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January 5, 2004

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

Sent Via E-Mail: regulations@aphis.usda.gov.

Re: Docket No. 03-080-1: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities

Dear Administrator:

Thank you for the opportunity to comment on the Animal Plant Health Inspection Service's (APHIS's) proposal to amend the regulations regarding the importation of animals and animal 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 to add Canada to this category.

R-CALF USA had requested a 60-day extension of time for which to comment on this proposal given the complexity of this issue and the significant impact this proposal would have on the United States live cattle industry. While APHIS was not moved by this request, the December 23, 2003 discovery of a BSE infected cow with a Canadian ear tag suggests that this APHIS proposal is, at the very least, premature and should be withdrawn.

R-CALF USA submits the following comments concerning the aforementioned proposed rule and respectfully requests the opportunity to submit additional comments following the conclusion of the investigation into the December 23, 2003 BSE case discovered in Washington State:

INTRODUCTION

Our comments will be in three parts. The first and second parts will focus primarily on APHIS's general proposal to relax the current United States' regulations which were implemented to protect the United States from the introduction of BSE. The third part will address some of the more specific provisions within the proposed rules.

In Part I, we will provide a brief history of the regulations the United States has implemented to prevent the introduction of BSE into the United States. We will then demonstrate that the proposed APHIS rules are more lenient than the minimally accepted scientific standards adopted by OIE and that APHIS is arbitrarily picking and choosing which standards it intends to dismiss and which standards it intends to exceed, all without any internationally accepted scientific basis. R-CALF USA will further show that no new scientific evidence has been produced to suggest that the United States' current regulations are not yet an essential element in preventing the introduction of BSE into the United States from Canada.

In Part II, we will establish that the current BSE rules have been scientifically validated as essential elements of the United States' BSE defense strategy and that APHIS, through the United States Secretary of Agriculture, has repeatedly assured Congress and the public that current regulations provide the fundamental protection needed to prevent the introduction of BSE into the United States, thereby shaping Congress's and the public's perception that the United States current BSE safeguards are sufficient to ensure that it is highly resistant to any introduction of BSE or a similar disease. R-CALF USA will then address the effectiveness of current regulations in achieving the United States' goal of preventing the introduction of BSE into the United States and we will demonstrate that USDA-APHIS has been lax in its enforcement of current regulations, thereby subjecting the United States cattle industry and United States' consumers to unnecessary risk. Finally, we will show that APHIS could have easily avoided the BSE case discovered in an imported cow in Washington State if it had properly responded to the mitigation steps requested by the United States live cattle industry.

In Part III we will demonstrate that the USDA did not conduct a risk assessment that specifically addresses the probability of introducing BSE via live cattle, ruminant products, or contaminated feed from countries with confirmed cases of BSE in native cattle until after the USDA initiated a policy directive to resume trade with a country known to have BSE. We will show that the APHIS risk analysis supporting the proposed rules is outdated, inadequate, and fails to quantify any potential benefit to the United States live cattle industry in return for assuming the greater risk associated with relaxing the United States regulations. We will then describe how the proposed rule fails to provide United States producers with the ability to differentiate their product and consumers with additional product information commensurate with the increased risk associated with importing ruminant and ruminant products from a BSE infected country. Finally, we will demonstrate that the proposed animal identification system is inadequate.

PART I

A. Brief History of Current USDA Rules

BSE became a reportable disease in the United States in 1986.^{1[1]} The United States subsequently established its regulatory safeguards to prevent the introduction of BSE in a multi-step process. It first prohibited the importation of ruminants and certain ruminant products in

^{1[1]} Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States, Harvard Center for Risk Analysis, Harvard School of Public Health, November 26, 2001, p. 41.

1989 and then strengthened this prohibition to include ruminant meat and edible products and certain byproducts from countries known to have BSE in a native animal in 1991.^{2[2]} In 1990, the United States began active disease surveillance efforts.^{3[3]} The Food and Drug Administration (FDA) then instituted a feed ban in 1997 to prevent recycling of potentially infectious cattle tissues.^{4[4]}

The United States did not ban the import of milk and milk products, non-edible ruminant products, and gelatin (though there are certain restrictions on gelatin) consistent with the recommendation of the World Organization for Animal Health (OIE) which had determined that such products should be traded without restriction regardless of the BSE status of the exporting country, thus implying that they are not capable of transmitting the BSE agent.^{5[5]}

B. The Proposed Rules Are More Lenient Than the Minimally Accepted Scientific Standards Adopted by the OIE and APHIS is Arbitrarily Picking and Choosing which Standards it Intends to Dismiss and which Standards it Intends to Exceed, All Without Any Internationally Accepted Scientific Basis

The World Organization for Animal Health or Office International des Epizooties (OIE) sets international standards for managing the human and animal health risks associated with BSE. As APHIS acknowledged in its proposed rule, the OIE recommendations are recognized by the World Trade Organization (WTO) as international recommendations for animal disease control.^{6[6]} Among the stated missions of the OIE is “To guarantee the sanitary safety of world trade by developing sanitary rules for international trade in animals and animal products.”^{7[7]} To accomplish this mission, “The OIE develops disease prevention standards that Member Countries can use to protect themselves from diseases, without setting up unjustified sanitary barriers.”^{8[8]} Among the relevant standards relevant to the instant APHIS proposal is the International Animal Health Code. There are 165 member countries, including the United States, which are members of the OIE.

Importantly, the OIE offers expertise to the poorest countries to “help them control animal diseases that cause livestock losses, presents a risk to public health and threaten other member countries.”^{9[9]}

The procedure by which the OIE establishes its standards is relevant in that the standards set forth in the Terrestrial Animal Health Code are prepared by elected Specialist Commissions and Working Groups bringing together internationally renowned scientists, most of whom are

²[2] Id.

³[3] Id. at 44.

⁴[4] Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States, Harvard Center for Risk Analysis, Harvard School of Public Health, November 26, 2001, p. ii.

⁵[5] Terrestrial Animal Health Code, 11th Edition – 2003, Office International des Epizooties.

⁶[6] Federal Register, Vol. 68, Number 213, at 62388.

⁷[7] What is the OIE? Webpage of the Office International des Epizooties, available at http://www.oie.int/eng/oie/en_oie.htm, obtained from the Internet on 1-02-04.

⁸[8] Id.

⁹[9] Id.

experts within the network of OIE's 152 collaborating centers and reference laboratories. The recommendations of the Specialist Commission are then voted on for adoption by the OIE delegates at the General Session.¹⁰[10]

Thus it is that the OIE standards are initiated by international scientists, affording the OIE with a solid, internationally accepted scientific basis, and then finalized through a more politicized process allowing OIE delegates to take into account such factors as the economic and political ability of poorer countries to meet necessary criterion, for example. It can be presumed that such a structure which combines both science and politics results in standards that are universal in nature and should be viewed as the minimal standards that must be met to effectively control a particular animal disease, including the introduction of BSE into the United States cattle herd.

It is important to note that the OIE, in its formulation of its BSE standards, was fully cognizant of the European Union's vehement opposition to a zero-risk approach to protecting animal health.¹¹[11] The main objective of the EU animal health policy is "reaching and maintaining a high status of animal health throughout the EU, which is essential for . . . establishment and functioning of the EU single market (which is not compatible with a zero-risk approach!)"¹²[12] For the EU, which has had outbreaks of BSE in most, if not all EU Member States, and which must work to harmonize legislation binding on all EU Member States, it makes sense that it would adopt a position whereby its Member States would "Live up to the risks"¹³[13] associated with the establishment of trade rules. ¹⁴[14] Obviously, if the EU did not subscribe to such a position and instead adopted a zero-risk approach to the trade of livestock and ruminant products within the EU, trade in these commodities would likely cease given their current disease situation.

The OIE has established five separate risk categories to enable a scientific evaluation of the BSE risk associated with the trade of cattle; fresh meat and meat products from cattle; gelatin and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices; and tallow. The five categories are, from lowest to highest risk: BSE Free, BSE Provincially Free, Minimal BSE Risk, Moderate BSE Risk, and High BSE Risk.¹⁵[15] In contrast, the United States recognize three categories: A Region Free of BSE, A Region in Which BSE is Known to Exist, and A Region that Presents an Undue Risk of BSE.¹⁶[16] The United States' standards are consistent with the OIE Code in that the United

¹⁰[10] Id.

¹¹[11] Alberto Laddomada, The EU Approach to Regionalization, The Example of Classical Swine Fever, European Commission, DG Health and Consumer Protection, presented to United States Industry Representatives in Brussels, Belgium on December 17, 2003.

¹²[12] Id.

¹³[13] Dr. Alf-Eckbert Fussel, EC Legislation on FMD, European Commission – DG Health and Consumer Protection, presentation to United States Industry Representatives in Brussels, Belgium on December 17, 2003.

¹⁴[14] Dr. Alf-Eckbert Fussel, EC Legislation on FMD, European Commission – DG Health and Consumer Protection, presentation to United States Industry Representatives in Brussels, Belgium on December 17, 2003.

¹⁵[15] Terrestrial Animal Health Code, 11th edition – 2003, Part 2, Section 2.3, Chapter 2.3.13. et.seq., Office International des Epizooties.

¹⁶[16] Federal Register, Vol. 68, No. 213, at 62387.

States essentially recognizes the OIE's two BSE Free categories as containing countries that may trade with the United States without restriction, and the United States two additional categories contain country's whose disease status is lower than the OIE's "BSE Provincially Free" and falling within any one of the OIE's higher risk categories. The United States chooses to prohibit ruminant and ruminant-product trade with these countries because they do not qualify under the OIE standards as BSE free countries.

Thus the OIE standards provide guidance for Members with vary different objectives. The EU, for example, can choose to adopt the OIE risk mitigating measures to minimize the associated risks when trading among and between their Member States that have a "high BSE risk." The United States, likewise, can adopt the OIE's standards for ascertaining a country's BSE risk based on the criterion established by OIE, and it can choose to trade only with countries that are determined to be free of BSE. This is what the United States has done since the implementation of its current BSE mitigation rules. And, it is precisely what the United States should continue doing until Canada is recognized by the OIE as being free of BSE. Perhaps APHIS should review the stringent BSE-related import regulations of Australia, the largest exporter of beef in the world and a major competitor to the United States live cattle industry, before APHIS considers initiating steps that would competitively disadvantage the United States cattle producer.

The United States has long measured its BSE mitigation efforts against the recommendations of the OIE. As a result, there is an implicit expectation among animal industry participants that the United States would both recognize and respect the disease categories of the OIE as they pertain to guaranteeing the sanitary safety of world trade vis-à-vis diseases like BSE. The OIE uses seven years as the period in which a country or zone must have no case of BSE in indigenous cattle in order to achieve a BSE Free status, representing the lowest level of risk.¹⁷[17] A country that has a case of BSE in an indigenous animal can achieve no higher rating than a "Moderate BSE Risk" unless it has implemented a feed ban for at least 8 years, regardless of the country's BSE incidence rate. The criterion requiring an 8-year feed ban before a country can achieve a "Minimal BSE Risk" status is significant as it reflects the scientifically-based risk associated with the long incubation period of BSE. Canada is not eligible for a "Minimal BSE Risk" designation by the OIE because its feed ban has only been in place for 6 years.¹⁸[18]

Under no circumstances should APHIS attempt to redefine a "Minimal Risk Region" in contradiction to the internationally accepted "Minimal BSE Risk" category established within the OIE Code. This is particularly important given the recent announcement of the OIE expert group which considered the United States' request on September 26, 2003, 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."¹⁹[19]

¹⁷[17] Bovine Spongiform Encephalopathy, Chapter 2.3.13, International Animal Health Code -2003, World Organization for Animal Health, available at http://www.oie.int/eng/normes/mcode/A_00067.htm.

¹⁸[18] 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 9.

¹⁹[19] 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.

Obviously, there may be compelling reasons for a nation to require actions well beyond the minimal requirements adopted by the OIE. Indeed, the United States, in its efforts to alleviate public fear following the announcement of a BSE infected cow in Washington State touted the fact that the United States tests far more animals than is required by the OIE. “For the last two years we conducted approximately 20,000 tests each of those two years -- more than 45 times what the World Animal Health Standard would call upon us to test,” stated Dr. Ron DeHaven, Chief Veterinarian for USDA.²⁰[20] Secretary of Agriculture Ann Veneman also demonstrated the United States resolve to prevent the spread of BSE by touting the superiority of the United State’s BSE testing procedure. On December 30, 2003, she said, “The United States has tested over 20,000 head of cattle for BSE in each of the past two years, 47 times the recommended international standard.”²¹[21] It would be unconscionable for USDA-APHIS to unilaterally establish BSE risk categories that fail to meet the scientifically based and internationally accepted minimal standards of the OIE.

C. No New Scientific Evidence Has Been Produced to Suggest that the United States’ Current Rules and Policies Are Not Yet an Essential Element in Preventing the Introduction of BSE into the United States from Canada

The Canadian BSE investigation has not produced any new scientific evidence to suggest that the United States’ current policies are not yet an essential element in preventing the spread of BSE from Canada to the United States. In fact, the Canadian investigation came up woefully short in that it could not determine the contamination source of the BSE agent. While Canada claims to have implemented a feed ban in 1997, the index cow was reported to have been six to eight years old.²²[22] The Canadian review team reported:

Canadian experts have established epidemiological evidence that supports the probability that the expression of BSE in the case animal was associated with exposure to infected material through the feeding system at some point early in the life of the animal.²³[23]

Therefore, this cow could well have contracted BSE after Canada’s feed ban was in place.

Even more alarming is that the BSE infected cow discovered in Canada on May, 20, 2003 was rendered in Canada and APHIS reported that the rendered cow could have been distributed

²⁰[20] Transcript of Technical Briefing and Webcast with U.S. Government Officials on BSE Case, Monday, December 29, 2003, available at <http://www.usda.gov/news/releases/2003/12/0447.htm>, obtained from the Internet on January 2, 2004.

²¹[21] Veneman Announces Additional Protection Measures to Guard Against BSE, USDA News Release, Release No. 0449.03, December 30, 2003.

²²[22] Summary of the Report of the Investigation of Bovine Spongiform Encephalopathy (BSE) in Alberta, Canada, July 2, 2003, available at <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/evalsume.shtml>, downloaded August 18, 2003.

²³[23] Report on Actions taken by Canada in Response to the Confirmation of an Indigenous Case of BSE, Canadian Food Inspection Agency, available at <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/internat.shtml>, downloaded August 18, 2003.

to approximately 1800 sites, including 1200 individual producers or consumers.²⁴[24] The chief mechanism for determining the disposition of the remains of the rendered cow was a survey that revealed that 1 to 3 percent of the possible distribution sites had incremental or limited exposure, “examples included cattle breaking into feed piles, sheep reaching through a fence to access feed, and a goat with possible access to a feed bag.”²⁵[25] Canada, therefore, is not able to definitively state that the remains of the rendered cow have not been consumed by cattle in Canada. This raises the possibility that a new cycle of BSE may have begun in Canada as a result of rendering this cow in 2003. APHIS reinforces this concern by stating in its risk analysis that it cannot be assumed that there is complete compliance with a feed ban.²⁶[26]

APHIS suggests it can mitigate this lack of compliance with a feed ban using a joint Canadian Food Inspection Agency (CFIA) and USDA-Food Safety Inspection Service (FSIS) certification process. Until the USDA-APHIS can establish a certification process for Canada that can be better enforced than the feed ban itself, R-CALF USA does not believe the APHIS recommendation is adequate to prevent the introduction of BSE into the United States.

Less than a year ago, in October 2002, the scientific-based World Health Organization issued its international report “Understanding the BSE Threat.” This report states:

Of all the lessons learned from the BSE epidemic in the UK, one in particular stands out: BSE is a threat that must be taken seriously by all. . . Countries with no detected case of BSE should not become complacent in the face of a potential global epidemic. The extremely low initial incidence and the low within-herd incidence of BSE cases, long incubation period, and non-specific nature of the early clinical signs can delay the detection of the first cases of disease and mask epidemic spread.²⁷[27]

R-CALF USA does not understand why USDA is willing to subject the U.S. cattle industry to the unnecessary risk associated with importing live cattle and edible ruminant products from a country known to have BSE, especially given the lack of any internationally accepted scientific evidence to establish the new risk exposure associated with doing so. It remains scientifically recognized that the U.S. ban on the import of live ruminants and ruminant meat that has since been expanded to 24 countries, including Canada, is the United States’ main line of defense against the introduction of BSE.

R-CALF USA views APHIS as the United States cattle industry’s principle line of defense from the incursion of foreign diseases. Given the volatility of current worldwide conditions, now is not the time to relax any safeguards or restrictions. R-CALF USA implores APHIS to immediately upgrade its present safeguards and restrictions for all imported beef and cattle and to mobilize all its available resources to vigorously enforce these restrictions.

²⁴[24] 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.

²⁵[25] Id.

²⁶[26] Id. at 16.

²⁷[27] Understanding the BSE Threat, World Health Organization, Document WHO/CDS/CSR/EPH/2002.6, October 2002, p. 19.

PART II

A. USDA's Current Rules Have Been Scientifically Validated as Essential Elements of the United States' BSE Defense Strategy

Notwithstanding the December 23, 2003 confirmation of a BSE case in a cow affixed with a Canadian ear tag in Washington States which proves that current USDA rules were insufficient to protect the U.S. live cattle industry and U.S. consumers from the introduction of BSE, the USDA's current BSE rules have twice been scientifically validated by USDA's own choice of an independent scientific institution, and this institution agreed that the USDA's rules are essential elements of the United States' BSE defense strategy.

The Harvard Center for Risk Analysis has twice evaluated "the robustness of U.S. measures to prevent the spread of bovine spongiform encephalopathy (BSE or 'mad cow disease') to animals and humans if it were to arise in this country."²⁸[28] The first comprehensive evaluation completed in November, 2001, began in 1998, and took three years to complete. This initial scientific evaluation stated:

Measures in the U.S. that are most effective at reducing the spread of BSE include the ban on the import of live ruminants and ruminant meat and bone meal from the UK (since 1989) and all of Europe (since 1997) by USDA/APHIS, and the feed ban instituted by the Food and Drug Administration in 1997 to prevent recycling of potentially infectious cattle tissues.²⁹[29] [Note: At the time of this scientific evaluation, there were no cases of BSE reported outside of Europe.]

The 2001 Harvard evaluation concluded that "measures taken by the U.S. government and industry make the U.S. robust against the spread of BSE to animals or humans should it be introduced into this country."³⁰[30] In addition, the Harvard evaluation concedes that if the United States becomes infected with BSE, the disease should be eliminated within 20 years of its introduction. However, this prediction assumes that the conditions affecting the spread of BSE, i.e., the current USDA rules, remain unchanged for the 20 years following its introduction.³¹[31]

The 2003 Harvard evaluation built upon the 2001 Harvard evaluation and uses the same simulation model. This second evaluation did not change the fundamental assumption that USDA rules would remain in effect. It, too, concluded that in the event of a BSE introduction in

²⁸[28] Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States, Harvard Center for Risk Analysis, Harvard School of Public Health, November 26, 2001, at i.

²⁹[29] Id. at ii.

³⁰[30] Id. at iv.

³¹[31] Id. at i.

the United States through contaminated feed or an infected animal, BSE would likely be eliminated by 2020.³²[32]

The USDA's rules have been scientifically validated by an independent scientific institution. The scientific validation of USDA's rules assumes that the rules would remain in effect when it predicted the United States could eradicate the disease within 20 years. That scientific validation further concludes that, based on the current USDA rules, the United States is robust against the spread of BSE. USDA-APHIS has represented these rule-dependent evaluations to Congress and the public as scientific evidence of the United States' ability to prevent or subsequently contain BSE. Given the strong political, economic, and public trust placed in the effectiveness of these scientifically validated rules, these rules should not be relaxed without a comprehensive scientific re-evaluation of the implications of relaxing current USDA rules.

R-CALF USA contends that the possible risk of waiting 20 years to eradicate BSE should it enter the United States is itself an unacceptable risk to the United States live cattle industry.

B. The United States Secretary of Agriculture has Repeatedly Assured Congress and the Public that Current Regulations Provide the Fundamental Protection Needed to Prevent the Introduction of BSE Into the United States, Thereby Shaping Congress's and the Public's Perception that the United States Current BSE Safeguards are Sufficient to Ensure that it is Highly Resistant to Any Introduction of BSE or a Similar Disease

Notwithstanding APHIS's current efforts, the USDA has made numerous assurances to Congress that its current rules are effective in preventing the introduction of BSE in the United States. The Secretary of Agriculture in her January 2003 BSE report to Congress, stated, "Since 1989 APHIS has prohibited the importation of live ruminants from countries where BSE is known to exist in native cattle."³³[33] In addition, the report contained the following highlights:

The U.S. approach to managing the risk of BSE is focused on three primary goals:

- Prevent the agent of BSE from entering the United States and infecting U.S. cattle;
- Prevent the amplification of the agent of BSE throughout the U.S. cattle herd, were it to penetrate the primary firewall at the borders and infect U.S. cattle; and
- Prevent the exposure of Americans to the agent of BSE via food and other products that are fully or partially of bovine derivation.³⁴[34]

³²[32] Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the United States from Canada, Joshua T. Cohen and George M. Gray, Harvard Center for Risk Analysis, Harvard School of Public Health, at

³³[33] This is not inconsistent with the fact that the United States continued to import live cattle from Canada following Canada's 1993 case of BSE. The 1993 case was determined to be from an animal imported directly from a foreign country. The OIE distinguishes an "indigenous" case of BSE from a BSE case demonstrated as "originating directly from the importation of live cattle." In the latter case, the 7 year period does not apply in order for a country to retain its BSE Free status.

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

The report further informed Congress:

The U.S. Government's actions to restrict imports from Europe have played an important role in excluding BSE from this country. Since 1989 APHIS has prohibited the importation of live ruminants from countries where BSE is known to exist in native cattle. Other products derived from ruminants (for example, meat and meat products, fetal bovine serum, meat-and-bone meal, blood meal, offal, fats, and glands) are also prohibited from entry, except under special conditions or under USDA permit for scientific or research purposes. These restrictions were initially applied to the United Kingdom in 1989, and then were applied to each country that subsequently identified native cases of BSE. In 1997 APHIS extended these restrictions to include most of the countries in Europe, due to concerns about widespread risk factors and inadequate surveillance for BSE. As of December 2000, USDA prohibited all imports of rendered animal protein products, regardless of species, from BSE-restricted countries. This decision followed the recent determination by the European Union that feed of non-ruminant origin was potentially cross contaminated with the BSE agent. The restriction applies to products originating, rendered, processed or otherwise associated with products from BSE-restricted countries. When BSE was recently identified outside Europe, in native-born cattle in Japan, APHIS restricted imports of ruminants and ruminant-origin products from there also.³⁵[35]

Moreover, USDA's current guidelines for the importation of cattle into the United States from countries other than Canada and Mexico require "that the animals were born, raised, and continuously resident in a country recognized by USDA as free of FMD, BSE, and rinderpest."³⁶[36] Further, the guidelines state, "Cattle from countries affected with bovine spongiform encephalopathy (BSE) OR foot-and-mouth disease (FMD), OR rinderpest are not permitted to be imported into the United States."³⁷[37] R-CALF USA respectfully submits that now that BSE has crossed the Atlantic, the current APHIS rules prohibiting the importation of live cattle fresh, chilled or frozen meat, meat products and edible products other than meat are essential to protecting the health and safety of United States consumers and the United States cattle herd.

C. Effectiveness of Current USDA Regulations in Achieving the United States' Goal of Preventing the Introduction of BSE into the United States

Since the initial outbreaks of BSE occurring in the United Kingdom in the mid- to late 80s, BSE is known to have spread to 23 additional countries.³⁸[38]

³⁵[35] Id. at 50.

³⁶[36] Guidelines for the Importation of Cattle (ruminants) Into the United States (except from Canada and Mexico), USDA-APHIS, available at http://www.aphis.usda.gov/vs/ncie/cattle_ruminants.html, downloaded on May 28, 2003.

³⁷[37] Id.

³⁸[38] Number of Reported Cases of Bovine Spongiform Encephalopathy (BSE) Worldwide (excluding the United Kingdom, World Organization for Animal Health, Updated December 31, 2003, available at http://www.oie.int/eng/info/en_esbmonde.htm, obtained from the Internet on January 2, 2004.

Since 1989, nearly one-half (11) of the 23 non-U.K. countries with reported cases of BSE each reported only one case of BSE in the calendar year during which the first case was reported. Nearly two-thirds (7) of these countries which reported only a single case of BSE during the initial year of discovery had subsequent outbreaks of BSE, either during the following year or, in the case of 4 countries, several years later. For example, the period between the first case and second or more cases for Denmark was 8 years; for Germany, 2 years; and for Luxembourg, 5 years.³⁹[39] Based on the Canadian ear tag attached to the BSE infected cow discovered in Washington State, Canada has now had two cases of BSE within a 7-month period.

The frequency of BSE cases among the 23 countries other than the U.K. that have reported one or more cases of BSE since 1989 has increased significantly over the past three years. The total numbers of BSE cases reported by the 23 non-United Kingdom countries that reported one or more cases of BSE has increased from 513 cases in 2000 to 652 cases in 2003, with 6 of the 23 countries not yet reporting their 2003 cases.⁴⁰[40]

Moreover, BSE has been rapidly spreading to new countries since 2000. In 1999 only 12 countries in addition to the U.K. had reported one or more cases of BSE. By end of year 2003, as stated previously, there are now 23 countries in addition to the U.K. reporting one or more cases of BSE. ⁴¹[41] BSE has only recently crossed the Atlantic as evidenced by the May 20, 2003 Canadian case of BSE found in a native Canadian cow and the second case discovered on December 23, 2003, in a cow that, according to its ear tag and associated Canadian records, was imported from Alberta, Canada, in 2001. This data demonstrates that the geographical distribution of BSE has increased by 92 percent since 2000.⁴²[42] Therefore, the worldwide spread of BSE is not yet contained. Just since 2000, the countries of Austria, Canada, Czech Republic, Denmark, Finland, Greece, Israel, Italy, Japan, Poland, Slovakia, Slovenia, and Spain have all had one or more confirmed cases of BSE originating in native cattle.⁴³[43]

The OIE uses a 7-year period in which a country must have no cases of BSE in order to qualify for a BSE free designation, presumably due to the long incubation period associated with BSE. While this 7-year period is not the only criterion, it is the common criterion for all the OIE categories.⁴⁴[44] To date, not a single country that has reported a case of BSE has gone without reporting at least one BSE case in the preceding 7 years. This raises the question of why APHIS feels compelled to relax the current rules designed to protect the United States from the introduction of BSE when not a single country which APHIS has listed under 9 CFR 94.18 (a) (1) as regions in which BSE is known to exist, can qualify as either a BSE free or BSE provincially free country according to the international scientific standards established by the World Organization for Animal Health (OIE).

³⁹[39] Id.

⁴⁰[40] Id.

⁴¹[41] Id.

⁴²[42] Id.

⁴³[43] Number of Reported Cases of Bovine Spongiform Encephalopathy (BSE) Worldwide (excluding the United Kingdom, World Organization for Animal health, available at http://www.oie.int/eng/info/en_esbmonde.htm.

⁴⁴[44] Terrestrial Animal Health Code, 11th edition – 2003, Part 2, Section 2.3, Chapter 2.3.13., Office International des Epizooties.

To the extent that the existing USDA rules are intended to prevent the introduction of BSE into the United States, the discovery of a BSE case in a Washington State dairy cow affixed with an ear tag indicating it was imported from Canada in 2001 reveals that the existing rules are not sufficiently robust to protect the U.S. cattle industry and the United States consumer from the introduction of BSE.

D. USDA-APHIS Has Not Adequately Enforced Its Existing BSE Regulations, Thereby Subjecting the United States Cattle Industry and United States Consumer to Unnecessary Risk

Despite APHIS's current efforts to expose the U.S. cattle industry and consumers to a greater risk to BSE by relaxing current safeguards, USDA has recently experienced several close calls indicating its enforcement of existing safeguards is inadequate. For example:

The New York Times reported in August, 2001, that a total of 756,000 pounds of prohibited European meat was discovered in U.S. inspection warehouses in at least three states, indicating that United States BSE safeguards were not being adequately enforced by USDA.

In February of 2002, R-CALF USA obtained a report from the USDA-Economic Research Service (ERS) identifying 27 countries that exported beef to the United States in 2001. On the ERS report were nine countries with confirmed cases of BSE. R-CALF USA cross-checked this report with the USDA Foreign Agricultural Service (FAS) which indicated that the United States imported beef from three countries with confirmed cases of BSE. R-CALF USA contacted APHIS which did not confirm or deny that the United States was importing beef from countries prohibited from exporting beef to the United States because they were listed as regions where BSE is known to exist. R-CALF USA submitted two separate Freedom of Information Act (FOIA) requests in an attempt to either confirm or deny the ERS and FAS reports. To date, USDA-APHIS has failed to respond to R-CALF USA's February 21, 2002 FOIA request (FOIA number 02-248), or to R-CALF USA's second FOIA request of March 14, 2002 (FOIA No. 02-266), strongly suggesting that APHIS does not know if the U.S. imported prohibited products from various countries in 2001.

In August of 2001, APHIS considered the country of Slovakia as a "substantial risk associated with BSE due to lack of implementation of an adequate surveillance program."⁴⁵[45] Yet, on August 13, 2001, the USDA proposed a rule in the Federal Register to add Slovakia to the list of countries eligible to export meat products into the United States.⁴⁶[46] Even before the expiration of USDA's October 12, 2001 comment period, Slovakia announced it had its first case of BSE, with four more cases reported by December 31, 2001; six cases in 2002, and another case in 2003.⁴⁷[47]

⁴⁵[45] Addition of Slovakia to the List of Countries Eligible to Export Meat Products Into the United States, Comments to USDA by R-CALF USA, September 5, 2001.

⁴⁶[46] Federal Register, Vol. 66, No. 156, August 13, 2001.

⁴⁷[47] Number of Reported Cases of Bovine Spongiform Encephalopathy (BSE) Worldwide (excluding the United Kingdom, World Organization for Animal Health, available at http://www.oie.int/eng/info/en_esbmonde.htm.

On September 10, 2001, the Associated Press reported Japan's first case of BSE. The Associated Press article stated that Japan only began prohibiting the importation of animal feed from Europe in 2001.^{48[48]} Given that Japan did not implement internationally recommended feed import restrictions, and because Japan's import requirements were less restrictive than those that would be acceptable for import into the United States, APHIS should have included Japan as a region that presents an undue risk of BSE following the United States' 1997 feed ban. However, USDA-APHIS did not recognize this deficiency and according to the USDA livestock Marketing Information Center, Japan continued to export fresh and chilled boneless processed cuts of beef into the United States at the rate of 33,510 pounds in 1999 and 5,290 pounds in 2000.

Given the immediate and substantial drop in live cattle prices following the announcement of the United States' first case of BSE, and which drop occurred despite the fact that the cow's ear tag indicated it was imported from Canada, R-CALF USA firmly believes that USDA-APHIS would better serve the United States live cattle industry and United States consumers by focusing its limited resources toward the effective enforcement of its existing BSE regulations, including the active monitoring of the specific BSE mitigation efforts of all United States trading partners to ensure that they are at least as stringent as the United States' regulations rather than to work to subject the industry and consumers to an even greater risk associated with relaxing its current regulations.

E. USDA-APHIS Would Have Avoided the December 23, 2003, BSE Case Discovered in an Imported Cow if it had Properly Responded to the Mitigation Steps Requested by the United States Live Cattle Industry

R-CALF USA has demonstrated within these comments that APHIS should not relax its current regulations established to protect the United States from the introduction of BSE. In addition, R-CALF USA has specifically called for the strengthening of existing protective measures. Specifically, in January of 2001, R-CALF USA's membership adopted a resolution calling for a moratorium on all imports of live cattle, beef, pre-cooked beef and all beef products for a period of three years in order to give the USDA sufficient time to implement stronger BSE and FMD safeguards.^{49[49]}

On March 26, 2001, R-CALF USA sent a letter to President Bush stating its support for the 15 western state veterinarians, Senator Daschle, and others that called for an immediate moratorium on all animals, cut products, and byproducts until the United States took additional measures to protect itself from the incursion of Foot and Mouth Disease (FMD) and BSE.^{50[50]}

R-CALF USA aggressively called on the Administration and Congress to implement the moratorium until stricter safeguards were in place to protect the United States live cattle industry and United States consumers from BSE. In meetings with USDA officials and Congressional Members in June of 2001, R-CALF USA urged the implementation of a moratorium and urged

^{48[48]} Japan May Have Asia's First Case of Mad Cow Disease, Associated Press Article, September 10, 2001.

^{49[49]} R-CALF USA Membership Resolutions, 2001, available at the R-CALF USA office.

^{50[50]} R-CALF USA Letter to the President, March 26, 2001.

the USDA to accurately determine the level of risk our trading partners face relative to FMD and BSE.⁵¹[51] In testimony before the United States Senate Agriculture Committee on July 25, 2001, R-CALF USA testified that “The USDA has not been as vigilant as needed to protect the cattle industry.”⁵²[52]

If the United States had timely responded to the request of R-CALF USA, which request was made at the behest of the U.S. live cattle industry, to implement a temporary moratorium in response to the then rapid spread of BSE and FMD, the BSE infected cow whose ear tag indicates it was imported from Canada in October of 2001 would have been denied entry into the United States.

PART III

A. The USDA did Not Conduct a Risk Assessment that Specifically Addresses the Probability of Introducing BSE Via Live Cattle, Ruminant Products, or Contaminated Feed From Countries with Confirmed Cases of BSE in Native Cattle Until After the USDA Initiated a Policy Directive to Resume Trade With a Country Known to Have BSE

The World Organization for Animal Health or Office International des Epizooties (OIE) recommends that countries evaluate the outcome of a risk assessment identifying all potential factors for BSE occurrence.⁵³[53] Of greatest concern to the United States live cattle industry is the specific risk associated with the calculated probability of introducing BSE through the importation of live cattle, ruminants, or contaminated feed from a country with a native case of BSE or a country that has not implemented the full range of BSE mitigation measures at the same time as did the United States. The USDA has not calculated the probability of risk associated with current USDA trade policies and is, consequently, functioning in a reactionary mode rather than a preventive mode as would be preferred by the U.S. live cattle industry.

Neither of the aforementioned Harvard evaluations addressed this specific risk. Instead, the 2001 Harvard evaluation only evaluated the United States measures to “prevent the spread of bovine spongiform encephalopathy (BSE or “mad cow disease”) to animals and humans if it were to arise in this country.” (Emphasis added.) The Harvard evaluation merely presumed that imports of live cattle from Canada and Mexico are “extremely unlikely to pose a risk of introducing BSE to the U.S.”⁵⁴[54] The updated, 2003 Harvard evaluation specifically stated that it did not calculate the probability of introducing BSE from either Canadian live cattle or

⁵¹[51] Protection from BSE and FMD, R-CALF USA Position Brief, June 15, 2001, Distributed to the USDA, USTR, DOC and Members of Congress during June 17, 2003, Washington, D.C. Fly-in.

⁵²[52] R-CALF USA Testimony: Farm Bill Can Restore Producers’ Share of Consumer Beef Dollar, R-CALF USA News Release, July 25, 2001.

⁵³[53] Terrestrial Animal Health Code, 11th edition – 2003, Part 2, Section 2.3, Chapter 2.3.13., Office International des Epizooties.

⁵⁴[54] Id. at 22.

feed because of the “absence of strong evidence about the prevalence of BSE in the Canadian herd.”⁵⁵[55]

It remains particularly frustrating to the United States live cattle industry that the USDA’s primary focus is on managing the BSE disease after its occurrence rather than to prevent its introduction in the first place. This concern is heightened by the Harvard evaluations that strongly suggest it would take 20 years to eradicate the disease following its introduction into the United States. Moreover, these scientific evaluations clearly state that the primary risks of introducing BSE into the United States is through the importation of live cattle and feed, factors over which APHIS has clear jurisdiction.

The initial 2001 Harvard evaluation identified three possible sources and pathways by which BSE could be introduced in the United States. It identified 1) the development of a spontaneous BSE case, 2) importation of an infected animal into the U.S., 3) contamination from recycled products, i.e., contaminated feed, 4) cross-contamination from related diseases such as Chronic Wasting Disease (CWD), Scrapies, or other TSE diseases.⁵⁶[56] However, this field of possible sources was narrowed by the second, 2003 Harvard evaluation to only two plausible sources of introducing BSE into the United States from Canada, and presumably from any other exporting country. The 2003 Harvard evaluation states:

Based on the CFIA [Canadian Food Inspection Agency] finding that CWD, scrapie, and the spontaneous development of disease are unlikely to have caused the BSE case in Canada, it appears that any related introduction of BSE into the U.S. from Canada would have been due to the import of either infected animals or contaminated feed.⁵⁷[57]

APHIS acknowledges the findings of the Harvard evaluations which found that the United States’ primary risk of BSE infection was from imported ruminants and ruminant products. In its proposed rule, APHIS emphatically states:

Ruminants in the United States could be exposed to the disease [BSE] if materials carrying the BSE agent – such as certain meat, animal products, or animal byproducts from ruminants – were imported into the United States and were fed to ruminants in this country. BSE could also be introduced into the United States if ruminants with BSE were imported into the United States.⁵⁸[58]

⁵⁵[55] Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the United States from Canada, Joshua T. Cohen and George M. Gray, Harvard Center for Risk Analysis, Harvard School of Public Health, at 2.

⁵⁶[56] Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States, Harvard Center for Risk Analysis, Harvard School of Public Health, November 26, 2001, p. 41.

⁵⁷[57] Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the United States from Canada, Joshua T. Cohen and George M. Gray, Harvard Center for Risk Analysis, Harvard School of Public Health, at 2.

⁵⁸[58] Federal Register, Vol. 68, No. 213, November 4, 2003, at 62386.

R-CALF USA has been cognizant of the fact that BSE is not indigenous to the United States and that only through the inadequacy of United States' trade policies would the BSE disease be introduced into the United States cattle herd. This is why, again, R-CALF USA called for a moratorium on imports in 2001 and urged the USDA to accurately determine the level of risk our trading partners face relative to FMD and BSE.⁵⁹[59]

It was not until October of 2003 that the USDA-APHIS completed a risk assessment specifically addressing the risk of introducing BSE into the United States from importing live animals and ruminant products. However, this risk assessment was specific to Canada and conducted for the express purpose of supporting the agency's instant rule.⁶⁰[60] The analysis, therefore, should be viewed as a policy-driven position paper rather than an independent evaluation of the probability of introducing BSE from Canadian imports.

B. The APHIS Risk Analysis Supporting the Proposed Rules is Outdated, Inadequate, and Fails to Quantify any Potential Benefit to the United States Live Cattle Industry in Return for Assuming the Greater Risk Associated with Relaxing United States' Regulations

The APHIS analysis has been rendered non-applicable and outdated by the December 23, 2003 discovery of a BSE infected cow affixed with an ear tag indicating she was imported from Canada in 2001. APHIS's stated objective for its analysis was to "assess the risk of resuming trade in designated ruminants and ruminant products from Canada to the United States in view of the confirmation of a single case of BSE in Canada in 2003."⁶¹[61] (Emphasis added.) Given that USDA's primary line of inquiry regarding the origin of the latest BSE case is Canada, APHIS must change the objective of the analysis before its applicability to the United States live cattle industry can be ascertained.

Further, the analysis builds upon the conclusion of the Harvard Center for Risk Analysis which concluded that the introduction of BSE into the United States would be an "unlikely event."⁶²[62] Again, the fact that the remains of the BSE infected cow discovered in Washington State are known to have entered the food chain renders APHIS's analysis relative to human health issues likewise non-applicable and outdated.

APHIS's attempt to unilaterally designate Canada as a minimal risk country does not comply with the OIE's internationally accepted scientific standards,⁶³[63] and is in defiance of those standards following the OIE's September 2003 affirmation that the science backing the

⁵⁹[59] Protection from BSE and FMD, R-CALF USA Position Brief, June 15, 2001, Distributed to the USDA, USTR, DOC and Members of Congress during June 17, 2003, Washington, D.C. Fly-in.

⁶⁰[60] 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 6.

⁶¹[61] Id.

⁶²[62] Id.

⁶³[63] Terrestrial Animal Health Code, 11th edition – 2003, Part 2, Section 2.3, Chapter 2.3.13., Office International des Epizooties.

OIE's Code remains valid.⁶⁴[64] APHIS fails to address the likelihood that United States' beef export customers would reject the United States' proposed relaxation of its regulations. However, APHIS indicates the value of exports, including indirect and job losses, at risk is \$6.5 billion.⁶⁵[65] R-CALF USA fails to see any benefits to the United States live cattle industry or to consumers for assuming the greater risk embodied in the proposed rule.

APHIS has not properly analyzed the risk associated with Canada's inability to identify the source of the BSE case discovered on May 20, 2003. Given that Canada's feed ban was implemented in 1997, and that the BSE cow was infected while alive in Canada, there is a strong likelihood that other Canadian cattle have been exposed, presenting a likelihood that infected cattle still reside in Canada. It is important to note that given the 3 to 6-year incubation period associated with BSE; that the infected cow was 6 years of age;⁶⁶[66] and, again, that Canada could not identify the source of infectivity, it is possible that the infectious agent was consumed by the cow anytime prior to May of 2000, when she was approximately 3 years old. This possibility cannot be dismissed based on the Canadian investigative report. Because the analysis of this data lends itself to a range of possibilities, APHIS's analysis should have included the range of risk associated with importing cattle following Canada's first case of BSE. APHIS did not present the range of risk possibilities associated with this issue and, instead, presented only a best-case scenario in its analysis.

The APHIS analysis fails to disclose the dissimilarities between the BSE risk mitigation measures implemented by the United States versus the measures implemented by Canada, and the varying risks associated with these differing measures. For example: It appears that Canada's feed ban implemented in 1997 does not prohibit the feeding of "rendered animal fat from all species" to ruminants.⁶⁷[67] The United States' feed ban, however, does not include this exemption.⁶⁸[68] R-CALF USA does not know the related risks associated with this difference but believes this and other differences between the United States' and Canada's risk mitigation measures must be analyzed. Under no circumstances should the United States accept any cattle, beef, or beef products from countries that do not maintain identical or more stringent safeguard measures than is presently required in the United States and which have been enforced for at least as long as the United States'.

C. The Proposed Rule Fails to Provide United States Producers with the Ability to Differentiate their Product and Consumers with Additional Product Information Commensurate with the Increased Risk Associated with Importing Ruminant and Ruminant Products from a BSE Infected Country

The United States should immediately suspend all shipments of beef and beef products from Canada pending the conclusion of the investigation of the BSE infected cow discovered in

⁶⁴[64] 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.

⁶⁵[65] Id. at 34.

⁶⁶[66] Id. at 7.

⁶⁷[67] Canada: A Minimal BSE Risk Country, Canadian Food Inspection Agency, Animal Products, Animal Health and Production Division, October 2003.

⁶⁸[68] 21 CFR 589.2000, Animal Proteins Prohibited in Ruminant Feed, at 541.

Washington State. As a precondition to allowing any ruminant or ruminant product into the United States from Canada, the USDA should fully implement the existing mandatory country of origin labeling (COOL) law so consumers will have more specific knowledge as to the origin of beef, and cattle producers would be able to differentiate their product in the market place. This mitigation step will likely curb the negative price impacts United States' producers are presently experiencing.

D. The Proposed Animal Identification System Is Inadequate for the Purpose of Readily Identifying Cattle from Canada

The proposed ear tattoo consisting of the letters "CAN" is an inadequate and unreliable means of readily identifying Canadian cattle. R-CALF USA strongly recommends that a redundant system be adopted. A hot iron brand in combination with a tattoo and/or permanent ear tag would eliminate the possibility of losing the identifying mark should the animal's extremities be damaged, such as by freezing. The hot iron brand as required by APHIS on Mexican steers and spayed heifers would be a far more reliable identification method when backed up with an ear tag and/or tattoo.

CONCLUSION

R-CALF USA appreciates the opportunity to submit these comments to APHIS and, again, respectfully requests and opportunity to resubmit comments following the conclusion of the investigation of the Washington State BSE infected cow affixed with a Canadian ear tag.

Sincerely,

A handwritten signature in blue ink that reads "Leo R. Mc Donnell". The signature is written in a cursive, flowing style.

Cc: Members of Congress