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December 9, 2004

Docket No. 03-080-1
Regulatory Analysis and Development
PPD, APHIS, Station 3C71
4700 River Road, Unit 118
Riverdale, MD 20737-1238

Via Hand Delivery

**Re: R-CALF USA's Second Submission of Supplemental Comments for
Docket No. 03-080-1: Bovine Spongiform Encephalopathy; Minimal
Risk Regions and Importation of Commodities**

Dear Administrator DeHaven:

R-CALF USA submits these supplemental comments to ensure that the Animal Plant Health Inspection Service (APHIS) and the United States Department of Agriculture (USDA) have reviewed critical information before issuing a final rule to amend the regulations regarding the importation of live ruminants (particularly cattle) and ruminant (particularly cattle) products to recognize a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States via live ruminants and ruminant products, and now to add only Canada to this category.

R-CALF USA previously submitted comprehensive comments to APHIS on its proposed rule on January 5, 2004 and April 7, 2004. In both of its previous comments, R-CALF USA urged APHIS to withdraw the proposed rule because compelling scientific evidence suggested that the proposed rule will expose U.S. and international consumers plus the U.S. cattle industry to substantially greater and unacceptable risks that BSE will be introduced into the United States. R-CALF USA requested APHIS to continue to enforce the APHIS longstanding policy of prohibiting the importation of ruminants and ruminant products from any country known to have BSE or that presents an undue risk of introducing BSE into the United States. R-CALF USA continues to urge APHIS to enforce its prohibition on imports of ruminants and ruminant products from each of the 37 countries listed at 9 CFR 94.18, which includes Canada and Japan.

During the eight months since the end of the comment period for the proposed APHIS rule, numerous significant scientific developments have reinforced the already compelling need for APHIS to withdraw its proposed rule. Therefore, R-CALF USA respectfully requests that APHIS and USDA consider the following new developments related to BSE:

1. In May 2004, the World Organization for Animal Health (OIE) adopted more stringent BSE mitigation measures.¹
2. In May 2004, the OIE decided not to list the United States as a country free of BSE or provisionally free of BSE.²
3. APHIS's dramatically increased BSE surveillance program has found no native cases of BSE in the United States after testing to date over 153,000 high-risk cattle in 2004.³
4. New scientific research suggests that BSE has just begun to emerge in North America.⁴
5. A growing body of scientific research confirms that BSE prions, as well as prions associated with other transmissible spongiform encephalopathies (TSE) such as scrapie, can be detected in ruminants as well as muscle tissues.⁵
6. A substantial number of scientists and other experts have called for more stringent control measures to prevent the spread of BSE.⁶

¹ OIE Terrestrial Animal Health Code, 12th edition, 2004. For a country with moderate BSE risk, the 2004 edition updated on September 6, 2004, for the first time, recommends restrictions on the use of intestines and tonsils from cattle of any age (Article 2.3.13.18.1).

² Resolutions Adopted by the International Committee of the OIE during its 72 General Session, 72 GS/FR – Paris, May 2004, at 49, available at: http://www.oie.int/download/SG/2004/A_RESO_2004_WP.pdf. The OIE designated only Argentina, Iceland, Singapore and Uruguay as 'provisionally free' from BSE.

³ BSE Test Results, USDA – APHIS, Weekly Summary, available at:

http://www.aphis.usda.gov/lpa/issues/bse_testing/test_results.html. See also *USDA BSE Surveillance Plan:*

Background on Assumptions and Statistical Inferences, September 9, 2004, available at:

<http://www.aphis.usda.gov/lpa/issues/bse/BSEOIG.pdf>. A total of 17,121 head of cattle were tested from January 1, 2004 through May 2004, prior to the outset of USDA June 1, 2004 accelerated testing program. From June 1 through December 3, 2004, a total of 136,153 cattle were tested. No positive cases of BSE have been detected.

⁴ R. Bradley, P. Liberski, Bovine Spongiform Encephalopathy (BSE): The End of the Beginning or the Beginning of the End?, *Folia Neuropathol.* v. 42 suppl A., 55-68 (2004).

⁵ G. Kovacs, the prion protein in human neuromuscular disease, *J. Pathol.* v. 204, 241-247 (July 2004), attached hereto as Attachment A; P. Hayward, Prion protein in muscle tissue of sheep, *Lancet Neurol.*, v. 3 n. 7 at 389 (July 2004), attached hereto as Attachment B; O. Andreoletti, S. Simon, C. Lacroux, N. Morel, G. Tabouret, A. Chabert, S. Lugan, F. Corbiere, P. Ferre, G. Foucras, H. Laude, F. Eychenne, J. Grassi, F. Schelcher, PrPSc accumulation in myocytes from sheep incubating natural scrapie, *Nat Med.*, v. 10 no. 6, 591-3. (June 2004), attached hereto as Attachment C; A. Thomzig, A. Schulz-Schaeffer W, Kratzel C, Mai J, Beekes M, Preclinical deposition of pathological prion protein PrPSc in muscles of hamsters orally exposed to scrapie, *J. Clin Invest*, v113 no. 10), 1465-72 (May 2004), attached hereto as Attachment D; M. Glatzel, E. Abela, M. Maissen, A. Aguzzi, Extraneural pathologic prion protein in sporadic Creutzfeldt-Jakob disease, *N Engl J Med.*, v. 349 no. 19,1812-20 (Nov 2003), attached hereto as Attachment E; A. Thomzig, C. Kratzel, G. Lenz, D. Kruger, M. Beekes, Widespread PrPSc accumulation in muscles of hamsters orally infected with scrapie, *EMBO Rep.*, v. 4 no. 5, 530-3 (May 2003), attached hereto as Attachment F; M. Brazier, R. Cappai, S. Collins, Prions in skeletal muscle, *Aust Vet J.*, v. 80 n. 8, 484-5 (August 2002), attached hereto as Attachment G; P. Bosque, C. Ryou, G. Telling, D. Peretz, G. Legname, S. DeArmond, S. Prusiner, Prions in skeletal muscle, *Proc Natl Acad Sci USA*, v. 99 n. 6, 3812-7 (March 2002), attached hereto as Attachment H.

⁶ S. Prusiner, Detecting Mad Cow Disease, *Sci. Amer.*, 86-93 (July 2004), attached hereto as Attachment I; John A. Fox, Hikaru Hanawa Peterson, Risks and implications of Bovine Spongiform encephalopathy for the United States: insights from other countries, Department of Agricultural Economics, Kansas State University, Manhattan, KS, *Food Policy* 29 (2004) 45-60, attached hereto as Attachment J;

7. New scientific discoveries suggest variant Creutzfeldt-Jakob disease (vCJD) is transmissible through human blood.⁷
8. New scientific evidence showing heightened risks to human health from BSE in Great Britain and Europe.⁸
9. The value of information study (VOI) that R-CALF USA provided to APHIS and USDA in June 2004, which shows the vital importance of testing not only Canadian cattle in Canada for BSE, but also Canadian cattle that were previously imported to the United States.⁹
10. BSE testing in Canada remains inadequate to determine with any certainty the prevalence of BSE in Canada.

R-CALF USA requests that APHIS and USDA carefully consider all of these developments before amending USDA regulations to establish a new category of regions that present a minimal risk of introducing BSE into the United States via live ruminants (especially cattle) and ruminant (especially cattle) products, and to list Canada as the first such region in this category. In light of these developments, R-CALF USA reiterates its previous suggestion that the proposed rule should be withdrawn until the agency adequately addresses the risk posed by the rule to both human as well as animal health.

THE PROPOSED APHIS RULE IGNORES SCIENTIFICALLY ESTABLISHED INTERNATIONAL BSE STANDARDS

- 1. The proposed APHIS rule will allow Canadian-origin cattle to be slaughtered in the United States without requiring the removal of SRMs and will result in the United States producing beef that does not meet the OIE's internationally accepted BSE risk mitigation standards as adopted this year.**

The proposed APHIS rule will allow cattle born and raised in BSE-infected Canada to be imported into the United States and slaughtered in U.S. packing plants without requiring the removal of any SRMs, other than the intestines.¹⁰ Other than removal of the intestines, these imported Canadian cattle would be subject to only the requirements for processing U.S. cattle that are slaughtered before reaching the age of 30 months, i.e., only the tonsils and distal ileum (a section of the small intestine) are considered SRMs.¹¹

⁷ C. Llewellyn, P. Hewitt, R. Knight, K. Amar, S. Cousens, J. Mackenzie, R. Will, Possible transmission of variant Creutzfeldt-Jakob disease by blood transfusion, *The Lancet*, v. 363, 417-21 (Feb 2004), attached hereto as Attachment K.

⁸ D. Hilton, Prevalence of lymphoreticular prion protein accumulation in UK tissue samples, *J Pathol.*, v. 203 no. 3, 733-9 (July 2004), attached hereto as Attachment L.

⁹ Louis Anthony Cox, Jr., Ph.D., et al, Optimal Tracking and Testing of U.S. and Canadian Herd for BSE: A Value-of-information (VOI) Approach ("Cox VOI Study"). A copy of Dr. Cox's study is attached to these comments as Attachment M. A Microsoft Excel spreadsheet containing the actual VOI model is attached on the CD-ROM as Attachment N.

¹⁰ Federal Register, Vol. 68, No. 213, November 4, 2003, Proposed Rules, Section 93.436 (a) and (b), at 62401-62402. Only the animal's intestines are required to be removed from Canadian cattle.

¹¹ 9 CFR 310.22 (a) USDA Food Safety and Inspection Service definition of specified risk materials (SRMs).

The resulting meat from these imported Canadian cattle will then be marketed to U.S. and international consumers. However, the meat from these imported Canadian cattle will not meet the latest international health and safety standards established by the OIE.¹² As a result, the health and safety of U.S. and international consumers will be compromised plus the U.S. cattle industry will be harmed because the economic well being of U.S. cattle producers is intrinsically tied to U.S. and international consumer confidence in the safety of U.S. beef.

Currently, the most favorable BSE risk category that Canada can now achieve under the standards of the World Organization for Animal Health (OIE) is that of a “Country or Zone with a Moderate BSE Risk.” The new 2004 code of the OIE states:

Countries or zones where the BSE incidence rate has been less than one indigenous case per million within the cattle population over 24 months of age during each of the last four consecutive 12-month periods, but where at least one of the other requirements to be considered as provisionally free from BSE or as presenting a minimal BSE risk is not complied with, shall be considered as countries or zones with a moderate BSE risk.¹³

Canada’s known BSE incidence rate based on current testing is less than one case per million within its cattle population.¹⁴ However, Canada does not meet at least two requirements to be considered a minimal BSE risk country. The OIE minimal risk requirements that Canada does not meet include:

1. Canada’s meat-and-bone meal (MBM) feed ban has not been enforced for the required minimum of 8 years.¹⁵
2. Canada did not completely destroy the BSE-diseased cow detected on May 20, 2003, as required by the OIE.¹⁶ Instead, Canada rendered the BSE-diseased cow and processed it into animal feeds. These animal feeds were distributed to as many as 1,800 sites where some was possibly consumed by Canadian cattle.¹⁷ Information obtained by the Canadian Broadcasting Corporation through Canada’s Access to Information Act indicates that as many as 1,832 head of Canadian cattle from 10 sites were exposed to the BSE-contaminated feed. There

¹² OIE Terrestrial Animal Health Code, 12th edition, 2004, Article 2.3.13.15 (5) and Article 2.3.13.18 (2). For countries with a moderate risk for BSE, the skull and vertebral column are to be completely removed in animals over 6 months of age and brains, eyes, spinal cord, skull and vertebral column and protein derived thereof are not to be used for the preparation of food, fertilizer, cosmetics, pharmaceuticals or medical devices from animals over 12 months of age.

¹³ OIE Terrestrial Animal Health Code, 12th edition, 2004, Article 2.3.13.6.

¹⁴ Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States, Animal and Plant Health Inspection Service, Veterinary Services, October 2003, at 8.

¹⁵ OIE Terrestrial Animal Health Code, 12th Edition, 2004, Article 2.3.13.5(2)(b)(1).

¹⁶ *Id.* Article 2.3.13.5(2)(b)(iii).

¹⁷ Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States, Animal and Plant Health Inspection Service, Veterinary Services, October 2003, at 14.

is no indication that any more than 63 of these potentially BSE-exposed cattle were destroyed.¹⁸

Under OIE standards, these two points alone show that Canada is clearly a moderate BSE risk country. Current OIE international risk mitigation standards require moderate BSE risk countries to remove all SRMs from all cattle over 6 months old.¹⁹ The proposed APHIS rule does not include this or any similar requirements.

In 2003, the United States, Canada, and Mexico unsuccessfully petitioned the OIE to amend the Terrestrial Animal Health Code's BSE standards used for categorizing countries according to their respective BSE risks.²⁰ This effort was precipitated by Canada's admission that it does not meet all of the OIE standards for a country with a "Minimal BSE Risk." Specifically, Canada admits it does not meet the standard that requires a country to have effectively enforced a meat-and-bone (MBM) feed ban for a minimum of eight years. But, Canada argued that while its MBM feed ban has not been in place for eight years, Canada claimed it could provide an equivalent level of assurance.²¹ The OIE BSE expert group considered this request and concluded, "One of the most important conclusions of the recent OIE expert group is that the scientific basis used in the present Code is still valid."²²

The effect of APHIS's proposed rule, therefore, will be that beef from Canadian cattle slaughtered in the United States, which does not meet the minimal requirements of the OIE, will be commingled with beef from United States cattle, which exceeds the OIE standard. This will also be the case for Canadian beef and beef products imported under the proposed rule as it, likewise, imposes no restrictions on SRMs from beef produced from Canadian cattle less than 30 months of age in Canadian slaughter plants.

Moreover, this commingled beef from Canadian cattle will not be differentiated with a label clearly denoting the product's Canadian country-of-origin. As a direct result, U.S. and international consumers will not have the option to try to reduce their risk of exposure to BSE by eliminating consumption of Canadian beef products, which are all produced under substandard BSE risk conditions. This effect will compromise the health and safety of U.S. and international consumers, which will in turn jeopardize the economic well being of the U.S. cattle industry.

¹⁸ Documents describing On Farm Trace-out Inspections conducted by the Canadian Food Inspection Service. These documents were obtained by the Canadian Broadcasting Corporation through Canada's Access-to-Information Act and received by R-CALF USA via fax on October 7, 2004.

¹⁹ OIE Terrestrial Animal Health Code, 12th Edition, 2004, Article 2.3.13.15(4).

²⁰ OIE Addresses Demands on Clarification of BSE Standards, OIE Press Release, October 2003, available at: http://www.oie.int/eng/press/en_031002.htm.

²¹ Canada: A Minimal BSE Risk Country, Executive Summary, Canadian Food Inspection Agency, December 2003, available at: <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/minrisexece.shtml>. Canada stated: Although it has only been six years since the introduction of a feed ban in 1997, an equivalent level of assurance to the requirement that a feed ban has been in place for at least eight years can be provided on the basis that: . . . "

²² OIE Addresses Demands on Clarification of BSE Standards, OIE Press Release, October 2003, obtained from the Internet at http://www.oie.int/eng/press/en_031002.htm, on January 4, 2004.

2. The proposed APHIS rule, coupled with a recently adopted FDA rule, does not follow internationally accepted OIE standards and does not adequately restrict the use of products from Canadian cattle for food, feed, fertilizers, cosmetics, pharmaceuticals or medical devices sold in the United States.

Current OIE standards restrict the use of SRMs from cattle over 12 months old, when they originate from a country with a moderate BSE risk, in the preparation of foods, feeds, fertilizers, cosmetics, pharmaceuticals including biologicals, or medical devices.²³ However, the proposed APHIS rule would allow Canadian-born cattle over 12 months old to be slaughtered in U.S. slaughter plants without restricting the use of SRMs in the preparation of the abovementioned products. The FDA has issued an interim rule that restricts only the tonsils and small intestines in the preparation of these products from cattle less than 30 months old.²⁴

The proposed APHIS rule allows both cattle less than 30 months old and beef derived from cattle less than 30 months old to be imported into the United States. The proposed APHIS rule does not restrict SRMs from cattle over 12 months of age in the production of the products listed above in accordance with current OIE standards. Thus, U.S. and international consumers will be subjected to a greater risk of BSE than is allowed under current international OIE standards. Such an effect will compromise the health and safety of U.S. and international consumers, which will in turn jeopardize the financial well being of the U.S. cattle industry.

3. The proposed APHIS rule effectively allows beef and beef products from Canada to be produced under less stringent health and safety standards than recommended by the OIE for a country with Canada's BSE-risk classification.

The OIE currently recommends that SRMs be removed from all cattle over 6 months old if a moderate BSE risk country exports beef from such cattle.²⁵ Canada is a moderate BSE risk country. However, the proposed APHIS rule imposes no additional requirements for the removal of SRMs in cattle less than 30 months old.

The effect of the proposed APHIS rule will be to compromise the health and safety of U.S. and international consumers, which in turn will jeopardize the financial well being of the U.S. cattle industry because the beef produced in Canada from cattle aged 6 months to 30 months old will not comply with OIE standards. Furthermore, this beef will be commingled with U.S. beef without a label denoting the Canadian country-of-origin so that U.S. and international consumers can choose whether to accept beef produced under substandard BSE risk conditions.

²³ OIE Terrestrial Animal Health Code, 12th Edition, 2004, Article 2.3.13.18(2).

²⁴ Federal Register, Vol. 69, No. 134, July 14, 2004, at 42262.

²⁵ OIE Terrestrial Animal Health Code, 12th Edition, 2004, Article 2.3.13.15 (5).

THE PROPOSED APHIS RULE FAILS TO DISTINGUISH BETWEEN WHAT IS SCIENTIFICALLY KNOWN AND UNKNOWN ABOUT BSE

- 4. Recent studies show that APHIS has not adequately addressed all the vectors for BSE transmission. Such vectors include: 1) animal blood; 2) poultry litter, 3) plate waste; 4) and cattle less than 30 months old.**

APHIS assumes there is no risk to humans from exposure to Canadian cattle and beef, because APHIS assumes BSE is not evident in cattle less than 30 months of age and APHIS assumes meat from older cattle cannot harbor the BSE disease if SRMs have been removed. Recent scientific studies of BSE and vCJD, as well as increasing detections of BSE in cattle less than 30 months old, demonstrate that those assumptions are false.

USDA acknowledged last year that BSE can be detected in cattle less than 30 months of age.²⁶ That was based on the limited occurrences in younger cattle in England.²⁷ Since that time, there have been additional discoveries of BSE in younger cattle in Japan. Japan's eighth and ninth cases of BSE were detected in cattle aged 23 months and 21 months, respectively.²⁸ In addition, and as discussed above, the latest OIE standards recommend removal of SRMs from all cattle from moderate BSE risk countries that are over 6 months of age. Also as noted below, a joint U.S.-Japan working group of experts acknowledged an unquantified risk of BSE from younger cattle, and the United States apparently has agreed to the removal of SRMs from cattle of any age where the meat is destined for Japan. The United States will also restrict exports of meat to Japan to cattle under 21 months of age. These scientific and policy developments dramatically undercut APHIS's assumption in the proposed rule that cattle under 30 months do not present a risk of BSE transmission or of vCJD infection.

Similarly, APHIS's assumption that the MBM feed ban provides protection against the BSE disease entering the United States in Canadian cattle is inaccurate. Because there is a gap in the MBM feed ban caused by feeding ruminant protein to poultry and then feeding poultry litter to cattle, bringing Canadian cattle into the United States for slaughter increases the potential for the spread of BSE in the U.S. herd through that route. SRMs (as defined by the OIE) removed from Canadian cattle in U.S. slaughterhouses can be used in the manufacture of poultry feed. Numerous studies confirm that BSE prions are highly persistent, so there is reason to believe that prions from a BSE-infected cow could enter poultry feed, and then be re-introduced into U.S. cattle through poultry litter, inadvertent exposure to poultry feed, or cross contamination occurring within feed processing facilities. So long as the MBM feed ban allows ruminant protein to be used in poultry food, and plate waste to be used as ruminant food, introducing Canadian cattle into U.S. slaughtering facilities increases the risk of BSE in the U.S. herd through that route. The International Review Team convened by the Secretary of Agriculture following the discovery of a BSE-infected Canadian-born cow in Washington state reported to

²⁶ See, e.g., USDA, Transcript of October 31, 2003 press conference, remarks of Dr. Elsie Ferguson and Dr. George Gray.

²⁷ *Id.*

²⁸ Final Report Japan – United States BSE Working Group, July 22, 2004, at 2, attached hereto as Attachment O.

the USDA Secretary that “. . . the partial (ruminant to ruminant feed ban that is currently in place is insufficient to prevent exposure of cattle to the BSE agent.”²⁹

5. APHIS acknowledges that presently undetectable levels of BSE in central nervous system (CNS) tissues present an unknown risk to consumers, but APHIS takes no steps to protect U.S. and international consumers or the U.S. cattle industry from exposure to this unknown risk.

There is general agreement within the scientific community that current BSE testing methods have limited capacity to detect BSE in infected cattle below the age of about 30 months. However, as of December 2004, BSE has been confirmed in 21 head of cattle under 30 months old, including 13 head of cattle that were 24 months of age or younger.³⁰ There is uncertainty regarding the exact age under which BSE is detectable in infected cattle. USDA, in its negotiations with Japan, has conceded that the agency does not know the risk to human health associated with central nervous system (CNS) tissues from cattle that carry the BSE disease, but are too young for BSE to be detected using current testing methods. This admission strongly suggests that any exposure to beef from younger cattle originating in a country where BSE is known to exist presents an unknown risk to consumers. In the July 22, 2004 report issued by USDA, “Final Report Japan-United States BSE Working Group,” the Japan-United States working group (WG) comprised of experts and working-level officials reported:

Japan and the U.S. agree that accumulated abnormal prion protein in younger animals is unlikely to be detected using current testing methods. Japan and the U.S. agree that at present any relationship of such undetectable levels of abnormal prion protein in CNS tissues to consumers’ risk is unclear.³¹

The APHIS rule ignores this unknown risk to consumers and requires no mitigation measures other than the removal of the distal ileum and tonsils from cattle less than 30 months old, thereby subjecting U.S. and international consumers to whatever risk scientists may later determine is present in the remaining CNS tissues of younger cattle. USDA designates the following CNS tissues in cattle over 30 months old as SRMS: brain, skull, trigeminal ganglia, eyes, spinal cord, dorsal root ganglia and vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum).³²

²⁹ Report of an international panel of experts appointed by the Secretary of Agriculture to review U.S. BSE response actions and make recommendations on the U.S. national program, Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States, February 2004, at 5.

³⁰ Statistics – Youngest and oldest cases by year of onset – GB (Passive Surveillance Only), Department of Environment, Food and Rural Affairs, United Kingdom, as of October 1, 2004, available at: <http://www.defra.gov.uk/animalh/bse/statistics/bse/yng-old.html>. See also Attachment O at 2.

³¹ See Attachment O.

³² *Id.* at (2 (2)).

6. Recent scientific discoveries suggest that USDA's assumption that removal of SRMs provides complete protection against BSE is not valid.

Researchers at the National Veterinary School in Toulouse, France, in May, reported that prions have been found in sheep muscle tissue.³³ Although the specific prion found was for scrapie not BSE, the French findings confirm the substantial body of work by many researchers that confirm that TSE prions are present in muscle tissue.³⁴ This group includes Dr. Stanley Prusiner, the 1997 Nobel Laureate in Medicine who discovered prions.³⁵ Swiss researchers have found prions in the muscles of humans with sporadic Creutzfeldt-Jakob disease.³⁶ These findings confirm the value of the levels of BSE testing in Europe and even Japan to prevent products from BSE infected cattle from reaching consumers. Indeed, in an article published in Scientific American in July, Dr. Prusiner called for testing to ensure food safety.

Given that seemingly healthy animals can potentially carry pathogenic prions, I believe that testing all slaughtered animals is the only rational policy. Until now, the tests have been inadequately sensitive. But the advent of rapid, sensitive tests means universal screening can become the norm.³⁷

The findings regarding prions in muscle tissue and calls by the preeminent scientists in prion research for testing is particularly significant given USDA's acknowledgement of gaps in its current understanding of prions including BSE as discussed more fully below. Consequently, APHIS is premature in its attempts to relax current Canadian BSE safeguards while recent scientific discoveries are beginning to erode basic assumptions about BSE. As recently as January 21, 2004, USDA assured the public that, "The scientific community believes that there is no evidence to demonstrate that muscle cuts or whole muscle meats that come from animals infected with BSE are at risk of harboring the causative agent of the disease."³⁸ The recent discoveries of scrapie prions in sheep muscle and prions in human muscle cast doubts as to whether this currently held belief will remain valid following the expansive research contemplated by USDA as noted below.

Given the ongoing advancements in BSE testing sensitivity and the recent findings of prions in the muscles of other species, the prudent course of action is to maintain the United States' current standard of providing U.S. and international consumers plus the U.S. cattle industry with complete protection from known sources of BSE. To do this, USDA must maintain the current rule that prohibits the importation of ruminants and ruminant products from countries where BSE is known to exist.

³³ Donald G. McNeil, Jr, Malformed Proteins Found in Sheep Muscle, New York Times, May 24, 2004.

³⁴ See supra note 5, Attachments A-H.

³⁵ See Attachment H.

³⁶ See Attachment E.

³⁷ See Attachment I at 92.

³⁸ Bovine Spongiform Encephalopathy Q&A, USDA-APHIS, January 21, 2004, available at: http://www.aphis.usda.gov/lpa/issues/bse/bse_q&a.html.

7. Recent scientific research shows that the extent of vCJD infection in Great Britain and Europe may be much greater than previously thought as well as the corresponding risk of transmission of vCJD through human blood and tissue as well as contact with surgical instruments

Several news articles from the United Kingdom (U.K.) and Canada suggest that the human form of BSE can be spread through blood transfusions. Such articles include:

- According to a September 10, 2004, news article from the United Kingdom Mirror.co.uk, the U.K. Department of Health is actively notifying patients who have had blood transfusions that they could be infected with the human form of BSE.³⁹
- According to an August 5, 2004, Associated Press article written in London, “Human Mad Cow May be More Widespread,” Dr. Kumanan Wilson, a blood safety expert at Toronto General Hospital in Canada, indicated that new evidence suggests that the human form of BSE can be spread through blood transfusions.⁴⁰
- According to a May 21, 2004, Reuters news article, Sir Leszek Borysiewicz of Imperial College in London indicated that the findings of a recent report published in the Journal of Pathology and authored by David Hilton, of Derriford Hospital in Plymouth, reinforce the safety measures to reduce the spread of vCJD through blood transfusions or surgical equipment.⁴¹

These articles reflect a growing body of scientific knowledge regarding the role blood may play in the spread of the vCJD. These and other articles reinforce the need to ban blood from animal feed until science can definitively dismiss animal blood as a contaminant source of BSE. In the absence of such a ban, importing Canadian cattle (with their known incidence of BSE) for slaughter in the U.S. increases the risk of introduction of BSE into the U.S. cattle herd.

In addition, the fact that vCJD apparently can be transmitted through human blood, and the reasonable inference that BSE likewise could be transmitted through animal blood, call into question the assumptions behind APHIS’s assertion that removal of SRMs is a sufficient step to protect humans from exposure to the BSE agent. Both the presumption that the BSE infectious agent resides only in SRMs, and the implicit assumption that SRMs can be removed from the carcass without exposing any of the remaining meat to contamination with the BSE infectious agent, are unjustified if BSE may be transmitted through blood.

³⁹ Alert on Mad Cow Infection, Mirror.co.uk, September 10, 2004.

⁴⁰ Human Mad Cow May Be More Widespread, Emma Ross, AP Medical Writer, Associate Press, August 5, 2004.

⁴¹ More Human Mad Cow Disease Cases Possible, Reuters, London, May 21, 2004.

- 8. USDA and Health and Human Services (HHS) have jointly acknowledged there are gaps in the scientific knowledge about BSE and that additional research is needed to understand and deal with the threat BSE poses to livestock. In spite of these acknowledged gaps, the APHIS rule proposes to lower the United States' current BSE defenses before the agencies conduct the research needed to fill this knowledge void.**

In a September 2004 news release issued by the Office of Science and Technology Policy of the Executive Office of the President (OSTP), USDA and the Department of Health and Human Services jointly announced the creation of a federal interagency working group to identify gaps in scientific knowledge about abnormal prion proteins, believed to be the causative agent of BSE and other diseases. Dr. John H. Marburger III, OSTP director and National Science and Technology Council Co-Chair was quoted as saying, "Although a significant amount of research has been conducted worldwide on prions in the past decade, there are still many vital questions for which we don't have answers."⁴² USDA Secretary Ann Veneman reportedly listed the crucial questions about BSE that needed to be researched. These crucial questions include:

- i. identifying the structural features of prions;
- ii. finding mechanisms by which prions reproduce themselves;
- iii. finding mechanisms by which TSEs cause disease; and
- iv. understanding the physiological function of the normal prion protein.

These BSE research needs appear to be fundamental to the formulation of any science-based BSE disease protection strategy. Knowing how prions reproduce and knowing the mechanisms by which TSEs cause disease are essential elements of determining what safety measures are needed to adequately protect U.S. and international consumers plus the U.S. cattle industry from BSE. Based on this officially pronounced knowledge void, USDA should withdraw the proposed APHIS rule, because it is predicated on the unproven assumption that APHIS already knows:

- 1) how BSE is reproduced;
- 2) how BSE causes diseases; and
- 3) what specific steps APHIS must take to prevent either from occurring.

⁴² Interagency Working Group to Focus on Prion Research, Office of Science and Technology Policy Executive Office of the President, September 21, 2004.

THE PROPOSED RULE IS INCONGRUENT AND DISADVANTAGES UNITED STATES AND INTERNATIONAL CONSUMERS PLUS THE U.S. CATTLE INDUSTRY.

- 9. Because of inadequate testing for BSE in Canada, the proposed APHIS rule affords preferential treatment to the Canadian cattle industry over the United States cattle industry and subjects U.S. and international consumers to great and unnecessary BSE risk.**

USDA has concluded that knowing whether BSE is prevalent in the U.S. cattle herd and, if so, what that prevalence is, is of paramount importance to maintaining the health and welfare of U.S. and international consumers plus the U.S. cattle industry, as well as maintaining the confidence of U.S. export consumers. In the transcript of a USDA technical briefing held May 21, 2004, APHIS Administrator Ron DeHaven stated:

So I guess nothing in this world is absolute including surveillance testing. But certainly for our own purposes as we look at our overall BSE program and any changes we might need to make to our program, certainly in the context of communicating with our trading partners in terms of the prevalence or lack of prevalence of the disease in this country, this surveillance program is of paramount importance.

And so the bottom line is, the more samples we test, the greater accuracy and the more confidence we can say whether or not we have the disease and at what prevalence.⁴³

In APHIS's action to carry out this proclaimed important objective, APHIS has BSE tested 153,274 cattle in the United States from January 1, 2004 through December 3, 2004.⁴⁴ The United States has never detected a case of BSE in its native cattle herd. While two BSE cases have been detected in native Canadian cattle, Canada has BSE tested only 15,817 cattle in 2004 through November.⁴⁵ The U.S. cattle herd size is 94.9 million head⁴⁶ and Canada's herd size is 14.7 million head.⁴⁷ Thus cattle in the United States are subject to a production-related BSE testing regime at twice the frequency than are cattle in Canada, despite the fact that BSE is known to exist in the Canadian herd and not in the U.S. herd. Furthermore, to establish the

⁴³ Transcript of Technical Briefing, USDA, Release No. 00204.04, available at: <http://www.usda.gov/Newsroom/0204.04.html>.

⁴⁴ USDA BSE Surveillance Plan: Background on Assumptions and Statistical Inferences, available at: <http://www.aphis.usda.gov/lpa/issues/bse/BSEOIG.pdf>. *See also*, USDA's BSE Testing, Test Results, Updated 11-04-04, available at: http://www.aphis.usda.gov/lpa/issues/bse_testing/test_results.html.

⁴⁵ Sample Status and Testing Results, BSE Enhanced Surveillance Program, Canadian Food Inspection Agency, Last Updated 2004-11-03, available at: <http://www.inspection.gc.ca/english/anima/heasan/diseasala/bseesb/surv/surve.shtml>.

⁴⁶ USDA Economics, Statistics, and Market Information System, Cattle, 1-30-04, available at: <http://usda.mannlib.cornell.edu/>.

⁴⁷ Livestock Population of Canada, 2003 Annual Livestock and Meat Report, Agriculture and Agri-Food Canada, available at: <http://www.agr.gc.ca/misb/aisd/redmeat/03tabl40.xls>.

prevalence of BSE in Canada with any certainty, the absolute size of the sample is critical.⁴⁸ The current level of testing for BSE in Canada is far too small to determine the prevalence of BSE in Canada.

The proposed rule has the effect of giving preferential treatment to cattle and beef produced in Canada while simultaneously subjecting U.S. and international consumers to greater and unacceptable BSE risks and without requiring the higher-BSE risk Canadian beef to be labeled with its Canadian country-of-origin so that U.S. and international consumers can choose whether or not to accept the risk of BSE from Canadian cattle.

10. USDA appears willing to accept a higher health and safety standard for U.S. beef exports than it will require for U.S. beef imports, effectively affording export consumers greater BSE protection than it will afford United States consumers.

As discussed in greater detail below, the proposed APHIS rule effectively changes the United States BSE protection standard for beef imported from countries where BSE is known to exist from one of risk avoidance and prevention to a lower standard based on controlled risk and acceptable risk (disease management).⁴⁹ However, USDA states it has agreed with Japan that, “As per international guidelines, tissues and ages of SRMs will be determined by the BSE risk in the respective country.”⁵⁰ The OIE international guidelines, however, categorize a country’s risk based on the prevalence of BSE in the respective country’s native cattle herd.⁵¹ The effect of this action will be that Japan’s consumers will continue to be afforded protection under a “prevalence-based” risk approach using international OIE guidelines for U.S. beef exports while U.S. consumers will be afforded only the lower “risk-based” approach inconsistent with OIE guidelines for cattle and beef imported from BSE-infected Canada. Again, as discussed above, the proposed APHIS rule does not require the removal of SRMs from Canadian cattle over 6 months old as recommended by the OIE for a moderate BSE risk country (Canada).

Whereas the proposed APHIS rule requires the removal of SRMs only from Canadian cattle over 30 months of age, USDA has, at least preliminarily, agreed that U.S. cattle over 20 months of age present an unacceptable risk for consumers in Japan. In its October 23, 2004 news release, USDA announced that it had reached an agreement with Japan whereby only beef from cattle under 21 months old would be eligible for export to Japan.⁵² Prior to USDA’s concession on the appropriate age under which the risk of BSE would be acceptable, and consistent with APHIS’s proposed rule, USDA argued that 30 months was the appropriate age under which SRMs need

⁴⁸ M. DeGroot and Schervish, *Probability and Statistics*, 3rd ed., Addison Wesley, 1986; Larsen and Marx, *An Introduction to Mathematical Statistics and its Applications*, 2nd ed., Prentice Hall, 1986; Hogg and Craig, *Introduction to Mathematical Statistics*, 4th ed., Macmillan, 1978.

⁴⁹ Comments from the United States on the OIE’s proposed changes to the Code Chapter on Bovine Spongiform Encephalopathy December 2003 Report of the Terrestrial Animal Health Standards Commission Comments, March 12, 2004, at 4. APHIS refers to this disease management standard as a “risk-based approach classification rather than a prevalence-based approach.”

⁵⁰ See Attachment O.

⁵¹ OIE Terrestrial Animal Health Code, 12th edition, 2004.

⁵² U.S. – Japanese Officials Conclude Agreement for Resumption of Beef Trade, Release No. 0465.04, October 23, 2004.

not be removed. However, for Japan, USDA has agreed that SRMs would be removed from cattle of all ages.⁵³

Because USDA has repeatedly stated that it will only base USDA BSE decisions on sound science, it is presumed USDA has a scientifically justified reason for conceding to Japan's request that additional BSE risk mitigation measures be applied to beef destined for the Japanese export market. It is not apparent why USDA would choose to not provide comparable risk mitigation measures to protect United States consumers from the BSE risk associated with Canadian cattle under 30 months old.

11. Under the proposed APHIS rule, United States consumers and international consumers of U.S. beef plus the U.S. cattle industry will be afforded fewer BSE protections from Canadian beef than consumers in the European Union are afforded who consume beef from countries that, like Canada, have detected BSE in their native cattle herds.

In addition to the European Union's requirement that SRMs be removed from all cattle over 12 months old, the EU also includes more tissues in its definition of SRMs than does the United States. While the United States will prohibit the introduction of tonsils and the distal ileum from cattle of all ages into the human food supply, the EU further prohibits the intestines from the duodenum to the rectum and the mesentery of cattle of all ages from its human food supply.⁵⁴ Also, EU consumers are further protected against the amplification of the BSE agent within any of the EU's member countries because, unlike the U.S. requirement, the EU prohibits the use of blood products in cattle feed.⁵⁵ In addition, the EU tests, at a minimum, all cattle over 30 months old (with the single exception of Sweden)⁵⁶ and consumers are afforded country of origin labeling so they can choose to purchase beef produced under the production regime of their choosing.

The foregoing reveals that U.S. beef consumers and international consumers of U.S. beef plus the U.S. cattle industry are afforded fewer protections under the proposed APHIS rule against the introduction of BSE from Canada than are provided to European consumers. The effect is that the United States will import Canadian beef that does not meet the minimal BSE risk mitigation measures established by either the OIE or the EU – measures that have not been challenged for lack of scientific justification.

⁵³ USDA Transcript: J.B. Penn Under Secretary of Agriculture for Farm and Foreign Agricultural Services Press Briefing, Release No. 0466.04, 3:45 p.m., U.S. Embassy, Tokyo, Japan, October 23, 2004.

⁵⁴ BSE-New State of Play, Activities of the European Union, Regulation (EC) No. 999/2001, available at: <http://europa.eu.int/scadplus/leg/en/lvb/f83002.htm>.

⁵⁵ *Id.*

⁵⁶ *Id.*

12. The proposed rule requires permanent identification of Canadian cattle imported into the U.S. but has no requirement to also identify imported beef or beef derived from these imported cattle for U.S. and international consumers.

The APHIS rule contains only *de minimis* requirements for identifying imported Canadian cattle and lacks any requirement to identify beef from Canadian cattle. Under the APHIS rule, only importers, handlers and packers that procure, feed and slaughter, respectively, imported Canadian cattle, and importers of Canadian beef will have access to information regarding the Canadian origins of beef derived either directly from Canada or from Canadian cattle slaughtered in the United States. United States and international consumers will not have this information.

As recently as last year, APHIS and the Department of Health and Human Services (DHHS) informed Congress of the health- and safety-related importance of identifying the country-of-origin of imported products originating from BSE affected countries. In 2003, APHIS and DHHS reported to Congress:

As BSE cases are confirmed in other countries, USDA and DHHS need to update risk assessments, import regulations, and guidance on enforcing regulations at ports-of-entry . . . To require that all imported products containing either mammalian or mammalian-sourced ingredients be declared with country-of-origin documentation of all such ingredients on import manifests.⁵⁷

Because the proposed APHIS rule allows both imported Canadian beef and beef derived from Canadian cattle to be commingled in the U.S. market without differentiation as to country-of-origin, USDA cannot exercise any actions associated with the health- and safety-related importance it attributes to identifying the country of origin of imported cattle and beef. This is a dangerous oversight by APHIS, particularly given USDA's failure to effectively recall all the beef products derived from the Canadian-origin BSE-diseased cow discovered in Washington State in December 2003. U.S. and international consumers deserve and require the reasonable and effective protection provided by simply requiring a country-of-origin label on Canadian beef imports and all beef derived from Canadian cattle.

THE PROPOSED APHIS RULE FAILS TO CONSIDER KNOWN COMPLIANCE COMPLICATIONS

13. Canada has already demonstrated that it cannot adequately ensure that products exported to the United States are compliant with U.S. BSE-related regulations.

Canada has already violated U.S. BSE-related regulations from September 2003 through April 2004, and again in July 2004. In violation of the BSE-related regulations imposed by USDA on Canada following the August 2003 partial lifting of the U.S. ban on Canadian beef and cattle, Canada in violation exported beef products including tongues, ground beef and bone-in beef

⁵⁷ Federal Inter-agency Working Group, Final Report, January 2003, Animal Disease Risk Assessment, Prevention, and Control Act of 2001, (PL 107-9), January 2003, at 44-45.

during the period September 2003 through April 2004 to the United States. USDA has acknowledged that millions of pounds of these unauthorized beef products were imported from Canada. According to a May 21, 2004 statement made by Dr. Elsa Murano, USDA Under Secretary for Food Safety, “So according to our import inspection records, what has come in from Canada that is not part of what was eligible on August 8th of last year, that’s up to about 7.3 million pounds.”⁵⁸

A July 29, 2004 Associated Press (AP) story reported that a Pennsylvania company recalled about 77,000 kilograms of hamburger patties containing unauthorized Canadian beef. According to the AP, the imported meat was mislabeled:

The imported meat was labeled ‘fine beef trim,’ which can be shipped from Canada legally. But in fact the meat was ‘finely textured beef trim’ which Canada may not send to the United States. Such meat comes from scavenged beef taken off the bone at high pressure.⁵⁹

The AP story stated that Dr. Elsa Murano, Under Secretary for Food Safety, reported that the problem was Canadian.

The foregoing evidence demonstrates that Canada has already violated current APHIS requirements and this raises the concern that the assumption that Canada will properly comply with the additional changes proposed in the APHIS rule may not be valid.

THE PROPOSED APHIS RULE OVERTURNS THE UNITED STATES’ HISTORICALLY SUCCESSFUL DISEASE PROTECTION POLICY

14. The proposed APHIS rule constitutes a wholesale abandonment of the United States longstanding BSE disease protection strategy. APHIS has radically changed its BSE disease protection strategy without first providing any scientific justification, informing the public that it is currently being subjected to increased risk, or even completing its rulemaking process before implementing such a profound change.

The United States’ longstanding and successful BSE protection strategy is intrinsically based on standards of avoidance and prevention. APHIS and other federal agencies jointly set forth this strategy in their 2003 Final Interagency Working Group Report to Congress on foot-and-mouth disease (FMD), bovine spongiform encephalopathy (BSE), and other diseases.⁶⁰ APHIS jointly and succinctly described the U.S. BSE strategy as consisting of three primary goals:

1. Prevent the agent of BSE from entering the United States and infecting U.S. cattle;

⁵⁸ Transcript of Technical Briefing with Bill Hawks, Under Secretary of Marketing and Regulatory Services, Dr. Elsa Murano, Under Secretary for Food Safety, Dr. Ron DeHaven, Administrator, Animal Health Inspection Service, Dr. Barbara Masters, Acting Administrator, Food Safety Inspection Service, USDA, Release No. 0204.04, May 21, 2004, available at: <http://www.usda.gov/Newsroom/0204.04.html>.

⁵⁹ Beef Recalled Over Mad Cow Rules, AP, Thursday, July 29, 2004.

⁶⁰ Federal Inter-agency Working Group, Final Report, January 2003, Animal Disease Risk Assessment, Prevention, and Control Act of 2001, (PL 107-9), January 2003.

2. Prevent the amplification of the agent of BSE throughout the U.S. cattle herd if it does penetrate the primary BSE safeguards at the U.S. borders and infect U.S. cattle; and
3. Prevent the exposure of Americans to the agent of BSE via food and other products that are fully or partially of bovine derivation.⁶¹

APHIS validated the scientific basis for the first two of these three goals by citing a conclusion of the Harvard Center for Risk Analysis study⁶² (Harvard-Tuskegee Study). APHIS characterized this conclusion as:

[T]he most effective measures for reducing potential introduction and spread of BSE are: (1) The ban placed by APHIS on the importation of live ruminants and ruminant meat-and-bone meal from the United Kingdom since 1989 and all of Europe since 1997; and (2) the feed ban instituted in 1997 by FDA to prevent recycling of potentially infectious cattle tissue.⁶³

Obviously, the ban on the importation of live ruminants and ruminant meat-and-bone meal (MBM) feeds is a measure to prevent the agent of BSE from entering the United States and infecting U.S. cattle (the first of its three stated goals). And, the U.S. MBM feed ban instituted in 1997 is a measure to prevent the amplification of the agent of BSE throughout the U.S. cattle herd (the second of its three stated goals).

APHIS also validated the historical effectiveness of the first two of its three stated goals by acknowledging that not a single case of BSE has ever been detected in the native U.S. cattle herd. It is important to note that the United States exceeds the OIE BSE surveillance testing standard, an accomplishment the United States has achieved every fiscal year since 1993.⁶⁴

Notwithstanding the APHIS validations of both the scientific and historical effectiveness of the agency's primary goal of preventing the agent of BSE from entering the United States and infecting U.S. cattle, the proposed APHIS rule focuses exclusively on only the second and third goals for protecting the United States from BSE, i.e., preventing the amplification of BSE if it infects the U.S. cattle herd and preventing the exposure of Americans to the BSE agent via food and other products. The proposed APHIS rule does not address any measures to continue fulfilling the U.S. first line of defense, the primary goal of "preventing the agent of BSE from entering the United States and infecting U.S. cattle."

⁶¹ *Id.* The Interagency Working Group introduced these three primary goals by stating, "To date, there is no evidence of BSE in the United States, and the U.S. Government has worked proactively to keep BSE out of this country," at 49.

⁶² Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, "Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States," November 26, 2001, hereinafter "Harvard-Tuskegee Study." http://www.aphis.usda.gov/Ipa/issues/bse/risk_assessment/mainreporttext.pdf, 2001.

⁶³ Federal Measures to Mitigate BSE Risks: Considerations for Further Action, Proposed Rules, Federal Register, Vol. 69, No. 134, July 14, 2004, at 42290.

⁶⁴ *Id.* at 42295.

The proposed APHIS rule, instead, infers that the current ban on the importation of live ruminants, ruminant products, and ruminant meat-and-bone meal from all countries where BSE is known to exist is no longer necessary. This is contrary to the Harvard-Tuskegee Study validation that the ban remains one of the most effective measures in reducing the potential introduction and spread of BSE in the United States. The proposed APHIS rule would effectively overturn the present ban by allowing the importation of live ruminants from Canada and potentially from other countries where BSE has been reported.⁶⁵

APHIS has publicly demonstrated both the importance of, and its previous commitment to, a specific science-based surveillance program needed to achieve its primary goal of preventing the BSE agent from infecting U.S. cattle via the commingling of cattle previously imported from countries including Canada where BSE was subsequently detected. APHIS firmly established the necessity of locating and monitoring all cattle within the U.S. cattle herd that originated in countries where BSE has been detected. APHIS reported to Congress in 2003:

Another part of the surveillance program is to locate and monitor all cattle imported from the United Kingdom during the 1980s, before the USDA ban. Any of these cattle found to be still alive were monitored, and APHIS offered to purchase them. Upon purchase, they were destroyed and tested for BSE. No evidence of BSE has been found in any of these imported animals. Currently, three of these UK imports are still alive and are regularly monitored by a Federal veterinarian for clinical signs compatible with BSE. In addition, APHIS traced all 46 cattle imported from continental Europe in 1996 and 1997. As with the United Kingdom imports, APHIS has offered to purchase these animals. As purchases occur, the cattle are destroyed and tested for BSE. No evidence of BSE has been found. Five of the 46 European imports are still alive as of October 2001, and Federal veterinarians are monitoring them. APHIS is also tracing cattle imported from Japan during the last decade.⁶⁶

This U.S. stated policy of locating and monitoring all cattle imported from countries where BSE was subsequently detected affords U.S. and international consumers plus the U.S. cattle industry with significant protections, both economic and health related, should any of these imported cattle test positive for BSE. The World Health Organization explains this fact by stating:

As BSE does not spread from one animal to another, there is no risk that an imported case will spark an outbreak within the herd. When a country reports BSE cases, the first question to ask is whether the case involves an imported animal or one born within the native herd . . . Far more alarming is a case born within the national herd, as additional cases, caused by the same exposure to contaminated feed, will nearly always be uncovered. For cases occurring in the

⁶⁵ *Id.* at 42294.

⁶⁶ Federal Inter-agency Working Group, Final Report, January 2003, Animal Disease Risk Assessment, Prevention, and Control Act of 2001, (PL 107-9), January 2003, at 57.

native herd, the number of reported cases reflects the quality of the surveillance system and tells only part of the story. More important in terms of the degree of risk are the feeding practices allowed or followed in the country.⁶⁷

Since May of 2003, two confirmed cases of BSE have been detected in cattle originating from Canada, evincing that the BSE agent was – and most probably still is – infecting the Canadian cattle herd. Yet, other than the epidemiological investigation involving the Canadian source herd of the BSE-infected cow, the United States has made no effort to either locate or monitor the remaining population of Canadian-origin cattle in the United States.⁶⁸ Failure to locate and monitor these Canadian-origin cattle renders them undifferentiated from U.S. cattle, effectively forcing the U.S. cattle industry to assimilate these higher-risk Canadian-origin cattle into the U.S. cattle herd. This is an abrupt and radical departure from the very protections APHIS told Congress it was providing.

Should a BSE-positive test be detected in a Canadian-origin cow that is undifferentiated from a U.S.-origin cow within the borders of the United States, it would effectively become the first native case of BSE in the U.S. cattle herd, and U.S. cattle producers will be economically harmed. The value to the U.S. cattle industry of knowing which cattle in the United States are of Canadian origin at the time of testing for BSE is quantified in the attached study, “Optimal Tracking and Testing of U.S. and Canadian Herds for BSE: A Value-of-Information (VOI) Approach,” completed in July 2004 by nationally recognized expert on risk analysis Louis Anthony Cox, Jr., Ph.D. The study demonstrates that if a Canadian cow is found in the future to have BSE, and the cow is identifiable as to its Canadian origin, the U.S. cattle industry benefit by more than \$80 million annually.⁶⁹

By abandoning the U.S. longstanding BSE surveillance program of locating and monitoring cattle imported from countries where BSE has been documented, such as Canada, the United States is openly and intentionally ignoring the international science-based recommendations of the OIE. The OIE continues to specifically advise nations to consider targeting their BSE surveillance programs to test cattle imported from countries not free from BSE such as Canada.⁷⁰

Notwithstanding APHIS’s recent assurance to Congress that its surveillance efforts included a program to locate and monitor cattle in the United States that originated from countries with documented cases of BSE, such as Canada, along with the scientific validation by the OIE for implementing such a surveillance program, APHIS has taken no action to locate and monitor

⁶⁷ Understanding the BSE Threat, World Health Organization, Document WHO/CDS/CSR/EPH/2002.6, October 2002, at 18.

⁶⁸ Federal Measures to Mitigate BSE Risks: Considerations for Further Action, Proposed Rules, Federal Register, Vol. 69, No. 134, July 14, 2004, at 42291. The Joint Agency ANPR reports that a total of 255 cattle linked to the Canadian source herd were located at the time the United States concluded its active investigation and culling activities.

⁶⁹ See Attachments M and N.

⁷⁰ Terrestrial Animal Health Code, 12th edition – 2004, Appendix 3.8.4., Examination of cattle subject to normal slaughter, at Article 3.8.4.4.

cattle of Canadian origin, other than the narrow BSE epidemiological investigation conducted from December 2003 through February 2004.

In the wake of Canada's two confirmed cases of BSE in the Canadian native cow herd, APHIS is rushing ahead to alleviate the resulting trade impact between the U.S. and Canada. In doing so, APHIS is dangerously and carelessly compromising the welfare of U.S. and international consumers plus the U.S. cattle herd by not taking into account the importance of maintaining a universally applied BSE disease prevention strategy to provide a robust framework for protecting against both present and future cases of BSE diseases. Dismantling the U.S. underlying BSE disease-protection framework, as APHIS is attempting to do to achieve BSE-specific exceptions for Canada, will result in the weakening of the U.S. ability to protect U.S. and international consumers from BSE, prevent BSE from infecting U.S. cattle, and decrease the U.S. long-term ability to protect U.S. and international consumers and the United States from all animal diseases, current and future.

APHIS seems unmoved by the fact that BSE is only one of the numerous new diseases affecting people and/or animals that have emerged in recent years. According to the World Health Organization:

[N]ew diseases are emerging at an unprecedented rate. In the last decade of the 20th Century, more than 30 new diseases – including HIV/AIDS and Ebola haemorrhagic fever – were detected for the first time in history. Bovine spongiform encephalopathy (BSE), or “mad cow disease,” is one of these newly emerging diseases. Its related human form, variant Creutzfeldt-Jakob disease (vCJD), is another.⁷¹

Thus APHIS, while imposing an immediate risk to the welfare of U.S. and international consumers plus the U.S. cattle herd by willfully and knowingly allowing Canadian cattle from BSE infected Canada to be assimilated in the U.S. cattle herd, also imposes great and unacceptable future risk of BSE to U.S. and international consumers by not maintaining an adequate BSE disease protection framework that would, for example, enable the United States to immediately locate and monitor Canadian cattle already in the United States should a future case of BSE, or some other animal disease outbreak occur in Canada.

The dismantling of the current BSE disease protection framework predicated on OIE recommendations represents a monumental paradigm shift, significantly changing the United States' approach to new animal diseases including BSE. Such a departure from the historically successful, science-based BSE disease prevention strategy is inconsistent with APHIS's mandate under the Animal Health Protection Act.⁷² Under the new paradigm currently practiced by APHIS, the United States will no longer emphasize avoidance and prevention of animal diseases including BSE, but rather, the United States will focus exclusively on the management of such diseases including BSE, regardless of whether the disease is preventable or even prevalent. The effect of this new policy will be to cause greater and unacceptable risk exposure to U.S. and

⁷¹ Understanding the BSE Threat, World Health Organization, Document WHO/CDS/CSR/EPH/2002.6, October 2002, p. 1.

⁷² Animal Health Protection Act, 7 U.S.C. Section 8301 *et seq.*

international consumers plus the U.S. cattle industry to animal diseases while simultaneously forcing the U.S. cattle industry to incur the added expense associated with specific disease mitigations. This new patently unfair and unconscionable policy will burden the U.S. cattle industry with the disease-related risks and costs of its foreign competitors.

While APHIS continues to provide assurances that the United States is maintaining adequate safeguards to prevent BSE from entering the United States and infecting U.S. cattle, principally by continuously describing the current U.S. ban on live ruminants, ruminant products and ruminant meat-and-bone meal from BSE infected countries including Canada, APHIS is simultaneously lobbying the OIE to adopt the APHIS proposal to dismantle the current BSE disease protection framework. APHIS is clearly attempting to change current BSE disease control policy from one of BSE disease avoidance and prevention to a lesser standard based on controlled risk and acceptable risk (disease management). In comments submitted to the OIE the United States stated its policy as follows:

[T]he United States continues to believe that the risk status of a country or region be based on the results of a risk assessment which identifies key risk factors and determines the “overall effectiveness” of control and risk mitigation measures in place (i.e., surveillance, import controls, specified risk material removal and feed ban). Thus, the risk status of a given country/region should be based on the effective implementation of mitigation measures against known risk factors for BSE. It is a risk-based approach classification rather than a prevalence-based approach.⁷³

The economic risks to the U.S. cattle industry resulting from the United States’ unwillingness to locate and monitor imported Canadian cattle, a circumstance demonstrable of the United States’ abandonment of its primary disease prevention goal, can now be quantified by the attached Cox VOI Study. The VOI study introduces a formal decision-analytic value-of-information (VOI) framework to quantify and compare the economic costs to the United States of implementing a tracking program for imported Canadian cattle to the costs of not doing so. The study shows:

[T]he value of tracking information is great enough to justify locating and beginning to track Canadian cattle already in the US when this can be done for a reasonable cost, e.g., less than \$35 per head, even under the pessimistic assumption that the US has already permanently lost many of its export markets due to the Washington State BSE case discovered in a Canadian-origin cow in December, 2003. If aggressive tracking and testing can win back lost exports, then the VOI of a tracking program may increase by an order of magnitude, to over half a billion dollars per year.⁷⁴

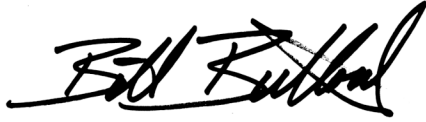
⁷³ Comments from the United States on the OIE’s proposed changes to the Code Chapter on Bovine Spongiform Encephalopathy December 2003 Report of the Terrestrial Animal Health Standards Commission Comments, March 12, 2004, at 4.

⁷⁴ See Attachments M and N.

CONCLUSION

Based on the overwhelming weight of scientific evidence regarding the risks posed by the proposed rule to consumers and the U.S. cattle herds, R-CALF USA urges USDA to withdraw it immediately.

Sincerely,

A handwritten signature in black ink, appearing to read "Bill Bullard". The signature is written in a cursive, somewhat stylized font with a prominent loop at the end.

Bill Bullard
CEO