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Docket No. APHIS 2006-0041  
Regulatory Analysis and Development, PPD  
APHIS, Station 3A-03.8  
4700 River Road Unit 118  
Riverdale, MD 20737-1238

Via Hand-Delivery, Overnight Mail, and Facsimile: 301-734-8934

**Re: Supplemental Comments by R-CALF USA in Docket No. APHIS-2006-0041:  
Bovine Spongiform Encephalopathy; Minimal-Risk Regions; Importation of Live  
Bovines and Products Derived From Bovines; Proposed Rule**

Dear Administrator:

R-CALF USA submits these supplemental comments to ensure that the U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS), has reviewed critical information before issuing a final rule to amend regulations regarding the importation of live bovines over 30 months (OTM) of age and products derived from bovines from Canada (Proposed Rule).

R-CALF USA previously submitted comments to APHIS on this Proposed Rule on March 12, 2007. In its initial comments, R-CALF USA urged APHIS to withdraw its Proposed Rule because compelling scientific evidence demonstrates that it would expose the U.S. cattle herd and U.S. consumers to a substantially greater and unacceptable risk that bovine spongiform encephalopathy (BSE) would be introduced into and spread within the United States.

During the approximate five months since the end of the comment period for the Proposed Rule, numerous and significant scientific and other developments have reinforced the already compelling need for APHIS to withdraw the Proposed Rule. Therefore, R-CALF USA requests that APHIS consider the following new developments related to BSE:

1. The Centers for Disease Control (CDC) has quantified that the proportion of Canadian-origin cattle detected with BSE is 26-fold higher than the proportion of U.S.-origin cattle detected with BSE, based on available testing data.<sup>1</sup>
2. The World Organization for Animal Health (OIE) has published a report in which the risk profiles of both Canada and the United States were evaluated. Contained in this

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<sup>1</sup> BSE (Bovine Spongiform Encephalopathy or Mad Cow Disease), Centers for Disease Control and Prevention, United States Department of Health and Human Services, available at <http://www.cdc.gov/ncidod/dvrd/bse/index.htm>, hereafter "CDC Report," attached hereto as Attachment A.

- report is a finding that improvements are needed to strengthen both the U.S. and Canadian feed bans to adequately prevent the spread of BSE. In addition, the report recommends that the U.S. prohibit specified risk materials (SRMs) in all animal feed.<sup>2</sup>
3. The Canadian Food Inspection Agency (CFIA) issued its report on the epidemiological investigation of the 79-month old Canadian bull detected with BSE on Feb. 7, 2007. This report indicates that numerous herd cohorts and feed cohorts of the infected bull could not be traced and that at least one herd and/or feed cohort was exported from Canada.<sup>3</sup>
  4. A U.S. news article was published that indicates USDA had acknowledged that at least one of the herd cohorts of the Canadian bull detected with BSE on Feb. 7, 2007, was known to have been exported to the U.S. where it was slaughtered and presumably introduced into the U.S. food supply.<sup>4</sup>
  5. The CFIA issued its report on the epidemiological investigation of the 66-month old Canadian cow detected with BSE on May 2, 2007. This report indicates that the source of contamination could not be definitively identified and that some herd cohorts and feed cohorts of the BSE-infected cow could not be traced. Further, the report implies that the CFIA failed to test several herd cohorts and feed cohorts before disposing of the animals and that CFIA intends to dispose of other animals without testing them for BSE.<sup>5</sup>
  6. The total number of probable and confirmed cases of Variant Creutzfeldt-Jakob disease (vCJD) in humans worldwide has risen from approximately 150 cases in 2005 to approximately 214 cases as of July 2007.<sup>6</sup>
  7. Despite USDA's insistence that beef from Minimal Risk Regions is safe, the CDC continues to advise that travelers may wish to avoid burgers from countries with BSE to avoid the risk of vCJD.<sup>7</sup>
  8. CFIA officials have been quoted by Canadian media as confirming the concern raised by R-CALF USA in its March 12, 2007, comments that Canadian meatpackers will have

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<sup>2</sup> Report of the Meeting of the OIE Scientific Commission for Animal Diseases, International Committee, World Organization for Animal Health (OIE), Paris, France, February 26-28, 2007, hereafter "OIE Report," attached hereto as Attachment B.

<sup>3</sup> Report on the Investigation of the Ninth Case of Bovine Spongiform Encephalopathy (BSE) in Canada, Canadian Food Inspection Agency, available at <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2007/9investe.shtml>, attached hereto as Attachment C.

<sup>4</sup> Canada Traces BSE Cohorts; 1 Animal Exported to U.S. Investigation Studied Alberta Ranch Herd, Feed Sources, Peggy Steward, Capital Press Staff Writer, Capital Press, April 6, 2007, attached hereto as Attachment D.

<sup>5</sup> Report on the Investigation of the Tenth Case of Bovine Spongiform Encephalopathy (BSE) in Canada, Canadian Food Inspection Agency, available at <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/bccb2007/10investe.shtml>, attached hereto as Attachment E.

<sup>6</sup> Variant Creutzfeldt-Jakob Disease, Current Data (July 2007), European and Allied Countries Study Group of CJD, The National Creutzfeldt-Jakob Disease Surveillance Unit, available at <http://www.cjd.ed.ac.uk/index.htm>, attached hereto as Attachment F.

<sup>7</sup> vCJD (Variant Creutzfeldt-Jakob Disease), Risk for Travelers, Centers for Disease Control and Prevention, United States Department of Health and Human Services, 2007, available at [http://www.cdc.gov/ncidod/dvrd/vcid/risk\\_travelers.htm](http://www.cdc.gov/ncidod/dvrd/vcid/risk_travelers.htm), attached hereto as Attachment G.

an incentive to dump their SRMs in the United States if the Proposed Rule is promulgated.<sup>8</sup>

R-CALF USA requests that APHIS carefully consider all of these recent developments before amending its regulations to allow the importation of OTM cattle, and products derived from Canadian cattle, into the United States. R-CALF USA reiterates its initial request that the Proposed Rule be withdrawn.

## **I. THE PROPOSED RULE MAKES CLAIMS THAT ARE REFUTED BY NEW DATA**

### **A. The Proposed Rule Claims that Data Demonstrate that Canada's BSE Prevalence Rate is Low and Not Dissimilar to the U.S. and that Canada's BSE Epidemic was Controlled and Has Declined – Claims Refuted by an Analysis by the U.S. Centers for Disease Control.**

The Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services (CDC) recently distributed a publication that describes the discovery of an additional case of BSE in Canada, confirmed on May 2, 2007, in a cow born about four years after the 1997 Canadian ban on the feeding of bovine protein to bovines. It notes that six of the 11 BSE cases in Canadian-born cattle were known to have been born after the implementation of the 1997 Canadian feed ban, with five of the six born more than 18 months afterward.<sup>9</sup>

The publication provides CDC's statistical analysis of BSE testing data for Canada and the United States, concluding that: "The proportion of Canadian-born BSE cases identified by Canadian authorities through the testing of animals in Canada, 2003-April 2007 (10 cases among 160,000 animals tested) is presently significantly higher (26 fold higher) than the proportion of U.S.-born BSE cases identified by U.S. authorities through the testing of animals in the U.S. during the comparable period (2 cases among more than 875,000 animals tested)."<sup>10</sup>

The CDC statistical analysis also concludes that the proportion of known BSE cases in U.S.-born cattle that were at least 10 years of age (100%) is statistically significantly different from the proportion of the 11 Canadian-born BSE cases known to be at least 10 years of age (one animal, or 9%).<sup>11</sup>

This analysis of BSE testing data, performed by a federal agency with responsibility for health protection is relevant to, *inter alia*, the statement in the Proposed Rule that it is "unlikely that feeds containing prohibited material were available for more than a few months after practical implementation of the feed ban;"<sup>12</sup> the statement in the Proposed Rule that it is unlikely that there is no decline in the Canadian BSE prevalence rate and that it is highly unlikely that BSE would become established in the U.S. due to implementation of the Proposed Rule;<sup>13</sup> and, the

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<sup>8</sup> Regulatory 'Loophole' Could Drive Cattle Herds to U.S. for Slaughter, Margaret Munro, CanWest News Service, July 11, 2007, attached hereto as Attachment H.

<sup>9</sup> See CDC Report, attached hereto as Attachment A.

<sup>10</sup> *Ibid.*

<sup>11</sup> *Ibid.*

<sup>12</sup> 72 Federal Register, at 1107.

<sup>13</sup> See *Id.*, at 1109.

statement in the Proposed Rule that the “Canadian feed ban was fully implemented and effectively enforced as of March 1, 1999.”<sup>14</sup>

In addition, the CDC analysis contradicts statements in the 2005 Minimal Risk Region Rule – statements upon which the Proposed Rule continues to rely – and APHIS has not explained why the facts belying its previous statements justify a further relaxation of U.S. import restrictions as contemplated in the Proposed Rule. For example, APHIS erroneously concluded:

We disagree that the possible presence of additional animals in Canada, infected before implementation of the Canadian feed ban, present risks that have not been addressed for this rulemaking. As stated in responses to several other comments, it is possible that cattle born *before* Canada initiated its feed ban in August of 1997 may still exist in Canada.<sup>15</sup> (Emphasis added.)

And, “. . . measures currently in place in Canada . . . make it unlikely that new cases are developing;”<sup>16</sup> and, “. . . animals born after the feed ban was implemented are unlikely to have been exposed to the infectious agent.”<sup>17</sup>

Moreover, the CDC analysis concluding that Canada’s proportion of BSE cases is 26-fold higher than that of the U.S. contradicts the APHIS estimate that Canada’s BSE prevalence rate is only 6.8 times greater than that of the United States.<sup>18</sup>

The CFIA’s completed investigation of the cow confirmed with BSE on May 2, 2007, reveals that contaminated feed was the likely source of infection,<sup>19</sup> indicating that BSE-infected cattle entered the Canadian feed system undetected by CFIA. In at least one previous investigation, the CFIA acknowledged that the “undetected first generation indigenous BSE cluster contained a minimum of two animals.”<sup>20</sup> The BSE prevalence rate calculated by APHIS and expressed in the Proposed Rule was predicated on detected cases of BSE known at the time, but not on the undetected cases that must have entered the Canadian feed system, such as the two already acknowledged by CFIA. APHIS must revise its prevalence rate estimate by incorporating the two confirmed BSE cases detected after the Proposed Rule was published and the estimated number of undetected BSE cases that must have entered and subsequently contaminated the Canadian feed system.

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<sup>14</sup> See 72 Federal Register, at 1107.

<sup>15</sup> 70 Federal Register, at 516; See also *id.* at 468, 473, 476, 485, 486, 511, and 513.

<sup>16</sup> 70 Federal Register, at 528.

<sup>17</sup> *Id.*, at 485.

<sup>18</sup> See 72 Federal Register, at 1108, (APHIS estimates that the prevalence of BSE in Canada is only 6.8 animals per every 10 million adult cattle and the prevalence of BSE in the U.S. is 1 animal per 10 million adult cattle.).

<sup>19</sup> See Report on the Investigation of the Tenth Case of Bovine Spongiform Encephalopathy (BSE) in Canada, Canadian Food Inspection Agency, available at <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/bccb2007/10investe.shtml>, attached hereto as Attachment E.

<sup>20</sup> Report on the Investigation of the Fifth Case of Bovine Spongiform Encephalopathy (BSE) in Canada, Canadian Food Inspection Agency, available at <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/comenqe.shtml>, attached hereto as Attachment I.

Before APHIS proceeds with the Proposed Rule, it should recognize the inconsistencies between its estimates and statements and the facts as they are now known, as presented in the CDC analysis. Given that these facts are substantially different from those that APHIS relied on in promulgating the 2005 Minimal Risk Region Rule, APHIS must modify the analysis it relied on in that rulemaking and explain why the modified analysis, reflecting currently known facts, shows that a ban on import of Canadian OTM cattle is no longer necessary to prevent the introduction into and dissemination in the United States of BSE from Canada.

**B. Contrary to APHIS' Claims that the U.S. and Canadian Feed Bans are Sufficient, the OIE has Found Both the U.S. and Canadian Feed Bans Lacking in Their Ability to Prevent the Spread of BSE.**

The World Organization for Animal Health (OIE) recently released a publication that contains an analysis by the "OIE *Ad Hoc* Group for Evaluation of Country Status for Bovine Spongiform Encephalopathy in Accordance with the Terrestrial Animal Health Code" (the OIE Report). This analysis found that, with respect to Canada, "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."<sup>21</sup> The report discusses Canada's recent decision that it needed to upgrade its feed ban:

Despite some reasonable gains in compliance rates with the feed ban there is still room for improvement. Although increased inspections will assist in raising the level of compliance further, as long as potentially infective material continues to be rendered and enter the animal feed chain there remains the potential for cross contamination.<sup>22</sup>

The likelihood of such events can be eliminated by excluding specified risk material from the animal feed chain. From July 2007, all specified risk material will be banned from animal feed, pet food and fertilizer.<sup>23</sup>

The OIE report describing the inability of Canada's "partial implemented" feed ban since 1997 to prevent the recycling and amplification of BSE in Canada belies APHIS' long-held contention that Canada's feed ban was sufficient to prevent the spread of BSE, beginning with the 2005 Minimal-Risk Region Rule (Final Rule) and continuing through the Proposed Rule. For example, APHIS, without foundation, stated in the 2005 Final Rule that Canada already had an effective feed ban in place in the rendering, feed manufacturing, and livestock raising industries.<sup>24</sup> In the Proposed Rule, APHIS stated that Canada's feed ban was fully implemented and effectively enforced as of March 1, 1999;<sup>25</sup> and, that APHIS had made the determination that the Canadian feed ban had demonstrated its effectiveness in reducing the likelihood of BSE transmission.<sup>26</sup>

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<sup>21</sup> OIE Report, at 21.

<sup>22</sup> *Id.* at 22.

<sup>23</sup> *Ibid.*

<sup>24</sup> See 70 Federal Register, at 467.

<sup>25</sup> See 72 Federal Register, at 1107.

<sup>26</sup> See *id.*, at 1108.

Importantly, the Proposed Rule uses the date that APHIS believes Canada had begun the effective enforcement of its feed ban as the governing factor for determining the safety of importing Canadian cattle into the United States.<sup>27</sup> However, the OIE Report has now addressed the question of whether a “partial implemented” feed ban, as was implemented in Canada until July 12, 2007, could be considered effective. With respect to Switzerland, which, like Canada, had initially implemented only a partial feed ban, the OIE noted that the Switzerland feed ban achieved “effectiveness” *after* it was extended to include a ban on the feeding of ruminant protein to all farm animals.<sup>28</sup>

With respect to the United States, the OIE report notes that: “the absence of a feed ban before 1997, the partial implemented feed ban since 1997 (potential cross-contamination, limited number of samples taken to control the implementation of the feed ban), 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.”<sup>29</sup> The OIE recommends that the U.S. exclude SRMs from all animal feed to eliminate the “likelihood” of cross-contamination:

Despite some reasonable gains in compliance rates of the feed ban, there is still room for improvement. Although the increased inspections will assist in raising the level of compliance further, as long as potentially infective material continues to be rendered and enter the animal feed chain, the potential for cross-contamination is still present. The likelihood of such events can be eliminated by excluding specified risk material from the animal feed chain.<sup>30</sup>

It is recommended that the United States carefully consider excluding specified risk material from use in animal feed.<sup>31</sup>

Because, as APHIS readily acknowledged in its 2005 Final Rule, “The Canadian feed ban is essentially the same as the feed ban in place in the United States,”<sup>32</sup> the deficiencies identified by the OIE Report demonstrate that neither the U.S. nor the Canadian feed ban were adequate to safeguard against a leading probable cause of BSE infectivity detected in Canadian cattle. According to the investigative reports completed for each of the 10 BSE cases detected in Canadian-born cattle (the Canadian-born cow detected in Washington State is not included in this number), the CFIA implicated some form of cross-contamination as a possible source, if not the most likely source of infectivity in half of all BSE cases detected in Canada, making cross-contamination a leading probable cause of BSE infectivity in Canadian cattle.<sup>33</sup>

The OIE Report contradicts APHIS’ assumption that the U.S. and Canadian feed bans, as implemented in 1997, comport with OIE guidelines, particularly APHIS’ erroneous assumption

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<sup>27</sup> See 72 Federal Register, at 1110.

<sup>28</sup> OIE Report, at 32.

<sup>29</sup> *Id.*, at 27.

<sup>30</sup> *Id.*, at 28.

<sup>31</sup> *Ibid.*

<sup>32</sup> 70 Federal Register, at 476.

<sup>33</sup> See Summary Reports 1-10, Completed Investigations, Canadian Food Inspection Agency, available at <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/comenqe.shtml>.

that the Canadian and U.S. feed bans are “consistent” with OIE recommendations.<sup>34</sup> It also contradicts APHIS’ assumption that the likelihood that Canadian cattle born after February 1998 would be exposed to the BSE agent continues to decrease over time and that a period of one year following the practical implementation of the feed ban is sufficient to allow measures taken by Canada to have their desired effect.<sup>35</sup> And, it contradicts APHIS’ statement that Canadian cattle born on or after March 1, 1999, or any date prior to July 12, 2007, for that matter, would be unlikely to have been exposed to the BSE agent via feed.<sup>36</sup>

Before proceeding with the Proposed Rule, APHIS should accept and incorporate the scientific recommendation of the OIE, which has clarified that a feed ban must include a ban on the feeding of SRMs to all animals before it can be considered effective at preventing the recycling and amplification of BSE.<sup>37</sup>

**C. Contrary to APHIS’ Claim that the Risk of Introducing BSE-Infected Cattle from Canada is Low and that it is Adhering to OIE Guidelines, the U.S. has Already Imported High-Risk Cohorts of Infected Canadian Cattle, and Canada has Not Met OIE Export Requirements for Countries with a Controlled BSE Risk.**

APHIS claims that the Proposed Rule is consistent with OIE guidelines, which recommend that cattle imported from a BSE-affected country be born after the date of an effectively enforced feed ban.<sup>38</sup> As discussed above, Canada did not have an effective feed ban, and therefore its feed ban could not have been “effectively enforced” until very recently – until July 12, 2007, when it began the upgrade of its “partial implemented” feed ban. Notwithstanding this fundamental insufficiency, the Proposed Rule also fails to meet other minimal guidelines recommended by the OIE for trade in live cattle. For example, the OIE recommends that cattle for importation from a BSE-affected country not include cattle reared with a BSE case during its first year of life, cattle that consumed the same feed as the BSE case, and cattle born in the same herd as, and within 12 months of the birth of, the BSE case, and that all of these cattle, commonly referred to as herd cohorts and feed cohorts, are identified, monitored, and completely destroyed.<sup>39</sup>

Based on the investigation reports completed by CFIA for each of the 10 BSE cases for which reports were completed, the CFIA was unable to identify, monitor, or destroy 118 herd cohorts and feed cohorts of known BSE cases. In addition, the CFIA investigation reports reveal that 22 herd cohorts and feed cohorts were known to have been exported to the United States.<sup>40</sup>

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<sup>34</sup> See 72 Federal Register, at 1105, 1109, and 1123.

<sup>35</sup> See 72 Federal Register, at 1123.

<sup>36</sup> See *Ibid.*

<sup>37</sup> See 2006 OIE Terrestrial Animal Health Code, Chapter 2.3.13.13 (1), (2), and (3), (The OIE guidelines make clear that specified risk materials must be banned from use in animal feed and fertilizer, though APHIS has continually ignored this recommendation.), attached hereto as Attachment J.

<sup>38</sup> See 72 Federal Register, at 1105 and 1109.

<sup>39</sup> See 2006 OIE Terrestrial Animal Health Code, Article 2.3.13.4(3)(b)(iii), attached hereto as Attachment J.

<sup>40</sup> See Summary Reports 1-10, Completed Investigations, Canadian Food Inspection Agency, available at <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/comenqe.shtml> (Reports for the Ninth, Tenth and Fifth Investigations are attached hereto as Attachments C, E, and I, respectively. Note that Attachment I reveals that 15 cohorts were exported to the U.S and 33 were untraceable; Attachment E reveals that 23 cohorts were untraceable; and Attachment C reveals that 42 cohorts were untraceable).



A news article published on April 6, 2007, dismissed the significance of the herd cohorts and feed cohorts exported to the U.S. using the pretense that “scientific data shows it is rare to find another infected animal in the same herd as a BSE-positive animal.”<sup>41</sup> This false assertion was attributed to USDA spokeswoman Andrea McNally. In direct contradiction to this false assertion is the scientific data compiled by the United Kingdom (UK) that belies the erroneous notion that multiple BSE cases in the same herd are “rare,” providing ample justification for the OIE’s science-based recommendation regarding the need to identify, monitor, and completely destroy all herd cohorts and feed cohorts. The UK found that only 35 percent of BSE-infected herds had only one case of BSE, while 49 percent of the BSE-infected herds had three or more BSE cases, with one herd having 124 confirmed BSE cases.<sup>42</sup>

Thus, as confirmed by scientific data, and as recognized and incorporated in OIE guidelines, herd cohorts and birth cohorts of BSE-infected cattle are cattle considered high-risk for harboring BSE infectivity. Canada has demonstrated its inability to identify, monitor, and safely destroy herd cohorts and feed cohorts and to keep them from export to the United States. The Proposed Rule fails completely to explain why APHIS believes that the risk of importing additional Canadian cattle, particularly Canadian cattle over 30 months of age, is acceptable, given that those cattle are likely to include herd and feed cohorts of BSE-infected Canadian cattle. In response to the higher risk associated with herd cohorts and feed cohorts of BSE-infected cattle, R-CALF USA has requested that USDA notify Canada that it is not in compliance with U.S. regulations and that it must begin testing such cohorts for BSE in order to maintain its status as a “minimal risk” region under the regulations.<sup>43</sup>

**D. Contrary to APHIS’ Claim that the Incidence of BSE Worldwide Continues to Decline Because of Applied Mitigation Measures, Data Show that the Incidence of BSE has Increased in Canada and the Incidence of vCJD has Increased Worldwide.**

APHIS claims that the incidence of BSE worldwide continues to decline because of the implementation of feed bans.<sup>44</sup> However, APHIS fails completely to explain why the incidence of BSE continues to increase in Canada when the Canadian feed ban is described as “effective”<sup>45</sup> and compliance with the Canadian feed ban was reported as “good.”<sup>46</sup> At the time of publication of the Proposed Rule, Canada had reported nine indigenous cases of BSE, four of which were born long after the implementation of Canada’s feed ban.<sup>47</sup> Since publication of the Proposed Rule, Canada has reported two more indigenous cases of BSE, both of which were born years after the Canadian feed ban.<sup>48</sup>

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<sup>41</sup> See Canada Traces BSE Cohorts; 1 Animal Exported to U.S. Investigation Studied Alberta Ranch Herd, Feed Sources, Peggy Steward, Capital Press Staff Writer, Capital Press, April 6, 2007, attached hereto as Attachment D.

<sup>42</sup> See BSE: Statistics – Distribution of Farms by Number of Confirmed Cases (Excluding Dealers and Survey Cases) as of 2 July, 2007, available at <http://www.defra.gov.uk/animalh/bse/statistics/bse/con-cases.htm>, attached hereto as Attachment K.

<sup>43</sup> R-CALF USA letter to USDA Secretary Johanns, July 26, 2007, attached hereto as Attachment L.

<sup>44</sup> See 72 Federal Register, at 1105.

<sup>45</sup> See *id.*, at 1109.

<sup>46</sup> See *id.*, at 1106.

<sup>47</sup> See 72 Federal Register, at 1108.

<sup>48</sup> See Report on the Investigation of the Ninth Case of Bovine Spongiform Encephalopathy (BSE) in Canada, Canadian Food Inspection Agency, available at <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2007/9investe.shtml>, attached hereto as



Prior to the detection of the two recent cases, APHIS asserted that the previous cases represent only “isolated incidents” and are “not epidemiologically significant” and they “do not contribute to further spread of BSE.”<sup>49</sup> However, APHIS completely fails to adequately explain why the increased number of BSE cases born after the Canadian feed ban, numbering four at the time of publication of the Proposed Rule, and increasing to six just a couple of months later, can be considered “isolated incidents,” why they are “not epidemiologically significant,” and why these cases “do not contribute to further spread of BSE.” If, indeed, the prevalence of BSE is declining “from its present minimal level” as APHIS claims<sup>50</sup> – in the face of empirical evidence to the contrary – then what was the level of BSE in Canada prior to the rising number of BSE cases that justify APHIS’ conclusion that the BSE incidence in Canada is declining? APHIS’ statement that BSE is declining defies any semblance of logic and is in direct contradiction of known facts.

While BSE outbreaks have declined in some countries, other countries, including Canada, have experienced an upward trend in recent years. According to the latest available report on the monitoring and testing of ruminants for BSE in Europe (2005) the Czech Republic, Austria, Poland, and Japan each experienced an increase in the number of BSE cases from 2003 through 2005.<sup>51</sup> Because the Proposed Rule involves trade with Canada, and not with the aggregated universe of BSE-affected countries, APHIS must fully explain why Canada, in particular, is not experiencing a downward trend in BSE cases while other countries appear to be experiencing a decline.

Such an explanation is particularly necessary given that the Proposed Rule did not take into consideration the impact that Canada’s July 12, 2007, feed ban amendment would have on the evolution of Canada’s BSE problem. APHIS stated that the July 12, 2007, amendment to ban SRM’s from all animal feeds, pet food, and fertilizer is “not included in this discussion.”<sup>52</sup> Yet, while APHIS insists that Canada’s BSE prevalence rate would continue to decline over the next 20 years,<sup>53</sup> even without the amendment, the CFIA states that “Based on risk analysis, BSE eradication, which is estimated to have taken *several decades* with the current feed ban, should now be achieved in approximately ten years.”<sup>54</sup> (Emphasis added.) Thus, the CFIA expects its BSE problem to persist until around year 2017, under the best of circumstances.<sup>55</sup>

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Attachment C; *see also* Report on the Investigation of the Tenth Case of Bovine Spongiform Encephalopathy (BSE) in Canada, Canadian Food Inspection Agency, available at <http://www.inspection.gc.ca/english/anima/heasan/diseas/bseeb/bccb2007/10investe.shtml>, attached hereto as Attachment E.

<sup>49</sup> See 72 Federal Register at 1108.

<sup>50</sup> See *Ibid.*

<sup>51</sup> See Table B4: Evolution of Positive Cases World-Wide since BSE was Recognised, Report on the Monitoring and Testing of Ruminants for the Presence of Transmissible Spongiform Encephalopathy (TSE) in the EU in 2005, at 15, attached hereto as Attachment M.

<sup>52</sup> 72 Federal Register, at 1107.

<sup>53</sup> See *id.*, at 1108.

<sup>54</sup> Feed Ban Enhancement Questions and Answers, Canadian Food Inspection Agency, available at <http://www.inspection.gc.ca/english/anima/feebet/rumin/enhqueste.shtml>, attached hereto as Attachment N.

<sup>55</sup> See CDC Report attached hereto as Attachment A.

The CFIA's assertion that its BSE problem would persist for *several* decades without an enhanced feed ban completely undercuts APHIS' assertion that any BSE infectivity introduced into the U.S., which has only a "partial implemented" feed ban, would be eradicated in "substantially less than 20 years."<sup>56</sup> In addition, this CFIA assertion undercuts Canada's classification as a "Minimal-Risk Region" under the Final Rule. The Final Rule requires that a "Minimal-Risk Region" have in place mitigation measures to prevent the "establishment" of the disease,<sup>57</sup> and APHIS defined "establishment" as "continued occurrence after 20 years."<sup>58</sup> Based on CFIA's projection that its BSE problem would not be eradicated for *several* decades without an amended feed ban, Canada did not have adequate mitigation measures in place and should not have been classified as a "Minimal-Risk Region" beginning in 2005.

Moreover, while the Proposed Rule states that "variant Creutzfeldt-Jacob Disease (vCJD), a chronic and fatal neurodegenerative disease of humans, has been linked via scientific and epidemiological studies to exposure to the BSE agent,"<sup>59</sup> the Proposed Rule fails completely to address the fact that in 2005, when APHIS published its Final Rule, APHIS stated that there were approximately 150 probable and confirmed cases of vCJD reported and today the number of probable and confirmed cases of vCJD worldwide has increased to approximately 214.<sup>60</sup> Before APHIS proceeds with its Proposed Rule, it should explain why the increase in vCJD cases worldwide provides justification for the Proposed Rule that would increase the risk of BSE introduction via the importation of older, higher-risk cattle from Canada into the United States.

**E. Notwithstanding APHIS' Claims that the Risk of Introducing BSE from Canada is Negligible, the CDC Advises that U.S. Citizens May Wish to Avoid Burgers from Countries like Canada with Ongoing Cases of BSE, and Yet, APHIS Provides U.S. Citizens with No Means to Identify Burgers from Canada or from Canadian Cattle, Let Alone to Avoid Them.**

APHIS asserts that the risk associated with the importation of Canadian cattle, and by extension beef and beef products from Canadian cattle, into the U.S. would be negligible.<sup>61</sup> However, in its 2007 travel advisory, the CDC continues to recommend that concerned travelers to Europe or other areas with indigenous cases of BSE (which would include Canada) who want to reduce any risk of acquiring vCJD from food "may consider either avoiding beef and beef products altogether or selecting beef or beef products, such as solid pieces of muscle meat (rather than brains or beef products like burgers or sausage) that might have a reduced opportunity for contamination with tissues that may harbor the BSE agent."<sup>62</sup> The CDC also states that the "current risk of acquiring vCJD from eating beef (muscle meat) and beef products produced from

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<sup>56</sup> 70 Federal Register, at 516; *see also* 506 and 507.

<sup>57</sup> *See id.*, at 463.

<sup>58</sup> *Id.*, at 507.

<sup>59</sup> *See id.*, at 1104.

<sup>60</sup> Variant Creutzfeldt-Jacob Disease, Current Data (July 2007), European and Allied Countries Study Group of CJD, The National Creutzfeldt-Jacob Disease Surveillance Unit, available at <http://www.cjd.ed.ac.uk/index.htm>, attached hereto as Attachment F.

<sup>61</sup> *See* 72 Federal Register, at 1108, 1109, and 1115.

<sup>62</sup> vCJD (Variant Creutzfeldt-Jacob Disease), Risk for Travelers, Centers for Disease Control and Prevention, United States Department of Health and Human Services, 2007, available at [http://www.cdc.gov/ncidod/dvrd/vcid/risk\\_travelers.htm](http://www.cdc.gov/ncidod/dvrd/vcid/risk_travelers.htm), attached hereto as Attachment G.

cattle in countries with at least a possible increased risk of BSE cannot be determined precisely.”<sup>63</sup>

Because the Proposed Rule does not require beef from Canadian cattle or beef products from Canada to be labeled as to its origin, the Proposed Rule fails completely to provide U.S. citizens with the ability to exercise any of the CDC recommendations should they desire to reduce *any* risk of acquiring vCJD associated with the *increased* risk of BSE, even if “negligible,” associated with beef and beef products derived from Canadian cattle. Before APHIS proceeds with the Proposed Rule, it should explain why the Proposed Rule does not include any mechanism to allow U.S. citizens, who may choose to follow the advice of the CDC by avoiding burgers or other beef products produced from Canadian cattle while traveling in Canada, to avoid also burgers or other beef products from Canadian cattle that are produced from Canadian cattle imported into the United States. It is incongruent that APHIS would promulgate regulations that would subject U.S. citizens to risks within the continental U.S. that the CDC advises travelers how to avoid while traveling outside the United States.

#### **F. USDA’s Assessment of the Risks of Importing OTM Canadian Cattle Wrongly Assumes their SRMs Will Be Removed.**

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 among other things 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.<sup>64</sup> 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 fact that Canadian health certificates apparently cannot be relied on to assure that OTM Canadian cattle will be identified as such and will have the full set of SRMs removed at slaughter represents a significant increased risk of Canadian cattle imports that USDA must assess and must communicate to the public prior to acting on the proposed OTM rule.

## **II. NEW EVIDENCE REINFORCES R-CALF USA’S ECONOMIC CONCERNS ARISING FROM CANADA’S IMPLEMENTATION OF ITS FEED BAN UPGRADE**

### **A. A Recent Canadian News Article Substantiates R-CALF USA’s Concern that, with promulgation of the Proposed Rule, Canada Would Have an Incentive to Export Cattle to the U.S. to Avoid Canada’s Stricter BSE Regulations.**

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<sup>63</sup> vCJD (Variant Creutzfeldt-Jakob Disease), Risk for Travelers, Centers for Disease Control and Prevention, United States Department of Health and Human Services, 2007, attached hereto as Attachment G.

<sup>64</sup> See June 12, 2007 letter to Secretary Johanns from Winonah Hauter, Executive Director of Food and Water Watch, attached hereto as Attachment O.

In its initial submission of comments on March 12, 2007, R-CALF USA expressed its concern that the Proposed Rule does not consider the economic implications resulting from the combination of the Proposed Rule and Canada's July 12, 2007, implementation of its upgraded feed ban. R-CALF USA stated that the Proposed Rule "would actually establish a disincentive for slaughtering over thirty-month of age cattle in Canada, and an incentive for exporting many or all of these cattle to the United States."<sup>65</sup>

A July 11, 2007, Canadian news article by CanWest News Service substantiates R-CALF USA's concern. The article states, "Canadian ranchers who want to avoid the cost and hassle of the government's [CFIA's] new rules to stamp out mad cow disease can send their young cattle across the U.S. border."<sup>66</sup> If imports of older Canadian cattle are allowed, there will be even more opportunity for Canadian ranchers to avoid the tighter Canadian restrictions on use of specified risk materials (SRMs) by sending their cattle to the U.S. for slaughter. APHIS should not proceed with the Proposed Rule, at least until it has upwardly harmonized the U.S. feed ban with the new Canadian Feed Ban, otherwise U.S. cattle producers would be economically disadvantaged by an increased flow of Canadian cattle imports driven solely by lax slaughtering standards in the U.S. when compared to Canada. At the very least, APHIS must assess how the new Canadian feed ban rules could result in new incentives for dumping older Canadian cattle in the U.S. market before finalizing the Proposed Rule.

### III. CONCLUSION

The foregoing new developments and information that surfaced after the expiration of the comment period for the Proposed Rule further demonstrate that the Proposed Rule is based on erroneous assumptions regarding the scope and severity of Canada's BSE problem, erroneous assumptions regarding the risks to the U.S. cattle herd and to U.S. consumers from Canadian cattle imports, erroneous assumptions regarding the sufficiency of Canada's feed ban prior to July 12, 2007, to prevent the recycling and amplification of BSE, and erroneous assumptions regarding compliance with OIE recommendations. In addition, the Proposed Rule would provide an incentive for Canada to dump high-risk cattle into the U.S. to avoid Canada's stricter BSE regulations.

R-CALF USA respectfully requests that APHIS immediately withdraw its Proposed Rule.

Sincerely,



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

Attachments: A through O

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<sup>65</sup> R-CALF USA Comments, Docket No. APHIS-2006-0041, March 12, 2007, at 55 and 56.

<sup>66</sup> Regulatory 'Loophole' Could Drive Cattle Herds to U.S. for Slaughter, Margaret Munro, CanWest News Service, July 11, 2007, attached hereto as Attachment H.