing Higher-Risk Canadian Cattle and Beef.

In its Final OTM Rule, APHIS explained that the 80 percent reduction in potential human exposure found in the 2004 FSIS analysis was correct, but was based on the assumption that 5 BSE-infected animals were introduced into the United States 12 months before FSIS implemented its BSE mitigation measures, including SRM removal. This assumption resulted in “a certain amount of infectivity [] becom[ing] available for human exposure” during the model’s simulated disease spread from 2003 to 2020. 72 Fed. Reg., 53336, col. 1. APHIS further explained that because the implementation of mitigation measures occurred after the simulated introduction of 5 BSE-infected cattle, the mitigation measures “could never eliminate all of the infectivity available” during the 17-year period of the study and “a certain amount of potential infectivity was allowed into inappropriate channels, such as human food.” 72 Fed. Reg., 53336, cols. 1, 2. APHIS concluded that because this study included the introduction of 5 BSE-infected cattle before FSIS implemented its BSE mitigation measures, “it is inappropriate to use this analysis as a citation for the level of public health protection provided by risk mitigation measures in place in the United States.” 72 Fed. Reg., 53336, col. 2. *Emphasis added.*

The FSIS subsequently modified its assumptions *for the United States* in a new analysis that was made available for public comment in 2006, and in which U.S. risk mitigation measures were assumed to have been implemented before the introduction of BSE-infected cattle. This modified analysis indicated that the FSIS measures implemented in the United States in 2004 would reduce “potential human exposure by more than 99 percent, on average.” 72 Fed. Reg., 53336, col. 2.

This latter FSIS analysis, which modified the FSIS’ original assumptions to reflect factors specific to United States, is wholly irrelevant to the issue of risk related to the importation of OTM beef from Canada. This is because the risk of OTM beef from Canada is wholly

¹⁵ *See* Preliminary Analysis of Interim Final Rules and an Interpretive Rule to Prevent the BSE Agent from Entering the U.S. Food Supply, Food Safety and Inspection Service, USDA, at 23, attached hereto as Exhibit 4.

¹⁶ Preliminary Analysis of Interim Final Rules and an Interpretive Rule to Prevent the BSE Agent from Entering the U.S. Food Supply, Food Safety and Inspection Service, USDA, at 58, attached hereto as Exhibit 4.

determined by Canada's specific BSE risk profile and Canada's specific BSE mitigation measures. Unlike the United States, for which there was no evidence of BSE infectivity in the native U.S. cattle herd prior to the completion of FSIS' modifications, which assumed no introduction of BSE until after the United States implemented FSIS' mitigation measures, Canada's risk profile is very different and, in fact, Canada is known to have had at least three generations of BSE infectivity in its native cattle herd prior to the time that Canada implemented its BSE mitigation measures, including SRM removal.¹⁷

Canada has had 16 confirmed cases of BSE in native cattle that were born during or before 2003, the year that Canada implemented its SRM removal measures.¹⁸ Therefore, and while APHIS asserts that the 2004 FSIS conclusion that SRM removal would reduce potential human exposure to BSE by only 80 percent does not reflect conditions *in the United States*, the assumption is applicable to Canada's condition where multiple generations of BSE infectivity is known to have been introduced into its native herd prior to the implementation of its SRM removal measures. Given that neither FSIS nor APHIS has analyzed the risk of beef derived from Canadian cattle slaughtered in Canada, the most optimistic risk reduction that can be assumed to apply to Canada's SRM removal measures for cattle slaughtered in Canada is that they *may* reduce the risk of human exposure by 80 percent.

The foregoing facts show that APHIS's analysis of the effectiveness of SRM removal requirements for cattle slaughtered in the United States was dependent on U.S. conditions that existed only in the United States prior to the implementation of such requirements. And, because conditions in Canada were very different than those in the United States prior to Canada's implementation of its SRM removal requirements, APHIS' recently modified, and more favorable conclusion regarding SRM effectiveness in the United States cannot be applied to the risks associated with meat and meat products derived from cattle slaughtered in Canada.

D. The Effectiveness of SRM Removal is Different for Canadian Cattle Born Before Effective Risk Mitigation Measures were Put in Place.

As stated above, APHIS' claim in its 2008 Notice that the risk analysis conducted for the 2005 Final MMR Rule demonstrated that the risk of importing Canadian meat and meat products is lower than the risk of importing live Canadian cattle is baseless because the referenced risk analysis was predicated on the meat and meat products only being derived from cattle subject to a feed ban. *See supra*, at 3-5. In addition, however, APHIS has explained in its Final OTM Rule

¹⁷ U.S. Department of Agriculture's Summary of the Epidemiological Findings of North American Bovine Spongiform Encephalopathy Positive Cattle, U.S. Department of Agriculture, April 2005, at 24 (According to APHIS, the Canadian Food Inspection Agency (CFIA) has postulated that Canada's exposure consists of three indigenous generations of the disease: "The first introduction of BSE would have been cattle imported from the early part of the UK epidemic (approximately 1986 to 1988). These animals would have reached a likely age to express the disease (three to six years) in the early 1990s during a period of lower surveillance testing. They would have then entered the rendering process and subsequently be re-fed back to ruminants. This second generation would have then been old enough to express the disease at about the time of the feed ban in 1997. The current third generation cases would have been infected by MBM from the second generation of infectivity in 1997 and would be expected to express the disease in 2002 to 2005.")

¹⁸ *See* Matrix of BSE Cases, Prepared by Bill Bullard, CEO of R-CALF USA, Revised November 17, 2008, attached hereto as Exhibit 3.

that the effectiveness of SRM removal requirements to protect against human exposure is approximately 19 percent less for cattle born before the implementation of risk mitigation measures such as an effective feed ban. APHIS succinctly explained that human exposure was found to be reduced by more than 99 percent, on average (when perfect compliance is assumed), in simulations “where the risk mitigation was applied during the entire simulation.” 72 Fed. Reg., 53336, col. 2. However, in simulations in which risk mitigation was *not* applied during the entire simulation, i.e., when an effective feed ban was not in place, the expected reduction in potential human exposure from SRM removal requirements was only 80 percent. *See id.; see also id.*, col. 1.

Thus, the Final OTM Rule clearly establishes that SRM removal requirements are less effective (approximately 19 percent less effective) in preventing human exposure from the BSE agent when applied to cattle born before effective BSE mitigation measures are in place, such as in cattle born before the Canadian feed ban became effective.

The risk modeling that APHIS relies on to support its erroneous claim that SRM removal alone is sufficient to mitigate the potential risk to humans shows otherwise. The risk modeling shows there are two significant factors that contribute to the reduction in potential risk to humans: 1) the amount of BSE infectivity in circulation (based on the number of BSE-infected cattle) and 2) compliance with SRM removal requirements. This is demonstrated by the fact that when the 2005 risk model was updated to include the presence of BSE-contaminated poultry litter, resulting in more BSE-infected cattle, the effectiveness of SRM removal in reducing potential risk to humans was decreased by nearly half (from 20 ID_{50s} to 11 ID_{50s}), even with perfect compliance with SRM removal requirements.¹⁹ Moreover, all else being equal, when compliance with SRM removal requirements drop by only 1 percent, the potential risk to human health is more than quadrupled (increasing from 20 ID_{50s} to 83 ID_{50s}).²⁰

The fact that the amount of circulating infectivity impacts human health even with perfect compliance with SRM removal requirements is further substantiated by the authors of the risk models when they explained why the potential risk to humans was reduced following a simulation that prohibited SRM in both human food and animal feed. The authors stated:

Removing infectious tissues from both human food and animal feed, assuming that the ban effectively covers dead stock, and assuming perfect compliance, together have a substantial impact on both the potential human exposure and spread of BSE. . . Potential human exposure decreases both because there are fewer BSE cases and because the measures remove infectious tissues from the human food supply. Average human exposure decreases by more than 99% from 3,800 cattle oral ID_{50s} to 10 ID₅₀.²¹

¹⁹ *See* Harvard Risk Assessment of Bovine Spongiform Encephalopathy Update, Phase IA, Supplemental Simulation Results, December 26, 2006, Appendix 2A, Section 2.1.2c, line 15 (AR 17464); *see also* Harvard Risk Assessment of Bovine Spongiform Encephalopathy Update, Phase IA, October 31, 2005, Appendix 2A, Section 2.1.2, line 15 (AR 17109).

²⁰ *See* Harvard Risk Assessment of Bovine Spongiform Encephalopathy Update, Phase IA, Supplemental Simulation Results, December 26, 2006, Appendix 2A, Section 2.1.2c, line 15 (AR 17464), Section 2.1.2f, line 15 (AR 17467).

²¹ Harvard Risk Assessment of Bovine Spongiform Encephalopathy Update, Phase IA, October 31, 2005, at 29 (AR17086).

The foregoing discussion clearly reveals that Canadian cattle born before Canada implemented an effective feed ban, i.e., when BSE infectivity was circulating in the Canadian cattle herd, present a higher risk of infecting humans with BSE even if compliance with SRM removal requirements is perfect.

E. APHIS Arbitrarily and Wrongly Assumed that Current SRM Removal Practices in the U.S. are Sufficient to Eliminate the Risks Associated with Higher-Risk Canadian Cattle.

Central to APHIS' 2008 Notice is its assumption that SRM removal will effectively protect consumers from exposure to BSE. APHIS has failed to respond adequately to previous comments demonstrating that current scientific knowledge calls that assumption into question. APHIS' decision to rely on this questionable assumption, rather than take the cautious approach of assuming that there might still be exposure to the BSE infectious agent even if there are regulations requiring SRM removal, was inconsistent with the congressional intent evidenced in the Animal Health Protection Act, 7 U.S.C. §§ 8301 *et seq.* and the Meat Inspection Act, 21 U.S.C. §§ 601 *et seq.*

There are numerous studies demonstrating the limitations on mitigating the risk of BSE exposure via SRM removal. Some of those studies are summarized succinctly in Dr. Cox's Declaration I filed in the U.S. District Court.²² The Centers for Disease Control has acknowledged that the risk of humans getting vCJD from eating muscles cuts from potentially BSE-infected cattle "cannot be precisely determined."²³ APHIS should have, but has not, explained why these uncertainties and concerns do not undermine its almost-exclusive reliance on SRM removal requirements to protect American public health from potentially hazardous Canadian imports.

The current inability to detect BSE prions in certain tissues does not mean that there is insufficient infectivity to be a hazard.²⁴ While BSE prions have only been found in a solitary bovine muscle of a single cow,²⁵ that likely is a function of the current, limited analytical sensitivity of the tests; all the other information points to the likelihood that they are there. *Id.*; see also Sigurdson, C., Glatzel, M., and Aguzzu, A., Letter to the Editor of Veterinary Pathology, *Veterinary Pathology* Vol. 42, 107-108 (2005).

APHIS' assumption that removal of a fraction of the small intestine and the tonsils removes any potential for transmission to humans also is unjustified given that APHIS has not evaluated the potential for contamination of tongue with tonsil tissue. APHIS claims this possibility is eliminated by current slaughter techniques. But this assumption is again contradicted by actual facts: scientists who examined over 250 bovine tongues intended for

²² Declaration of Dr. Louis Anthony Cox, Jr., January 28, 2005, at 8-9, attached hereto as Exhibit 5.

²³ Declaration of Dr. Louis Anthony Cox, Jr., May 7, 2005, at 11, attached hereto as Exhibit 6.

²⁴ See Declaration of Dr. Stanley Prusiner, June 28, 2005 at ¶¶14-16, attached hereto as Exhibit 7.

²⁵ WHO Guidelines on Tissue Infectivity Distribution in Transmissible Spongiform Encephalopathies, World Health Organization, 2006, at 5, attached hereto as Exhibit 8.

human consumption found tonsillar tissue in the vast majority, in some cases “even after the most rigorous trimming of the root of the tongue.” Wells, G., Spiropoulos, J., Hawkins, S., and Ryder, S., Pathogenesis of Experimental Bovine Spongiform Encephalopathy: Preclinical Infectivity in Tonsil and Observations on the Distribution of Lingual Tonsil in Slaughtered Cattle, *Veterinary Record* (2005) 156, 401-407. APHIS cannot simply assume this risk away by stating, without record support, that it is eliminated.

APHIS repeatedly claims that mitigation measures contemplated by the Final OTM Rule, such as SRM removal, have been demonstrated to be highly effective. Such demonstration is not apparent, though: SRM removal requirements have not been in place nearly long enough to see an effect, particularly in light of exceedingly long incubation periods assumed for humans. Any human who consumed beef from a BSE-infected animal slaughtered after SRM removal requirements were implemented would not be expected to show signs of vCJD for about 17 years. See 72 Fed. Reg., 53336, col. 1. To the extent that the reduction in diagnosed cases of BSE in recent years demonstrated that the extent of vCJD infection from consuming infected beef is decreasing, which itself is unclear, given recent data on prion infection in tonsil and appendix samples from seemingly healthy individuals in the UK,²⁶ it is much more likely that it results from decreases in the number of infected cattle in the past decade due to feed bans, rather than to the much more recent implementation of SRM removal.

APHIS has provided no basis to assert that the rate of compliance with SRM removal requirements conducted on Canadian cattle slaughtered in either the U.S. or in Canada is adequate to protect human health. Moreover, all countries with BSE (except Canada) remove the brain, spinal column, etc. at 12 months and over, not 30 months as APHIS requires, so the experience with SRM removal in those countries is inapplicable for predicting risk in the U.S. APHIS cannot simply declare that its more relaxed SRM removal policy has been demonstrated to have been highly effective, when it cannot point to any such demonstration.

F. APHIS’ Insistence that It Can Effectively Mitigate Canada’s Specific BSE Risk with Measures Designed to Address the Specific BSE Risk in the United States is Unwarranted.

APHIS’ 2008 Notice states that BSE is still present in Canada “at low levels.” (73 Fed. Reg., 54087, col. 3). In the Final OTM Rule APHIS described Canada’s BSE prevalence as “extremely low,” (72 Fed. Reg., 53320, col. 1; 53347, col. 1), and “very low” (*id.*, 53329, col. 2). APHIS characterizes the BSE prevalence in the United States as if it were at the same level as it is in Canada stating, “Aggressive surveillance conducted in both the United States and Canada indicate a very low prevalence of BSE.” *Id.*, 53351, col. 2. APHIS further states that like Canada, the prevalence of BSE in the United States is “extremely low.” *Id.*, 53363, col. 2.

However, the BSE prevalence in Canada is very different from the BSE prevalence in the United States. According to the Centers for Disease Control and Prevention (CDC) the prevalence of BSE in Canada “has been 90% likely to be between 18-fold and 48-fold higher

²⁶ See Prevalence of lymphoreticular prion protein accumulation in UK tissue samples, David A. Hilton, et al., *Journal of Pathology*, Pathal 2004; 203: 733-739, attached hereto as Exhibit 9.

than the previously published best estimate of the prevalence of BSE in the United States.”²⁷ Yet, the CDC points out that a prevalence of 23-fold higher than the United States “continues to be used in the Harvard Risk Assessments’ ‘worst case’ analysis when evaluating the risk of imported Canadian cattle causing BSE to spread among US animals.”²⁸

Importantly, APHIS’ estimation of Canada’s prevalence is based on the detection of only 11 cases of BSE.²⁹ Since that time, 5 additional cases have been detected and APHIS should not continue to rely on its outdated prevalence estimates to evaluate Canada’s BSE risk.

This information from the CDC clearly reveals that Canada’s BSE prevalence is significantly higher than is the BSE prevalence in the United States, and that APHIS has not properly evaluated the full range of risks associated with Canada’s ongoing BSE problem. As a result, APHIS has no basis to claim that the risk mitigation measures implemented in the United States to mitigate the disease’s prevalence in this country is sufficient to mitigate the much higher prevalence in Canada.

IV. APHIS HAS NOT ASSESSED THE RISKS FROM KNOWN AND SIGNICANT NON-COMPLIANCE WITH BSE-RELATED REGULATORY REQUIREMENTS

A. APHIS’ Reliance on the Equivalency of Canada’s Food Safety Requirements to Ensure Compliance with U.S. Food Safety Standards is Unsupported

APHIS’ 2008 Notice states that FSIS has determined that Canada has implemented food safety requirements that are equivalent to those in place in the United States, including Canada’s SRM requirements implemented in July 2003. *See* 73 Fed. Reg., 54086, col. 3. However, the USDA Office of Inspector General (OIG) found in December 2005 that Canadian plants were allowed to circumvent U.S. equivalency requirements for nearly two years:

In July 2003, FSIS found that Canadian inspection officials were not enforcing pathogen reduction and HACCP system regulations. These same types of concerns were identified again in June 2005, almost 2 years later. However, as of September 2005, FSIS has not made a determination whether the identified concerns are serious enough to limit the import of Canadian products. As a result, FSIS has allowed the importation of almost 700 million pounds of meat and poultry from plants that did not receive daily inspection, a requirement for all U.S. meat and poultry plants. Additionally, FSIS allowed the import of over 261 million pounds of ready-to-eat meat and poultry that had not been subjected to finished product testing for *Listeria monocytogenes*, as is required of U.S. plants.³⁰

²⁷ BSE (Bovine Spongiform Encephalopathy, or Mad Cow Disease), Centers for Disease Control and Prevention, available at <http://www.cdc.gov/ncidod/dvrd/bse/>, attached hereto as Exhibit 10.

²⁸ BSE (Bovine Spongiform Encephalopathy, or Mad Cow Disease), Centers for Disease Control and Prevention, available at <http://www.cdc.gov/ncidod/dvrd/bse/>, attached hereto as Exhibit 10.

²⁹ *See id.*

³⁰ Audit Report Food Safety and Inspection Service Assessment of the Equivalence of the Canadian Inspection System, U.S. Department of Agriculture, Office of Inspector General, Northeast Region, Report No. 24601-05-Hy, December 2005, at 4, attached hereto as Exhibit 11.

Thus, there is a disparity between what the FSIS is supposed to require of foreign plants that ship products to the U.S. and what is actually practiced. The OIG explained that FSIS does not have protocols or guidelines for evaluating deficiencies in a country's inspection system that could jeopardize a country's overall equivalence determination" and "FSIS did not institute compensating controls to ensure that public health was not compromised while deficiencies were present."³¹ The FSIS found that over 4.4 billion pounds of processed meat from Canada entered U.S. commerce during the period covered by the report – January 2003 through May 2005 – "even though FSIS officials questioned the equivalence of the Canadian inspection system."³²

In a follow-up report issued by the OIG in August 2008, the OIG reviewed four foreign countries, including Canada, and found continuing deficiencies in FSIS' policy controls for assessing the equivalence of the foreign countries' food safety systems. Specifically, the OIG found that FSIS could not demonstrate that the number of intensified inspection for physical and laboratory failures provided the appropriate level of protection to ensure the safety and wholesomeness of imported products."³³ In addition, the OIG found that FSIS could not demonstrate that it performed an adequate sample of foreign establishments to validate that the country's inspection system is equivalent to the United States.³⁴ And, the OIG found that FSIS did not visit the minimum number of establishments necessary to validate that inspection systems were equivalent to the United States in three of the four countries it reviewed and questioned whether FSIS had sufficient data to conclude that these countries' inspection systems were equivalent to the U.S. system.³⁵

APHIS has provided no evidence regarding Canada's compliance rate with U.S. food safety requirements and the evidence above shows that even after being aware of major deficiencies for five years, FSIS still can not adequately ensure the safety and wholesomeness of imported Canadian products or conclude that Canada's inspection system is equivalent to the U.S. system.

B. A Recent OIG Report Indicates that APHIS has Not Properly Enforced BSE Mitigation Requirements.

The OIG issued a report in 2008 regarding, *inter alia*, APHIS' enforcement of requirements contained in the Final MMR Rule and covering the period August 2006 through July 2007. The OIG found that APHIS has not properly or adequately enforced its Final MMR Rule. The report states in part: "APHIS' import controls are not sufficient to prevent, detect, or

³¹ Audit Report Food Safety and Inspection Service Assessment of the Equivalence of the Canadian Inspection System, U.S. Department of Agriculture, Office of Inspector General, Northeast Region, Report No. 24601-05-Hy, December 2005, at 4, attached hereto as Exhibit 11.

³² *Id.*

³³ Audit Report Followup Review of Food and Safety Inspection Service's Controls Over Meat and Poultry Products, U.S. Department of Agriculture, Office of Inspector General, Northeast Region, Report No. 24601-08-Hy, August 2008, at 5, attached hereto as Exhibit 12.

³⁴ *See id.*, at ii, iii.

³⁵ *See id.*, ii, iii.

address the entry of animals that do not meet import requirements,”³⁶ and that APHIS’ “animal import procedures were not sufficient to prevent unauthorized shipments [of live animals] into the United States.”³⁷ The OIG report states the problems that the OIG found regarding compliance with APHIS’ earlier [Final MMR Rule] rule “raise concerns with APHIS’ controls over live animal imports and whether the controls are adequate to ensure compliance with import restrictions [contained in the Final OTM Rule]”³⁸

Additional Findings in the OIG audit include:

- APHIS does not have adequate processes in place to determine the extent of import problems nationwide when individual violations are identified by field units (at 6).
- APHIS does not have effective systems or controls for approving and/or tracking live animals into and through the United States (at 6).
 - The OIG found cattle entered the United States that did not meet import requirements (at 7).
 - The OIG found 145 indications of noncompliance with the 2005 minimal-risk region rule (at 8).
- APHIS officials did not sufficiently document import problems (at 9).
- Animals entered the United States without APHIS inspection (at ii).
- During FYs 2005 and 2006, 161 animal shipments gained unauthorized entry into the United States (at iv).
- APHIS did not ensure that all restricted cattle arrived at an approved slaughter establishment (at 16).
- APHIS could not account for more than 14,000 official USDA seals at five area offices (at 25).
- APHIS failed to re-inspect slaughter establishments that imported live animals, as is required every six months by APHIS protocols to prevent the dissemination of animal diseases (at 29).
- Over 142,000 cattle and swine from Canada were slaughtered in U.S. slaughtering establishments without APHIS ensuring that proper import protocols were in place (at 29).
- APHIS lacks management oversight to ensure port officials properly implement import requirements (at 31).
- Port-of-entry officials did not ensure compliance with animal import requirements (at 32).
- Since 2002, APHIS did not review – at all – 51 ports-of-entry that were responsible for the majority of imported animals (at 32).
- APHIS used incorrect animal import data to prepare reports for stakeholders and to perform analysis of import patterns to develop models for emerging diseases (at 34).

³⁶ Audit Report, USDA’s Controls Over the Importation and Movement of Live Animals, Department of Agriculture, Office of Inspector General, Midwest Region, Report No. 50601-0012-Ch, March 2008, at 6, attached hereto as Exhibit 13.

³⁷ Audit Report, USDA’s Controls Over the Importation and Movement of Live Animals, Department of Agriculture, Office of Inspector General, Midwest Region, Report No. 50601-0012-Ch, March 2008, at 13, attached hereto as Exhibit 13.

³⁸ *Id.*, at 10.

In public comments submitted to APHIS in the Final OTM Rule rulemaking, R-CALF USA and other commenters raised concerns regarding non-compliance and violations with import requirements imposed in the Final MMR Rule. APHIS responded to those comments in its September 18, 2007 Final OTM Rule by denying any knowledge of “significant or repeated violations of the existing APHIS import regulations” (72 Fed. Reg., 53340, col. 1), and it denied that commenters had provided evidence of such violations. *See id.* The agency did, however, acknowledge that individual instances of “errors or violations” can, and have, occurred, but claimed these individual instances were dealt with appropriately. *See id.* Further, the agency denied that any of these errors presented a significant threat to animal or public health. *See id.*

As revealed by significant and serious violations listed above, the OIG directly contradicts APHIS’ claim that there were only individual instances of errors or violations to the agency’s Final MMR Rule. The OIG, in fact, found the errors and violations to be pervasive, stating that problems associated with inaccurate health, age, identification, and pregnancy status on Canadian health certificates used to import more than 7,000 cattle “were not isolated occurrences because they involved at least 52 different Canadian veterinarians and 40 CFIA officials.”³⁹

Even though APHIS was aware that the OIG was auditing its import controls and finding serious deficiencies during the period that overlapped the Final OTM Rule rulemaking, which auditing included fieldwork in APHIS’ national, regional and area offices, as well as ports-of-entry,⁴⁰ APHIS hid this important information from the public and irresponsibly denied that the agency was aware of serious violations of its enforcement of the Final MMR Rule at the time it finalized and published its Final OTM Rule, which occurred two months after the OIG’s fieldwork was completed.

This OIG audit report demonstrates that APHIS is incapable of properly and adequately enforcing import restrictions necessary to protect the health of U.S. cattle and U.S. consumers. Because APHIS has demonstrated its inability to ensure compliance, or even to verify or enforce compliance, with BSE import restrictions critical to the protection of the health of U.S. cattle, and ultimately consumers, the Final OTM Rule should be immediately withdrawn.

C. APHIS’ Assertion Regarding the Effectiveness of SRM Removal for Protecting Human Health Unreasonably Relies on Perfect Compliance

APHIS defends its Final OTM Rule in a manner that reveals its wanton disregard for the risks inherent in OTM Canadian beef and cattle. On the one hand, the agency justifies its disregard for the numerous cases of BSE-infected Canadian cattle born years after Canada’s feed ban was supposedly effectively enforced (now numbering 9) on the basis that, “Effective enforcement does not necessarily mean that 100 percent compliance with the feed ban will be achieved.” 73 Fed. Reg., 54087, col. 2, fn 4. On the other hand, the agency claims that “the

³⁹ Audit Report, USDA’s Controls Over the Importation and Movement of Live Animals, Department of Agriculture, Office of Inspector General, Midwest Region, Report No. 50601-0012-Ch, March 2008, at iv, attached hereto as Exhibit 13.

⁴⁰ *Id.*, at 37.

removal of SRMs effectively mitigates the BSE risk to humans associated with cattle that pass both ante-mortem and post-mortem inspections” (73 Fed. Reg., 54086, col. 3.), while the only reference regarding what the agency means by the phrase “effectively mitigates the BSE risks to humans” is APHIS’ assertion made to the U.S. District Court that the removal of SRMs almost completely eliminates potential human exposure to the BSE agent.”⁴¹ However, the FSIS states that this conclusion regarding the effectiveness of SRM removal is valid only “if compliance is perfect.” 72 Fed. Reg., 38726, col. 1. Emphasis added.

The agency cannot have it both ways. It is arbitrary and capricious for the agency to claim that a feed ban is effective and effectively enforced even without perfect compliance while claiming SRM removal requirements provide effective mitigation to human health even though this level of protection (i.e., “effective”) is predicated on perfect compliance. APHIS has failed to explain why its claim for the effective enforcement of Canada’s feed ban does not require perfect compliance while its claim of the effectiveness of SRM removal policies in protecting human health is expressly dependant on perfect compliance.

Even more important, however, is the fact that there have been numerous documented cases of non-compliance with FSIS’ SRM removal policies. In a 2006 report, the OIG found, *inter alia*, that the FSIS management system could not readily identify trends in SRM violations;⁴² that conditions at slaughtering facilities visited by the OIG “indicated SRM requirements had not been adequately implemented;”⁴³ cattle were being slaughtered without the requisite ante-mortem inspection;⁴⁴ reliable age documentation at slaughtering plants was lacking;⁴⁵ slaughtering facility’s establishment of SRM plans were inadequate;⁴⁶ inspectors did not always identify deficiencies in SRM controls;⁴⁷ and, the OIG stated, “However, without documentation, FSIS lacks an effective means of ensuring compliance [with SRM removal requirements].”⁴⁸ Even more recently, in 2008, the FSIS issued at least 4 separate Class II recalls for approximately 1.4 million pounds of cattle heads that were not processed according to FSIS’ SRM removal requirements.⁴⁹

Public Citizen independently obtained compliance data regarding SRM removal requirements from USDA pursuant to a December 2004 Freedom of Information Act request. The data was subsequently compiled and Public Citizen issued a report indicating 829 incidences of noncompliance with SRM removal policies.⁵⁰

⁴¹ See Memorandum Opinion and Order on Motion for Preliminary Injunction, United States District Court, District of South Dakota, Northern Division (hereafter “Court Order”), July 3, 2008, at 15.

⁴² See Audit Report, Animal and Plant Health Inspection Service, Bovine Spongiform Encephalopathy (BSE) Surveillance Program – Phase II and Food Safety and Inspection Service Controls Over BSE Sampling, Specified Risk Materials, and Advanced Meat Recover Products – Phase III, Office of Inspector General, Report No. 50601-10-KC, January 2006, at 59., attached hereto as Exhibit 14.

⁴³ *Id.*, at 62.

⁴⁴ *Id.*, at 51.

⁴⁵ *Id.*, at 52.

⁴⁶ See *id.*, at 53.

⁴⁷ See *id.*, at 54.

⁴⁸ *Id.*, at 55.

⁴⁹ See FSIS Recall Case Archive, 2008, attached hereto as Exhibit 15 (recalls of cattle heads that were not processed according to FSIS’ SRM removal requirements occurred on April 4, June 26 and Aug. 7, 2008).

⁵⁰ BSE Noncompliance Record Analysis, Public Citizen, attached hereto as Exhibit 16.

In June 2007, Food and Water Watch submitted to USDA sworn affidavits from USDA Food Safety Inspection Service (FSIS) inspectors at large meatpacking plants in the western U.S., indicating, *inter alia*, that Canadian cattle that clearly were over 30 months of age, based on observed dentition, have been slaughtered in the U.S. accompanied by health certificates from Canada indicating that the animals were under 30 months of age.⁵¹ FSIS inspectors were instructed to allow the cattle to be processed as under-30-month cattle, meaning that their brains, skulls, eyes, spinal cords, trigeminal ganglia, vertebrae columns and dorsal root ganglia were not required to be removed prior to processing. This is contrary to assumptions on which USDA's assessment of the risk of importing OTM Canadian cattle are based: that the only exposure to these potentially infected tissues would be through inadvertent contamination of the carcass when these material are removed. The occurrence of these violations has now been substantiated by the 2008 OIG report. *See supra*, at 15, 16.

In addition, the U.S. has been shut out of important export markets in recent years due to non-compliance with SRM removal requirements. For example: in January 2006, Japan closed its borders to U.S. beef for approximately 6 months after discovering a vertebral column in a shipment of beef.⁵² In October 2007, South Korea closed its borders to U.S. beef for approximately 8 months after the discovery of an SRM in a U.S. beef shipment.⁵³

APHIS provides no analysis in its 2008 Notice to address this series of known incidences of non-compliance with FSIS' SRM removal requirements. For this reason, the entire Final OTM Rule should be immediately withdrawn.

V. APHIS IMPROPERLY IGNORES IMPORTANT SCIENTIFIC FINDINGS AND IMPROPERLY RELIES ON THEORETICAL GUIDELINES RATHER THAN EMPIRICALLY PROVEN MITIGATION MEASURES

A. APHIS' Refusal to Take Any Precautions to Protect U.S. Consumers from Exposure to Peripheral Nerves Derived from Canadian Cattle that Were Not Subject to an Effective Feed Ban is Unjustified and Irresponsible.

Despite the detection of over 190,000 confirmed cases of BSE in the world from 1989 to present,⁵⁴ most of the information on the development and distribution of tissue infectivity in BSE-infected cattle relied on by APHIS has been derived from experimental pathogenesis

⁵¹ See June 12, 2007 letter to Secretary Johanns from Winonah Hauter, Executive Director of Food and Water Watch, attached hereto as Exhibit 17.

⁵² See Global Beef Trade: Effects of Animal Health, Sanitary, Food Safety, and Other Measures on U.S. Exports, U.S. International Trade Commission, USITC Publication No. 4033, September 2008, at 5-1, attached hereto as Exhibit 18.

⁵³ See *id.*, at 6-1.

⁵⁴ See Number of reported cases of bovine spongiform encephalopathy (BSE) in farmed cattle worldwide (excluding the United Kingdom), World Organization for Animal Health (hereafter "OIE"), available at http://www.oie.int/eng/info/en_esbmonde.htm, downloaded on Oct. 22, 2008, attached hereto as Exhibit 19 (there were 5,803 confirmed cases in the world excluding the UK); see also Number of cases of bovine spongiform encephalopathy (BSE) reported in the United Kingdom, OIE, available at http://www.oie.int/eng/info/en_esbru.htm, downloaded on Oct. 22, 2008, attached hereto as Exhibit 20 (there were 184,576 confirmed cases in the UK).

studies conducted in the United Kingdom (UK) that involved only 30 animals that were infected with BSE nearly two decades ago.⁵⁵ See 73 Fed. Reg., 54084, col. 3. Though the peak in BSE infectivity occurred in the UK in 1992, the peak in BSE infectivity detected in the rest of the world did not occur until a decade later, in 2002.⁵⁶ In Canada, however, the peak appears to have occurred even later, in 2006 if it has peaked at all.⁵⁷

Since the time of the UK pathogenesis studies conducted on cattle around the time of the earlier UK infectivity peak, several new developments have occurred in addition to the much later peak in infectivity detected in other geographic regions of the world, including Canada. Among those new developments are discoveries of the establishment of new variations of BSE in cattle infected in different geographic regions,⁵⁸ and new pathogenesis studies conducted on cattle from different regions.⁵⁹ These new studies, some of which were conducted in different geographical regions of the world, were conducted on cattle that were infected more contemporaneously with the more recently infected Canadian cattle than were the cattle used in the UK studies. Without providing any scientific basis, APHIS ignores the significance of recently detected BSE variations and summarily dismissed the relevance of the new, more contemporaneous studies that have detected BSE infectivity in new tissues, claiming only that the findings *could* be the result of more sensitive tests. See 73 Fed. Reg., 54085, col. 2.

APHIS specifically cites research that detected BSE infectivity at “low levels” in the sciatic nerve of cattle, but only after 30 months from exposure. See 73 Fed. Reg., 54085, col. 1. This reinforces APHIS’ previous contention that cattle over 30 months of age have an inherently higher risk for BSE than younger cattle due to the progressive nature of BSE.⁶⁰ APHIS further cites evidence of “low levels” of BSE infectivity found by *more than one* study in the sciatic nerve of cattle after 30 months from exposure (See 73 Fed. Reg., 54085, col. 1), yet it recommends no mitigation measures to address this known infectivity. See 73 Fed. Reg., 54086, cols. 1, 2. On the other hand, APHIS also cites evidence that demonstrates that *only one* study found what appears to be a “very low” level of infectivity in the tonsils of a BSE-infected animal, which “very low” level APHIS nevertheless deemed sufficient to cause BSE infectivity in cattle and deserving of mitigation. See 73 Fed. Reg., 54085, col. 2;⁶¹ see also 54086, col. 2. Based on this evidence, APHIS must conclude that the “low levels” of infectivity found by more than one study in the sciatic nerve of cattle 30 months from exposure are likely sufficient to

⁵⁵ The 30 cattle were born in 1991 and each dosed orally with 100 grams of pooled brain stems from 75 cases of BSE. See Preliminary observations on the pathogenesis of experimental bovine spongiform encephalopathy (BSE): an update, Wells et al., *The Veterinary Record*, January 31, 1988, at 103 (AR012502).

⁵⁶ See Number of reported cases of bovine spongiform encephalopathy (BSE) in farmed cattle worldwide (excluding the United Kingdom), World Organization for Animal Health (hereafter “OIE”), available at http://www.oie.int/eng/info/en_esbmonde.htm, downloaded on Oct. 22, 2008, attached hereto as Exhibit 19.

⁵⁷ *Ibid.*

⁵⁸ BSE (Bovine Spongiform Encephalopathy, or Mad Cow Disease), Centers for Disease Control and Prevention, available at <http://www.cdc.gov/ncidod/dvrd/bse/>, attached hereto as Exhibit 10.

⁵⁹ See, e.g., WHO Guidelines on Tissue Infectivity Distribution in Transmissible Spongiform Encephalopathies, World Health Organization, 2006, at 5, attached hereto as Exhibit 8 (studies conducted on a German cow).

⁶⁰ See 68 Fed. Reg., 62391, col. 2 (“In summary, infected cattle over 30 months of age . . . may have levels of the abnormal prion in affected tissues that are sufficient to infect other animals fed protein derived from these tissues. Infected animals less than 30 months of age . . . are unlikely to have infectious levels of the prion protein.”).

⁶¹ The referenced study found that one of five animals injected with tonsil material that harbored what appeared to be a “very low” level of infectivity developed clinical BSE at 45 months post-inoculation.

introduce BSE infectivity into a host animal than is the “very low” level of infectivity found by only one study to exist in the tonsils of infected cattle. However, without adequate explanation, APHIS takes the counterintuitive position that low levels of BSE infectivity found by more than one study in the sciatic nerve do not warrant mitigation, while the very low level of infectivity found in tonsils does warrant mitigation.

Facial and sciatic nerves are the *only* bovine tissues scientifically determined to harbor BSE infectivity by multiple studies for which APHIS makes no attempt whatsoever to mitigate, *including not even requiring Canadian beef imported into the United States to be derived only from cattle subject to a feed ban during their lifetimes. See supra.* Without adequate explanation, APHIS makes the extraordinarily inconsistent and baseless argument that the agency cannot extrapolate the experimental findings of infectivity in the facial and sciatic nerve into the context of the risk presented by natural (i.e., field) exposure pathways. *See 73 Fed. Reg., 54085, col. 2.*

APHIS’ unjust rationalization for this inconsistency includes the remarkable argument that suggests our scientific disease detection capabilities are now too good to be of benefit to either humans or animals. The agency all but apologizes for the scientific discoveries of infectivity in new bovine tissues, excusing the relevance of those discoveries on the grounds that the scientists’ detection tools are now too darn good and may over express the BSE agent. *See 73 Fed. Reg., 54085, col. 2.* The agency also all but complains that scientists have unfairly employed an efficient route of infection in order to detect infectivity in new tissues. *See 73 Fed. Reg., 54085, col. 3.* These school-yard antics applied to the importation of Canadian beef would be laughable but for the following scientifically documented facts: 1. BSE infectivity is known to exist in non-SRM tissues. *See supra.* 2. BSE infectivity is known to have been circulating in Canadian cattle for years, leading up to and including 2003.⁶² 3. APHIS does not know the minimum dosage necessary to cause BSE infectivity in either humans⁶³ or cattle.⁶⁴

The World Health Organization (WHO) emphatically states that, “It remains unknown whether tissues containing such very small amounts of infections material [detected by novel techniques] would transmit infection to humans.”⁶⁵ Based on this uncertainty, APHIS should

⁶² *See* Matrix of BSE Cases, Prepared by Bill Bullard, CEO of R-CALF USA, Revised November 17, 2008, attached hereto as Exhibit 3 (nine of the 16 native cases detected in Canada were born between 2000 and 2003).

⁶³ *See* Economic Analysis: Final Regulatory Impact Analysis, Final Rule, Prohibition of the Use of Specific Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle Offered for Slaughter and Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle during Slaughter (FSIS Docket No. 03-025F), USDA Food Safety and Inspection Service, June 28, 2007, at 148 (The FSIS stated: “Because the amount of the BSE agent necessary to cause disease in humans is unknown, FSIS has not estimated monetary values for reductions in human morbidity and mortality associated with these measures.”).

⁶⁴ Though APHIS does not know the amount of the infectivity consumed by BSE-infected cattle in the UK, it concluded, “Cattle may have become infected as a result of receiving low levels of infectious agent for a long period of time, a high infectious dose at a given point in time, or any combination of these two.” Analysis of Risk – Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, USDA APHIS, December 2004, at 11. Also, APHIS asserts, “Any animal, however, exposed to an infectious dose of the BSE agent and allowed to live to the end of its incubation period, would likely exhibit clinical signs.” 72 Fed. Reg., 53324, col. 3.

⁶⁵ WHO Guidelines on Tissue Infectivity Distribution in Transmissible Spongiform Encephalopathies, World Health Organization, 2006, at 10, attached hereto as Exhibit 8.

take precautionary steps to avoid human exposure to meat and meat products from Canadian cattle that pose the highest risk of infection, i.e., OTM Canadian cattle, particularly those born before the Canadian feed ban was effective.

APHIS argues that the studies that more recently detected abnormal PrP in the facial and sciatic nerves do not warrant new mitigation measures because “demonstrating the presence of PrP^{BSE} does not necessarily indicate the presence of BSE infectivity.” 73 Fed. Reg., 54085, col. 3. This argument is contradicted by the analysis conducted by the CDC, which stated that the WHO has now identified two classifications of tissue infectivity. According to the CDC, the WHO classifies “high-infectivity” tissues as the brain, spinal cord, retina, optic nerve, and dorsal root and trigeminal ganglia, “suggesting these tissues can pose a relatively high risk of transmission.”⁶⁶ The second classification identified is “lower infectivity” tissues, which include “peripheral nerves (e.g., sciatic and facial nerves), tonsils, nictitating membrane (third eye lid), distal ileum, bone marrow and possibly thigh muscle.”⁶⁷ In addition, and in direct contradiction to APHIS’ argument, the WHO has found *both* the presence of BSE infectivity and the presence of PrP^{TSE} in the peripheral nerves of cattle.⁶⁸

B. APHIS’ Reliance on Theoretical Measures Recommended by the World Organization for Animal Health (OIE) and its Rejection of Mitigation Measures that have a Proven Record of Effectiveness is Unwarranted.

APHIS’ 2008 Notice relies on recommendations by the World Organization for Animal Health (OIE) to justify its decision not to strengthen SRM removal requirements (*see* 73 Fed. Reg., 54086, col.1), and to allow the importation of OTM Canadian cattle into the United States. *See id.*, 54087, col.2, fn. 4. However, the OIE, an international standard setting body, has no experience in reducing either the incidence or spread of BSE. And, no country that has reported more than 2 native cases of BSE follows the more relaxed guidelines established by the OIE to mitigate their respective BSE problems, with Canada being the single exception. All countries other than Canada that have detected more than two native BSE cases, and which have been working to reduce both the incidence and spread of BSE for many years, impose far stricter SRM removal requirements and age requirements than is practiced by Canada and recommended by the OIE. For example, Japan removes SRMs from cattle of any age and the UK and Europe remove SRMs from cattle over 12 months of age. These countries also impose stricter age restrictions than those recommended by the OIE, e.g., Japan allows only imports of beef from cattle 20 months of age or younger.⁶⁹ The EU limits imports to beef from cattle under 30 months of age.⁷⁰

The only empirical evidence demonstrating the effectiveness of BSE mitigation measures in reducing the incidence and spread of BSE are data provided by BSE-affected countries such as

⁶⁶ Risk for Travelers, Centers for Disease Control and Prevention, 2007, attached hereto as Exhibit 21.

⁶⁷ *Id.*

⁶⁸ *See* WHO Guidelines on Tissue Infectivity Distribution in Transmissible Spongiform Encephalopathies, World Health Organization, 2006, Table 1B, at 24, attached hereto as Exhibit 8.

⁶⁹ *See* Global Beef Trade: Effects of Animal Health, Sanitary, Food Safety, and Other Measures on U.S. Exports, U.S. International Trade Commission, USITC Publication No. 4033, September 2008, at 4-9, attached hereto as Exhibit 18.

⁷⁰ *See id.*, at 7-11.

the EU, including the UK, and Japan, where each have practiced more rigorous mitigation measures for many years when compared to the less rigorous measures recommended by the OIE and practiced by Canada and the United States. APHIS fails to explain why it has chosen to impose unproven, less rigorous mitigation measures on Canadian imports than those measures that have been applied and practiced in the EU and Japan and that have a proven record for effectiveness.

VI. APHIS IMPROPERLY RELIES ON MITIGATION MEASURES THAT WERE BASED ON PREVIOUS ASSUMPTIONS THAT HAVE SUBSEQUENTLY BEEN DISPROVEN BY EMPIRICAL EVIDENCE

A. APHIS Improperly Relies on Outdated and Disproven Findings from its 2005 Investigations of Two Canadian Cases of BSE to Justify its Final OTM Rule.

As justification for its decision to lift the ban on OTM Canadian beef, APHIS asserts that its 2005 evaluation of the epidemiology of BSE cases identified at that time suggested that Canada's BSE outbreak was only a local exposure, "based on the relatively small geographical location, temporal association, and the clustering of cases." 73 Fed. Reg., 54087, col. 1. This conclusion is outdated and has been disproven by subsequent outbreaks of BSE that occurred prior to APHIS' publication of its Final OTM Rule. At present, BSE exposure in Canada is known to cover an expansive geographic region, encompassing three Canadian provinces (Alberta, British Columbia and Manitoba).⁷¹

As additional justification for its decision to lift the ban on OTM Canadian beef, APHIS asserts that its 2005 evaluation of the Canadian feed ban revealed that overall compliance with the feed ban was good and that the feed ban was reducing the risk of transmission of BSE in the Canadian cattle population. *See* 73 Fed. Reg., 54087, col. 2. This conclusion is also outdated and has been disproven by subsequent outbreaks of BSE that have been born years after the implementation of Canada's feed ban. APHIS has no basis to assume that Canada's BSE problem has not worsened in recent years as is evidenced by empirical data that support this conclusion. The CDC reports that the occurrence of BSE in Canada has indeed risen in recent years.⁷²

B. Empirical Evidence Disproves APHIS' Assumption that Canada's Feed Ban was Effectively Enforced on March 1, 1999.

Contrary to APHIS' claims, there is no evidence that Canada's BSE prevalence is decreasing at this time. Canada has now detected 16 native cases of BSE, 10 of which were born after Canada implemented its 1997 feed ban and 9 of which were born *after* the March 1, 1999 date that APHIS established as the date of effective enforcement of Canada's feed ban.⁷³ Thus,

⁷¹ *See* Matrix of BSE Cases, Prepared by Bill Bullard, CEO, R-CALF USA, Revised November 17, 2008, attached hereto as Exhibit 3.

⁷² *See* Risk for Travelers, Centers for Disease Control and Prevention, 2007, attached hereto as Exhibit 21.

⁷³ *See* Matrix of BSE Cases, Prepared by Bill Bullard, CEO, R-CALF USA, Revised November 17, 2008, attached hereto as Exhibit 3.

the vast majority of all BSE cases detected in Canada were cattle born after March 1, 1999. And the CDC has found that the highest number of reported cases by birth year occurred *after* 1999:

Based on the known or most likely year of birth, an average of just over 1 case of BSE occurred among the group of animals born each year in Canada from 1991 through 2003. The highest reported number of cases by birth year to date, 2 BSE cases occurred among the group of animals born in Canada during the year 2000.⁷⁴

The most recent epidemiological investigation conducted by Canada for a case of BSE in an animal born in 2003 shows that the most likely source of infection continues to be the consumption of commercial cattle feed produced in Canada.⁷⁵

These facts demonstrate, definitively, that BSE has continued to circulate in Canada's cattle feed, and has continued to infect cattle in at least two Canadian provinces years after March 1, 1999. As a result, cattle born after March 1, 1999 bear the same, higher-risk for BSE as cattle born before that date. The evidence shows that Canada's widespread exposure is the result of an inadequate and insufficient feed ban implemented by Canada in 1997, a feed ban that failed to address the cross-contamination of cattle feed with feed produced for other animals. This failure was not corrected on or after March 1, 1999, so Canada's problem persisted, and, in fact, worsened. As R-CALF USA pointed out in its March 12, 2007 comments, Canada's insufficient feed ban was not made whole until July 2007, at which time Canada took steps to ban ruminant protein from all animal feed and fertilizer. USDA should withdraw the Final OTM Rule in its entirety and initiate a rulemaking to determine if Canada's feed ban is likely to become effectively enforced after July 2007.

VII. APHIS' REFUSAL TO IMPOSE REASONABLE IMPORT RESTRICTIONS ON CANADIAN CATTLE AND BEEF THAT ARE DEEMED EFFECTIVE BY U.S. EXPORT MARKETS HAS INFLICTED BILLIONS OF DOLLARS IN DAMAGES TO THE U.S. CATTLE INDUSTRY AND HAS INCREASED THE RISK OF INFECTING U.S. CATTLE

A. The U.S. International Trade Commission has Determined that U.S. Export Markets Require Stricter Standards than the Standards the U.S. Applies to Cattle and Beef Imports from Canada.

The U.S. International Trade Commission (USITC) recently completed a study indicating that due to BSE restrictions imposed on U.S. exports during the 3-year period 2004-2007, the U.S. has lost \$5.7 billion in beef sales to Japan, \$3.7 billion in beef sales to Korea, and \$1.5 billion in beef sales to the rest of the world, for a total loss in U.S. beef sales of \$11 billion.⁷⁶

⁷⁴ BSE (Bovine Spongiform Encephalopathy, or Mad Cow Disease), Centers for Disease Control and Prevention, available at <http://www.cdc.gov/ncidod/dvrd/bse/>, attached hereto as Exhibit 10.

⁷⁵ Report on the Investigation of the Thirteenth Case of Bovine Spongiform Encephalopathy (BSE) in Canada, Canadian Food Inspection Agency, attached hereto as Exhibit X.

⁷⁶ See Global Beef Trade: Effects of Animal Health, Sanitary, Food Safety, and Other Measures on U.S. Exports, U.S. International Trade Commission, USITC Publication No. 4033, September 2008, at xvii, attached hereto as Exhibit 18.

The USITC stated that Japan and Korea impose BSE restrictions on U.S. beef that are more stringent than the OIE guidelines,⁷⁷ which are the standards the U.S. applies to imports of Canadian cattle and beef.

It is counterintuitive to assume that important export customers are not fully aware that the U.S. is accepting a greater risk of BSE introduction from the importation of cattle and beef from Canada than they are willing to accept in their respective countries. It is further evident by their ongoing restrictions on U.S. beef exports that they view OIE standards to be inadequate to protect their consumers from exposure to BSE. APHIS' refusal to impose stricter standards on Canadian cattle and beef imports continues to result in the global erosion of confidence in beef originating in the United States, a country that applies lax mitigation measures inadequate to prevent the introduction of BSE from a country known to be experiencing a continuing outbreak – Canada; and, this refusal continues to cost the U.S. cattle industry billions of dollars.

B. APHIS' Economic Analysis for the Final OTM Rule Greatly Underestimated the Number of OTM Cattle that would Enter the U.S. in 2008, Effecting Both Financial Loss Estimates and Risk Estimates.

In its Final OTM Rule, APHIS predicted that U.S. cattle producers would suffer revenue losses of over \$66,000,000 per year. *See* 72 Fed. Reg., 53356, col. 1. This loss estimate was predicated, *inter alia*, on APHIS' prediction that OTM cull cattle imports in 2008 would number only 75,000 head. *See* 72 Fed. Reg., 53333, col. 1. However, USDA data show that by November 8, 2008, the U.S. already imported more than twice that number of OTM cull cattle, approximately 167,224 slaughter cows and bulls (OTM cattle), from Canada in 2008.⁷⁸ Thus, APHIS' loss estimate contained in its Final OTM Rule is greatly understated and U.S. cattle producers continue to suffer increased financial losses as a result of the increased supply of higher-risk OTM cattle from Canada.

In addition, the potential exposure of U.S. cattle to BSE infectivity is directly proportional to the number of OTM cattle that are imported, and APHIS has explained that “projected imports are a key component of the likelihood of BSE infectivity.”⁷⁹ Thus, APHIS' prediction that the Final OTM Rule would cause the introduction of between 19 to 105 BSE-infected cattle into the United States, which would, in turn, produce BSE infections in 2 to 75 U.S.-born cattle, lasting over a 20-year period (*see* 72 Fed. Reg., 1109, col. 2; 72 Fed. Reg., 53347, col. 1) understates the actual level of BSE-infectivity that has likely entered the U.S. in 2008 as a result of already importing more than twice the number of OTM cattle than APHIS predicted.

⁷⁷ *See* Global Beef Trade: Effects of Animal Health, Sanitary, Food Safety, and Other Measures on U.S. Exports, U.S. International Trade Commission, USITC Publication No. 4033, September 2008, at xvii, attached hereto as Exhibit 18.

⁷⁸ *See* Canadian Live Animal Imports by State of Entry, Data for week ending 11/08/08, USDA Market News, attached hereto as Exhibit 23.

⁷⁹ Revised Assessment of Bovine Spongiform Encephalopathy (BSE) Risks Associated with the Importation of Certain Commodities from BSE Minimal Risk Regions (Canada), U.S. Department of Agriculture, Animal and Plant Health Inspection Service, September 2007, at 16.

VIII. THE ENTIRE FINAL OTM RULE APPLIES AN IMPROPER LEGAL STANDARD AND VIOLATES CONGRESS'S MANDATE TO PREVENT THE INTRODUCTION OF FOREIGN ANIMAL DISEASES INTO THE UNITED STATES

As stated in the introduction to these comments, APHIS acknowledged in its 2008 Notice that its mandate is “to prevent the introduction of various animal diseases,” including BSE. 73 Fed. Reg. 54084, col. 2. Despite this, APHIS inappropriately justifies its Final OTM Rule on an entirely different standard – which is not a standard of preventing introduction, but rather, a standard of preventing disease establishment *after* the disease is knowingly introduced. APHIS expressly stated that its risk assessment “assumed that infected animals could be imported into the United States under the provisions of the proposed rule [proposed OTM Rule],” but, it stated that “our [APHIS’] conclusion that the risk of the exposure of U.S. cattle and the establishment of BSE in the United States was negligible.” 73 Fed. Reg., 54087, col. 3. This new standard is improper and, therefore, the entire Final OTM Rule is in violation of the agency’s congressional mandate.

APHIS recognizes that “incidents of cross-contamination can, and most likely will, happen....” 72 Fed. Reg., 53329 col. 3. Indeed, this is consistent with the conclusions of the OIE, the Canadian Food Inspection Agency (“CFIA”), and USDA’s own “International Review Team” that the only way to prevent exposure of cattle to potentially BSE-contaminated feed is to eliminate the use of meat and bone meal from cattle in any type of animal feed.⁸⁰ As a result, APHIS acknowledges the likelihood that U.S. cattle will have BSE as a result of allowing imports of OTM cattle; in fact, its worst case estimate is that the Final OTM Rule will cause 75 new cases of BSE in U.S.-born cattle over the next 20 years. 72 Fed. Reg., 53347 col.1.

In short, the Final OTM Rule is expected, even by APHIS, to result in the importation of numerous BSE-infected cattle from Canada (and infected with a strain of BSE similar to that found in the UK, unlike the two pre-feed-ban cases found in the U.S.), i.e., the “introduction” of that form of BSE into the United States. And it is likely, even in APHIS’ view, that the Final OTM Rule will result in the spread of BSE infection from those Canadian cattle, i.e., the “dissemination” of BSE within the United States. USDA concludes, however, that these outcomes are acceptable because it deems them “negligible” and because it predicts that these BSE cases that the United States will knowingly suffer as a result of the Final OTM Rule will not result in the “establishment” of BSE in the United States, meaning that BSE will not be “perpetuated in the population without the need for reintroduction from an external source,” which will lead to “eventual eradication.”⁸¹ Thus, USDA is set to allow, through the OTM Rule, imports that it believes will produce BSE infections in 2 to 75 U.S.-born cattle, lasting over a 20-year period. 72 Fed. Reg. at 1109 col. 2; 72 Fed. Reg. at 53,347 col. 1.

⁸⁰ See, e.g., Report of the Meeting of the OIE Scientific Commission for Animal Diseases, at 21, 22, attached hereto as Exhibit 24 (The 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.”)

⁸¹ 72 Fed. Reg. at 53,318 cols. 1-2. USDA asserts that BSE has not been “established” in Canada, despite the discovery of the then 11 cases of BSE since 2003 and the prediction that BSE will not be eradicated in Canada for 20 more years (without new upgrades to feed ban, eradication would take decades).

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 take the steps necessary to detect, control, and eradicate animal disease, USDA acted outside of its statutory authority. 70 Fed. Reg., 513 (evaluating import controls in 2005 Minimal-Risk Region rule based on whether Canadian imports “would spread the disease to other animals within the United States, in other words, whether the imported source of infectivity would generate new cases within the United States”).

R-CALF USA respectfully implores APHIS to honor, respect, and carry out its congressional mandate to prevent the introduction into or dissemination within the United States of BSE-infected cattle and beef from BSE-infected cattle that originate in Canada.

IX. CONCLUSION

R-CALF USA appreciates this opportunity to comment on this important matter. For the reasons set forth above, APHIS should immediately withdraw its Final OTM Rule.

Sincerely,

A handwritten signature in cursive script that reads "R. M. Thornsberry D.V.M." with a stylized flourish at the end.

R.M. Thornsberry, D.V.M.
President, R-CALF USA Board of Directors

Attachments: Exhibits 1-24