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April 7, 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: Docket No. 03-080-1: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities – R-CALF USA's Addendum to Comments Submitted on January 5, 2004

Dear Administrator:

Thank you for the second 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 list Canada as the first region in this category.

The Ranchers-Cattlemen Action Legal Fund - United Stockgrowers of America (R-CALF USA) is a non-profit association representing over 52,000 cattle producers, of which 8,400 are voluntary, dues-paying R-CALF USA members and over 43,000 are members of R-CALF USA's 58 affiliated cattle associations. R-CALF USA represents U.S. cattle producers on issues concerning national and international trade and marketing and is dedicated to ensuring the continued profitability and viability of the U.S. cattle industry. R-CALF USA's membership consists primarily of cow-calf operators, cattle backgrounders, and independent feedlot owners. Various main street businesses are associate members of R-CALF USA.

R-CALF USA previously submitted comprehensive comments to APHIS on the proposed rule on January 5, 2004. In its 18-page January 5 comments, R-CALF USA urged APHIS to withdraw the proposed rule based on compelling scientific evidence that suggested that the regulations would expose the United States cattle industry to substantially greater and unnecessary risk that BSE would be introduced into a herd. Additionally, United States consumers would be subjected to both greater and unnecessary risk if the United States did not

continue to enforce its longstanding policy of prohibiting the importation of ruminants and ruminant products from any country known to have BSE.

Because APHIS was not moved by numerous requests to withdraw the proposed rule, including the comments submitted by R-CALF USA on January 5, 2004, we submit the following supplemental comments to further demonstrate that the proposed rule is reckless and irresponsible, and constitutes an endangerment of the health and economic viability of the United States cattle industry.

The APHIS proposal to amend its regulations to recognize a category of regions that present a minimal risk of introducing BSE into the United States via live ruminants and ruminant products, and to list Canada as the first region in this category should be withdrawn entirely for the following reasons:

1. The “Risk Analysis” Prepared by APHIS Does Not Provide an Adequate Basis for the Decision to Import Live Ruminants and Ruminant Products From Canada

In the November 4, 2003 and March 8, 2004 Federal Register notices of the proposed rule, APHIS asserts that the new “BSE minimal-risk region” category is supported by an October 2003 report entitled, “Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States” (the “Risk Analysis”), and a February 2004 “Explanatory Note” to supplement the Risk Analysis.¹ The Explanatory Note was filed after the December 23, 2003 discovery of a BSE-infected cow, of Canadian origin, in Moses Lake, Washington.

As demonstrated by the attached evaluation prepared by Dr. Louis Anthony Cox, Jr., a nationally recognized expert on risk analysis, the Risk Analysis provides only a superficial and rudimentary analysis of the risks posed by the proposed rule.² It lacks many of the key elements of a valid risk assessment.³ Little to no actual data was considered and, accordingly, the conclusions reached are expressed in vague, subjective terms.⁴ Such an analysis

¹ See 68 Fed. Reg. 62,386 (Nov. 4, 2003) and 69 Fed. Reg. 10,633 (March 8, 2004).

² L. A. Cox, Jr., Evaluation of the Adequacy and Appropriateness of Risk Analysis Used by the U.S. Department of Agriculture Animal and Plant Health Inspection Service in Support of Proposal To List Canada as a Bovine Spongiform Encephalopathy Minimal Risk Region (“Cox Evaluation”). A copy of Dr. Cox’s paper is attached to these comments as Appendix A.

³ Id. at 4.

⁴ Id.

is not a useful tool to use to make a decision on whether to take an action that could have a significant impact on human or animal health.⁵ According to Dr. Cox, at best, the Risk Analysis provides an interesting overview of the general risks of importing BSE-infected ruminants and ruminant products, and the safeguards in the proposed rule intended to reduce those risks.⁶ To fully understand the risks, a thorough, detailed, and methodologically valid risk analysis is needed. Dr. Cox states his conclusions regarding the adequacy of the Risk Analysis as follows:

In summary, the information provided by the Risk Analysis does not provide reasonable basis from which to make an informed decision on whether to reinitiate trade in ruminants and ruminant products with Canada. For at least the reasons discussed above, it does not provide a technically complete or sound risk analysis, as the term is usually understood. It does not provide the essential technical information needed to inform risk management decision makers about potential risks. This includes information about exposures, currently estimated true prevalence rates of BSE in Canada, frequencies of compliance and error rates, potential for unusually large or severe adverse consequences of BSE cases under some conditions, and remaining uncertainties. In the absence of such currently available risk assessment information, a decision based on the current USDA Risk Analysis will not be informed by an understanding of the relevant risks to US populations.⁷

A regulatory action such as this that can have a significant health and economic impact must only be made after the agency and the public have valid information on the actual risks posed by the action. Taking action without such information is irresponsible and a violation of the public's trust.

2. The Inadequate APHIS Risk Analysis Failed to Answer Key Questions Regarding the Impact of the Proposed Rule on Human Health

While the impact of the proposed rule on animal health and economic interests is extremely important, R-CALF USA believes that the paramount concern of a risk assessment should be the potential impact of the proposed rule

⁵ Id.

⁶ Id. at 6.

⁷ Id. at 19-20.

on the health and safety of U.S. consumers, and adopting a policy regarding imports of ruminants and ruminant products that results in the lowest risk of human exposure to BSE. While that may seem obvious, it is impossible to tell from the proposed rule, the APHIS Risk Analysis, or the Harvard University study, what effect, if any, the proposed rule will have on human health. The risk to human health has simply not been assessed. Dr. Cox states in his evaluation that the APHIS Risk Analysis did not address two key questions:

- (a) What is the probable change in human health risk (i.e., frequency and severity of adverse human health effects) that would be caused by each alternative risk management option considered (e.g., reopening the US to less restricted imports of Canadian ruminants vs. imposing different types of restrictions vs. keeping the status quo); and
- (b) How certain is the change in human health risk that would be caused by each proposed risk management action?⁸

It is now generally accepted that the agent that causes BSE, also causes a similar condition in humans known as variant Creutzfeldt-Jakob disease (“vCJD”). According to the World Health Organization “considerable epidemiological, neuropathological, and experimental data are consistent with the hypothesis that the agent that causes BSE in cattle also causes vCJD in humans.”⁹ Consumption of food contaminated with the BSE agent is thought to be the most likely way humans contract vCJD.¹⁰ Indeed, APHIS recognized that occurrences of vCJD is a public health consequence of the proposed rule.¹¹ However, APHIS fails to address at all the question of, even with the import restrictions in the proposed rule, how many new cases of vCJD could there be? None? One? Two? More? As Dr. Cox demonstrates, APHIS does not provide any real analysis of the risk.¹²

In its Risk Analysis, APHIS states:

Because of the limited scope of its regulatory authority, this APHIS analysis will not focus on human health issues, with one exception. Human health issues will be addressed solely in the

⁸ Id. at 4.

⁹ Understanding the BSE threat, World Health Organization, WHO/CDS/CSR/EPH/2002.6 (Oct. 2002), at 10.

¹⁰ Id.

¹¹ Risk Analysis at 3.

¹² Cox Evaluation at 6-7.

potential exposure of *and consequences to* humans should BSE infected material enter the United States AND enter the human food supply. Relevant to this, an evaluation conducted in the context of both human and animal health by the Harvard Center for Risk Analysis ... concluded that the United States is highly resistant to spread and establishment of BSE in the unlikely event of its entry into the United States.¹³

APHIS then devotes a mere two paragraphs to its conclusion on public health and, recognizing that “there are many unknown factors relative to the development of vCJD,” concludes that the “[r]isk of such public health consequences [i.e. vCJD] *should be* extremely low in the context of importation of BSE infected commodities from Canada.”¹⁴ Dr. Cox sums up the APHIS Risk Analysis as follows:

In summary, it is not clear what USDA’s “Risk Estimation” conclusions mean in terms of human or animal health impacts, or how they are derived from or supported by factual evidence and objective data. The resulting qualitative reassurances do not constitute an adequate “Risk Analysis”, as the essential components of what is usually meant by risk analysis are missing.¹⁵

The Harvard Risk Analysis similarly did not assess the risk of US consumers developing vCJD from imported cows or meat. The report provided:

The analysis is not a complete human health risk assessment in two respects. First, we do not quantify the probability that BSE will be introduced into the U.S. Hence, all our risk estimates are conditional on hypothetical scenarios. Second, although we quantify potential human exposure to BSE-contaminated food products, we do not estimate how many people will contract variant Creutzfeldt-Jakob Disease (vCJD). We have omitted quantitative treatment of both of these issues because the available information is inadequate.¹⁶

¹³ Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States, USDA – Animal and Plant Health Inspection Service, Veterinary Services, October 2003, at 7.

¹⁴ Id. at 33 (emphasis added).

¹⁵ Cox Evaluation at 7.

¹⁶ Harvard Study at 2.

R-CALF USA does not agree that limited information is a legitimate reason for not conducting a human health risk assessment. Furthermore, inadequate information does not obviate the need for a thorough human health risk assessment in the context of promulgating a rule that could have a significant adverse effect on human health. On the contrary, when maintaining the status quo will have no adverse impact on public health, and a proposed change could have a negative impact on public health, sound public health policy dictates that the change not be made until all information needed to adequately assess the public health risk is available, unless there is an overriding need to make the change before such information is available. Lower cattle prices simply cannot be such a need.

R-CALF USA is especially troubled by the lack of information on how this rule will effect human health. The proposed rule should not be promulgated until its potential impact on human health is fully assessed.

3. Secretary Veneman's Own Advisory Committee on Foreign Animal and Poultry Diseases Cautioned Her Against Making BSE-related Regulatory Decisions Until a More Thorough Scientific Risk Assessment is Completed.

The Secretary's Advisory Committee on Foreign Animal and Poultry Diseases reported:

“. . . [T]he Committee cannot adequately resolve the differing BSE risk assessment presented by the Subcommittee [International Review Subcommittee] compared to the assessment by Harvard University. . . The Committee must have this issue of risk resolved prior to completing its recommendations to the Secretary. It is imperative that the Secretary has the best available science and more precise risk assessments in order to make appropriate regulatory decisions.”¹⁷

After establishing that there is a major discrepancy between the scientific risk assessments completed by the International Review Subcommittee and Harvard University, the Committee reiterated the need to reconcile the discrepancy before making any future decisions. In the report's conclusion, the Committee wrote, “It is imperative that all future decisions be based on the best

¹⁷ Report to the Secretary's Advisory Committee on Foreign Animal and Poultry Disease, Measures Relating to Bovine Spongiform Encephalopathy in the United States, February 13, 2004, at 2.

available science and that all necessary steps be taken to protect the safety of the public as well as the economic viability of animal agriculture in the United States.”¹⁸

R-CALF USA supports the Committee’s recommendation regarding the risk assessment and urges APHIS to withdraw its proposed rule until the United States completes a new risk assessment that definitively establishes the United States risk of exposure to BSE from countries known to have BSE in their cattle herd.

4. The APHIS Risk Analysis Misrepresents and Misuses the Harvard Risk Assessment to Support the Proposed Rule, and, There is a Discrepancy Between the Two Documents Regarding the Prevalence of the BSE Agent in Canada.

In his evaluation of the APHIS Risk Analysis, Dr. Cox states that:

The “Risk Estimation” section of the Risk Analysis states that its conclusions “are consistent with the 2001 Harvard study, which found that the measures taken by the US government and industry make the United States robust against the spread of BSE, should it be introduced into the country.” This overstates what the Harvard Center for Risk Analysis (HCRA) model (the “Harvard Study”) actually found. While that study indicated that its *base case assumptions* implied a high degree of robustness against the spread of BSE, it also clearly indicated that there is enough uncertainty about the validity of these assumptions so that no single, unambiguous set of conclusions can be drawn with very high confidence.¹⁹

In Dr. Cox’s opinion, “The original Harvard Study was prepared in 2001 for a totally different purpose than to serve as analytic support for the importation of live ruminants and ruminant products from Canada.”²⁰ Based on his review of the two studies, Dr. Cox notes that:

The USDA Risk Analysis systematically misinterprets the Harvard Study as being more definitive and reassuring than it really is, e.g., by stating that “The Harvard study found that even if BSE were to

¹⁸ Id. at 3.

¹⁹ Cox Evaluation at 7 (footnotes omitted).

²⁰ Id.

enter the United States, it would be unlikely to spread.” That is not a correct summary of what the Harvard Study found.²¹

Furthermore, the October 2003 update to the Harvard University Risk analysis directly contradicts the APHIS Risk Analysis also conducted in October 2003 which describes the prevalence of BSE in Canada as “low” based on “only a single infected Canadian animal that has been identified.”²² However, the independent Harvard University Analysis, which was also conducted before the second Canadian BSE case, contradicts the APHIS claim by stating the prevalence of BSE in Canada could not be determined because of the “absence of strong evidence about the prevalence of BSE in the Canadian herd.”²³ Thus, the APHIS claim that Canada’s BSE prevalence is “low” cannot be supported, cannot be verified, and contradicts the more exhaustive Harvard study: What is ever more baffling, is that the discovery of a second case of BSE in a Canadian cow somehow caused APHIS to downgrade Canada’s BSE prevalence to “very low” in its February 2004 Explanatory Notes and in the Federal Register notice of March 8, 2004, without any support or evidence. As Dr. Cox noted, APHIS did not present any quantitative estimate of the prevalence of BSE in Canada.²⁴

R-CALF USA is concerned that the foregoing evidence suggests that APHIS is ignoring science, ignoring the actual risks, and is assuming a “lobbyist role” in its efforts to expose the U.S. cattle industry to greater risk.

5. APHIS’ Conclusion that the BSE Case in a Second Cow of Canadian Origin Does Not Alter Its Initial Risk Estimate is Without Foundation Because Neither APHIS Nor Canada has Taken, Nor do they Plan to Take, Any Meaningful Steps to Determine the Prevalence of BSE in Canada.

As stated previously, APHIS’ initial risk estimate described the prevalence of BSE in Canada as “low” based on “only a single infected Canadian animal that has been identified.”²⁵ However, there have now been two cases of BSE

²¹ Id. at 10.

²² Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States, USDA – Animal and Plant Health Inspection Service, Veterinary Services, October 2003, at 31.

²³ 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 (the “Harvard Study”), at 2.

²⁴ Cox Evaluation at 14.

²⁵ Risk Analysis at 31.

originating from Canada, and in neither case has the exact source or timing of the BSE infection been identified. Until the source of the contaminated feed is definitely known, it is not possible to conclude with certainty the age of the index cows at the time of infectivity. Even though animals are more susceptible during the first six months of life, the two- to eight-year incubation period for BSE provides the possibility that both infected cows were infected after the Canadian feed ban was in place.

The combined unknown source of infectivity and unknown timing of infectivity establishes a possibility that both index cows ingested the BSE agent after the feed ban was in place – a scenario suggesting there could be a continuing risk of BSE in younger Canadian cattle. APHIS must either identify the source and timing of infection in order to conclude that the prevalence of BSE is low in Canada, or Canada must begin testing a more representative sample of the Canadian herd than it is presently contemplating. Canada is planning to test approximately 8000 head of cattle during the next 12 months.²⁶ While this level of surveillance may suffice for a country in which BSE is not known to exist, it is woefully inadequate for a country which produced two cases of BSE in less than 12 months under limited surveillance.

Lacking any definitive evidence regarding the exact source of infectivity and timing of infectivity, Canada should be required to test all cattle over 24 months of age for a period of two years for purposes of determining the prevalence of BSE in the Canadian herd. The United States should not consider relaxing its border restrictions for countries in which the prevalence of BSE is unknown.

6. Canada's Feed Ban, Its Principle BSE Defense, is Less Stringent Than the United States' Feed Ban and the United States Should Not Accept Imports from Any Country that has Not Implemented Identical Feed Restrictions and That has Not Enforced Such Restrictions for at Least as Long as the United States.

It appears that Canada's feed ban implemented in 1997 exempts "rendered animal fat from all species" from its list of prohibited feeds.²⁷ The United States' feed ban, however, does not include this exemption.²⁸ In addition, Canada

²⁶ Id. at 7.

²⁷ Canada: A Minimal BSE Risk Country, Canadian Food Inspection Agency, Animal Products, Animal Health and Production Division, October 2003.

²⁸ 21 CFR 589.2000, Animal Proteins Prohibited in Ruminant Feed, at 541.

continues to allow the feeding of mammalian blood to ruminant animals.²⁹ The United States is finalizing more stringent regulations to prohibit the feeding of mammalian blood and blood products to ruminants,³⁰ and to prohibit poultry litter and plate waste from ruminant feed.³¹ APHIS is silent on whether Canada has any plans to modify its feed ban so as to be in compliance with the United States feed ban.

It further appears that Canada has only prohibited the practice of including beef derived from downer animals in export approved facilities.³² APHIS is silent on whether Canada has any plans to adopt the additional restrictions proposed by the FDA to ban “any material from nonambulatory or dead cattle, as well as SRM and mechanically separated beef, from FDA-regulated human food, including dietary supplements and cosmetics.”³³

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 or presently proposed in the United States and which measures have been enforced for at least as long as the United States’.

7. The Proposed Rule Establishes a Deceptively Named “BSE Minimal Risk Region” That Does Not Comply With the Scientifically Established and Internationally Accepted BSE Risk Classifications of the World Organization for Animal Health or Office International des Epizooties (OIE).

According to the OIE’s BSE risk classification standards, Canada became ineligible for a “BSE provisionally free” classification upon the first discovery of BSE in a native Canadian cow on May 20, 2003. As a result of this case, Canada can achieve no higher than a “BSE moderate risk” classification because it does not meet the “BSE minimal risk” classification requirement that a country with a native case of BSE must have had its feed ban in place for 8 years before being

²⁹ Canadian Food Inspection Agency’s (CFIA) Feed Ban, Canadian Food Inspection Agency, Animal Products, Animal Health and Production Division, available at <http://www.inspection.gc.ca/english/anima/feebet/rumin/ruminfse.shtml>, downloaded March 10, 2004.

³⁰ Explanatory Note: Risk Analysis: BSE Risk of Importation of Designated Ruminants and Ruminant Products from Canada into the United States, USDA Animal Plant Health Inspection Service, Veterinary Services, February 2004, at 4.

³¹ www.hhs.gov/news/press/2004pres/20040126.html

³² Id. at 8.

³³ Id. at 5.

upgraded to the "BSE minimum risk" classification. Thus, Canada will be recognized by the international community as no better than a "BSE moderate risk" country for approximately 1 ½ years because Canada's feed ban was not implemented until late 1997.

Nevertheless, in order to enable imports of Canadian cattle and beef products, USDA APHIS has proposed regulations that, although called "BSE Minimal Risk Region," do not comply with the OIE standards for "country or zone with a minimal BSE risk."³⁴ USDA has not provided any analysis of the impact of granting any other countries besides Canada BSE minimal risk status under the proposed rule. Nevertheless, the race for the new status is already on. In addition to Canada, two other countries, Finland and Norway, which are currently listed by USDA, respectively, as "a country affected with BSE" and "a country with substantial risk associated with BSE," have already petitioned USDA for recognition as "BSE minimal risk" regions.³⁵ Although R-CALF USA is not surprised that these applications have been submitted, there is no basis for USDA or APHIS to consider the applications and urges that they be rejected.

The APHIS proposal to designate Canada as a minimal risk region, therefore, is not based on any internationally accepted scientific standards and should be withdrawn.

8. By Unilaterally Designating Canada as a Minimal Risk Region in Direct Contradiction of the Internationally Accepted and Scientifically Established OIE Risk Categories, APHIS Will Cause Direct Economic Harm to the U.S. Cattle Industry.

The five BSE risk classifications established by the OIE are used by over 164 World Trade Organization (WTO) member countries to evaluate the relative BSE risks associated with importing ruminant and ruminant products from various countries. Many countries, including the United States, have elected not to assume the BSE risks associated with importing from countries that cannot meet the eligibility standards for an OIE BSE Free or BSE Provisionally Free classification. Common sense suggests that as a country's BSE risk increases, fewer countries will be willing to assume the greater risk of importing from that country if similar products are available from countries harboring a lesser BSE

³⁴ OIE Terrestrial Animal Health Code 2.3.13.5.

³⁵ See comments of Ministry of Agriculture and Forestry, Department of Food and Health, Finland (December 29, 2003) and Norway's Application for Being Recognized By the USDA as a "Minimal BSE Risk Country."

risk. Indeed, many countries currently refuse to accept imports of beef from the U.S. as a direct result of the discovery of the two BSE-infected Canadian cows in 2003.

The proposed rule unilaterally creates the so called "BSE minimal risk region" and, by doing so, characterizes Canada as having less risk than it would have under the classifications established by the OIE. Countries that import U.S. cattle and beef, however, are not likely to be fooled by APHIS's semantic trick. These countries all recognize that the United States is currently importing beef from Canada, a country with a higher BSE risk than they would be willing to assume. Consequently, since September 2003, after USDA partially lifted the May 20, 2003 ban on imports of Canadian beef, both Japan and South Korea have stopped importing United States beef. Japan and Korea have refused to resume beef imports from the United States until all beef products destined for these countries are labeled to guarantee that they do not contain any beef derived from Canadian cattle. It is important to note that both Japan and South Korea, our first and third largest beef export customers, respectively, have maintained this export restriction after APHIS published the proposed rule on November 4, 2003. More recently, despite intense pressure from the U.S. government, including USDA, Japan and Korea have continued to ban imports of U.S. beef. It is clear, therefore, that if the proposed rule is adopted in an attempt to reclassify Canada as having a more favorable risk designation than is recognized by the OIE, export markets for U.S. beef products will continue to be severely limited by importing countries such as Japan and Korea. On the other hand, as noted above, countries with BSE risks will clearly try and use the proposed rule to gain access to U.S. markets for their cattle and beef exports.

As evidenced by the approximate 20 percent reduction in U.S. cattle prices following the export restrictions placed on the United States by approximately 90 percent of our beef export customers, actions that cause restrictions on U.S. beef exports translates to lost revenues for live cattle producers. APHIS should withdraw its proposed rules to prevent additional harm to U.S. producers.

9. If the Proposed Rule is not Withdrawn, The Restriction that Limits Imported Fresh Meat to Bovines that were Less Than 30 Months of Age Must be Maintained Until the Risk of Eliminating the Age Restriction is Fully Assessed

Section 94.19 of the proposed rule would have restricted the importation of fresh (chilled or frozen) meat to bovines less than 30 months of age at the time of slaughter. That restriction arose out of APHIS' Risk Analysis, which placed

great importance on the age restriction as a risk reduction method. In fact, the age restriction was considered to be so important that in the Risk Analysis APHIS contemplated requiring CFIA to certify that the animals were less than 30 months of age at the time of slaughter and that they were slaughtered in a facility that only kills bovids less than 30 months of age (or complies with a facility segregation procedure approved by CFIA and endorsed by APHIS).³⁶ In sum, the entire Risk Analysis for the provision in the Proposed Rule permitting the importation of these materials is based on the existence of an age restriction.

While it was not obvious from a quick review, the March 8, 2004, Federal Register notice did more than reopen the comment period for the proposed rule. In fact, it made a significant, substantive change to the rule -- it eliminated the age restriction on imported beef from BSE-minimal risk regions.

APHIS noted that FSIS does not restrict the slaughter of cattle in the U.S. based on the age of the animal. Apparently based on that fact alone, APHIS concluded:

We now believe it would not be necessary to require that beef imported from BSE minimal-risk regions be derived only from cattle less than 30 months of age, provided equivalent measures are in place to ensure that SRM's are removed when the animals are slaughtered, and that such other measures as are necessary are in place. We believe such measures are already being taken in Canada.³⁷

APHIS knew that FSIS does not have age restrictions on U.S. beef prior to publishing the Proposed Rule in November 2003. The fact that BSE has been identified in Canadian cows provides a legitimate basis for imposing restrictions on Canadian beef that are not imposed on U.S. beef. However, with the only intervening event since the publication of the Proposed Rule being the discovery of a second Canadian cow infected with BSE, APHIS, with minimal discussion or justification, has decided to drop the age restriction on imported beef. APHIS has simply not articulated a rational basis for doing so.

Even assuming *arguendo* that there is a rational basis for dropping the age restriction on imported beef, APHIS has not provided the public a meaningful opportunity to comment on the new proposal. As an initial matter, as discussed above, the entire Risk Analysis is predicated on the age restriction. A new risk

³⁶ Risk Analysis at 28.

³⁷ 69. Fed. Reg., at 10,653.

analysis, without the age restriction, would have to be done and the public would have to be given an opportunity to review and comment on that risk analysis. Second, the analysis of the proposed rule required by Executive Order 12866 would have to be re-done since the current analysis expressly contemplates the age restriction. Finally, the language of the new "proposal" in the March 8 notice is too vague to be able to provide meaningful comment. What does "provided *equivalent measures* are in place to ensure that SRM's are removed when the animals are slaughtered, and that *such other measures as are necessary* are in place" mean? Will those terms be defined?

Although R-CALF opposes the proposed rule and calls on APHIS to withdraw it, if the rule is adopted, the age restriction on imported meat must be maintained until a new risk analysis incorporating any proposed change to the age restriction is completed and the public is given a meaningful opportunity to review and comment on the proposed change.

10. The Economic Analysis Prepared by APHIS Fails To Analyze the Full Effect of the Proposed Rule

The Economic Analysis prepared by APHIS to analyze the cost-benefit effects of the proposed rule is extremely limited and does not begin to measure the true impact of allowing imports from Canada. Dr. John J. VanSickle, Director of the International Agricultural Trade and Policy Center of the University of Florida, prepared an evaluation of the APHIS Economic Analysis.³⁸ Dr. VanSickle, a nationally recognized expert on agricultural markets has conducted a thorough review of the modeling that underlies the APHIS Economic Analysis. Based on his review, Dr. VanSickle's concludes "The USDA economic analysis of this proposed rule falls short of estimating the larger economic impacts this rule could have on the U.S. economy as it provides only a limited analysis of the effect of imports of Canadian cattle and beef on prices in the U.S."³⁹

The USDA economic analysis only considers the cost effects of increased supplies of beef and cattle resulting from imports of and their economic impacts on the domestic market. According to Dr. VanSickle, "The USDA analysis ignores the impacts this rule will have on associated industries and their

³⁸ J.J. VanSickle, Ph.D., Economic Analysis of Proposed Rule for Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities (APHIS Docket No. 03-080-1) ("VanSickle Analysis"). The VanSickle Analysis is attached to these comments as Exhibit B.

³⁹ Id. at 1.

productive output, and it ignores the impact it will have on employment."⁴⁰ Furthermore, the USDA Economic Analysis, which was prepared after the first BSE-infected Canadian cow was discovered in May 2003 but before the second BSE-infected Canadian cow was identified on December 23, 2003, ignores any costs associated with events such as discovery of additional BSE cases or human cases of vCJD. In Dr. VanSickle's opinion, such events could have catastrophic effects on the U.S. cattle market. Dr. VanSickle states "Estimates of the cost of the 1986 outbreak on the British economy, with a herd size of 12.04 million head, are \$5.8 billion. Given that the United States herd size is eight times larger, a worst case scenario suggests the impacts on the U.S. could be as large as \$46.4 billion."⁴¹

11. The Proposed Rule Ignores the Economic Risks Associated with the Known and Measurable Costs Previously Reported by Countries like Canada that have Identified BSE in their Cattle Herds.

Dr. VanSickle points out that the "[e]xperience of BSE in the European Union indicates that major categories of costs from a BSE introduction include agriculture, food consumption, trade and tourism." Despite the known susceptibility of these cost categories, the USDA Analysis only considered the costs of increased beef and cattle supplies and their impact on the domestic market. The VanSickle study shows that the cost of the BSE introduction in the UK totals over \$5.8 billion today, resulted in a 40 percent decline in beef consumption the first year, households cut their consumption 26 percent, and the long-run demand for beef and veal declined 4.5 percent.⁴²

At a minimum, the USDA should have attributed the portion of these known and measurable costs to the risks associated with resuming imports from a country that, like the UK, has identified BSE in its cattle herds. Dr. VanSickle's identification of these historical impacts demonstrates that the risks associated with the Proposed Rule "go beyond the simple supply impact if BSE is introduced."

⁴⁰ Id.

⁴¹ Id.

⁴² Id. at 3.

12. The Proposed Rule Ignores the Fundamental Consequences of a Change in Industry Output on the Overall Economy that would Result from Resuming Cattle and Beef Imports from Canada.

Dr. VanSickle's Analysis reveals that the overall impact on the economy is far greater than that estimated by the USDA because the USDA modeling did not include applicable industry multipliers to capture the total economic impacts resulting from the Proposed Rule.⁴³ To model total economic impacts, Dr. VanSickle used standard Implan multipliers that recognize that a \$1 decline in sales for the cattle and farming sector will have a \$3.87 impact on total output in the economy.⁴⁴ Different multipliers were used for the impacts on related jobs, the meat processing sector, and employment.

Dr. VanSickle's modeling shows that the proposed rule would impact the economic output of the cattle industry. Based on his modeling using Implan multipliers, Dr. VanSickle found that:

- output by \$701.5 million and cost the economy 7,883 jobs;
- allowing fed cattle imports from Canada would impact total economic output by \$1.7 billion and cost the economy 19,358 jobs;
- imports of beef resulting from this proposed rule would impact total economic output by \$5.8 billion and cost the economy 50,874 jobs and;

loss of exports as a result of this rule would impact total economic output by \$16.1 billion and cost the economy 140,068 jobs.⁴⁵

13. The Proposed Rule Fails to Address the Probable Consequences Lower Prices Would have on a Cyclical Cattle Industry Experiencing a Prolonged State of Contraction.

While the USDA economic evaluation of the Proposed Rule acknowledges negative price impacts for both feeder cattle and fed cattle, it fails to take into account the impact these lower prices would have on the U.S. cattle industry. Dr. VanSickle determines that there are "large consequences for the U.S. cattle industry" and lower cattle prices "will force many [cattle producers] to downsize or exit the beef production business."⁴⁶

⁴³ Id. at 3.

⁴⁴ Id. at 4.

⁴⁵ Id at 4-5.

⁴⁶

The consequences Dr. VanSickle predicts and the damage such consequences will likely inflict upon the overall economy become apparent upon a review of the current state of the U.S. live cattle industry. Live cattle production comprises the single largest sector of U.S. agriculture, contributing over \$40 billion annually to the United States economy.⁴⁷ Cattle are raised in all fifty states and half of all U.S. farms have beef cattle as part of their operations.⁴⁸ Given its size and revenue potential, the live cattle industry is of paramount importance to the United States economy and to the economy of rural America in particular.

U.S. cattle producers, and by extension America's rural communities, are experiencing a historically difficult period. The U.S. cattle herd underwent its eighth consecutive year of contraction in 2003.⁴⁹ This eight years of liquidation is unprecedented, and it extends the current cattle cycle to fourteen years, which is also unprecedented.⁵⁰ Normal cattle cycles last approximately ten years from peak to peak, *i.e.*, from herd contraction to herd rebuilding.⁵¹ As opposed to the current liquidation phase of eight years, the average liquidation phase of cattle cycles is two to three years.⁵² In 2002, the USDA predicted that by January 1, 2003, the U.S. cattle population would fall to 95.6 million, its lowest number since 1959.⁵³ However, by January 1, 2003, the U.S. cattle population had fallen even further to 95.1 million head and by January 1, 2004, to 94.9 million head.⁵⁴ Also in 2002, the USDA estimated that the U.S. calf crop in 2003 would be the smallest since the mid-1950s.⁵⁵

During this protracted herd liquidation, the U.S. cattle industry lost an average of 13,646 beef cattle operations each year. There are 805,080 beef cow

⁴⁷ USDA, ERS, *U.S. farm sector cash receipts from sales of agricultural commodities, 2000-2004F* found at http://www.ers.usda.gov/Briefing/FarmIncome/Data/cr_t3.htm.

⁴⁸ U.S. Department of Agriculture, *Where's the Beef? Small Farms Produce Majority of Cattle, Agricultural Outlook*, December 2002, at 21.

⁴⁹ U.S. Department of Agriculture, *U.S. Cattle Inventory*, (Jan. 2004), available at <http://usda.mannlib.cornell.edu/reports/nassr/livestock/pct-bb/cat10104.txt>, retrieved April 7, 2004.

⁵⁰ *Herd Rebuilding is Still Uncertain, Cattle Buyers Weekly*, January 27, 2003, at 1.

⁵¹ U.S. International Trade Commission, *Live Cattle from Canada and Mexico*, Inv. Nos. 701-TA-386 (Preliminary) and 731-TA-812-813 (Preliminary), Pub. No. 3155, February 1999, at 24.

⁵² *Id.*

⁵³ U.S. Department of Agriculture, *World Beef Trade Overview*, October 17, 2002, available at <http://www.fas.usda.gov/dlp/circular/2002/02-10LP/beefoverview.html>, retrieved January 8, 2003.

⁵⁴ Cattle, U.S. Department of Agriculture, National Agricultural Statistics Service, January 30, 2004, available at <http://usda.mannlib.cornell.edu/>, retrieved April 6, 2004.

⁵⁵ *Id.*

operations remaining in the U.S.⁵⁶ U.S. cattle operations form the backbone of rural America and are vital in maintaining and supporting local schools, hospitals, nursing homes, and communities. Collectively, these businesses are one of the most significant segments of the U.S. gross national product and their decline should evoke national concern.

The average returns to U.S. cow/calf producers during the 1992-2001 decade had fallen to an alarming level. Returns for cow/calf producers were actually a *negative* \$30.40 per bred cow per year during 1992-2001.⁵⁷ While 2003 saw cattle prices rise significantly due to the outbreak of BSE in Canada in May and the resulting closing of the Canadian border, that period of "boom" prices is already over. Cattle prices in December 2003 rose to \$93 cwt which was significantly higher than the \$72-73 cwt baseline average used for beef cattle by USDA from 1990-92.⁵⁸ However, the cattle industry faces a significant challenge as virtually all export markets have been closed to U.S. beef exports due to the discovery of BSE in an imported Holstein cow in Washington State. USDA predicts that cattle prices will fall significantly in 2004, back down to the depressed level of \$72 cwt.⁵⁹ Indeed, cattle prices in January and February have already eroded, hovering in the high 70s.⁶⁰ The return of these unsustainably low cattle prices signifies that the industry is returning to the crisis position that characterized most of the past twelve years.

Commensurate with low cattle prices, the average net income for United States beef cattle operations during the years 1998 through 2002 was only \$14,700.⁶¹ However in 2001 and 2002, the net incomes fell to \$12,200 and

⁵⁶ Number of All Cattle and Beef Cow Operations, 1988-2002, National Agricultural Statistics Service-USDA, Cattle Graphics, available at http://www.usda.gov/nass/aggraphs/acbc_ops.htm, retrieved on April 6, 2004.

⁵⁷ U.S. Cow-Calf Production Cash Costs and Returns, 1990-95; 1996-99; 2000-2001, Economic Research Service/USDA, available at <http://www.ers.usda.gov/data/farmincome/CAR/DATA/Appendix/Cowcalf/US9095.xls>; <http://www.ers.usda.gov/data/farmincome/CAR/DATA/History/CowCalf/US9699.xls>; and <http://www.ers.usda.gov/data/CostsAndReturns/data/current/C-Cowc.xls>, retrieved from the internet on October 18, 2002.

⁵⁸ USDA, NASS, *Agricultural Prices*, at 9 (Dec. 31 2003) found at <http://usda.mannlib.cornell.edu/reports/nass/price/pap-bb/2003/agpr1203.pdf>.

⁵⁹ USDA, ERS, *World Agricultural Outlook, Livestock*, Jan. 12, 2004.

⁶⁰ USDA, NASS, *Agricultural Prices*, at 20 (Feb. 27, 2004) found at <http://usda.mannlib.cornell.edu/reports/nass/price/pap-bb/2004/agpr0204.pdf>.

⁶¹ Agriculture Income and Finance Outlook, U.S. Department of Agriculture, Economic Research Service, AIS-81, November 5, 2003, at 6, available at <http://usda.mannlib.cornell.edu/reports/ers/economics/ais-bb/2003/ais81.pdf>, retrieved April 6, 2004.

\$12,100, respectively.⁶² The ongoing and systematic destruction of the U.S. cattle industry can be attributed to forces that systematically produce prices that are too low to sustain independent producers.

Not only does the USDA analysis ignore the effect lower cattle prices would have on the overall U.S. economy, Dr. VanSickle reports that USDA erred in its characterization of the economic relationship between the feeder and fed cattle sectors, resulting in an under-reporting of producer financial losses. While the USDA claims its estimated losses to the feeder sector and fed sector of \$182 million and \$448 million, respectively, are independent and further mitigated because losses to the feeder sector would translate into benefits for the fed sector, Dr. VanSickle suggests that these losses are additive, “implying that opening the border to trade with Canada on fed cattle and feeder cattle would likely have an effect of more than \$630 million.”

14. The Proposed Rule Fails to Properly Account for the Import Sensitive Nature of the U.S. Cattle Industry.

The USDA claims the price declines associated with the Proposed Rule would largely reflect a return to the more normal market conditions that prevailed before Canada’s BSE discovery.⁶³ But Dr. VanSickle reveals that the U.S. cattle industry is already weakened and the loss associated with the Proposed Rule would be difficult to recover.

In addition to the previous discussion regarding the ongoing constriction of the U.S. cattle industry, the import sensitive nature of the industry itself helps explain how circumstances preceding the Canadian BSE discovery, including trade with Canada, have contributed to the weakened condition of the U.S. cattle industry that Dr. VanSickle described.

The live cattle industry is highly sensitive to changes in the volume of beef in the market due to the disproportionate impact of changes in supply on prices. According to Chuck Lambert, formerly of the National Cattlemen’s Beef Association (NCBA) and currently Deputy Under Secretary for USDA’s Marketing and Regulatory Programs, increased imports of beef have reduced returns to U.S. cattle producers: “[t]he rule of thumb is that a 10% increase in beef

⁶² *Id.*

⁶³ Economic Analysis Proposed Rule Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities (APHIS Docket No. 03-080-3), USDA Animal and Plant Health Inspection Service (October 24, 2003), at 8.

supply results in a 15% to 20% decrease in price.”⁶⁴ Even small increases in supply – as little as 2 to 3 percent – can have significant downward effects on price.⁶⁵

While increased imports of both beef and cattle contribute to increased supplies, which directly lower cattle prices, imports also function to restrain price increases. This issue was specifically addressed by the Republican Commissioners of the United States Trade Deficit Review Commission in their November 14, 2000, report. The Republican Commissioners stated, “Easy availability of imports can limit price increases either by expanding available supply or reducing the ability of businesses to raise prices in order to pass on increases in their costs.”⁶⁶

Thus, increased cattle and beef imports can significantly reduce the price received by U.S. cattle producers and restrain price increases. Annual imports of fresh, chilled and frozen beef into the United States rose from \$1.5 billion and 2.1 billion pounds in 1995 to \$2.5 billion and 3 billion pounds in 2000.⁶⁷ In addition, other factors -- such as the declining share of the retail dollar passed on to U.S. producers -- have already injured the U.S. cattle industry, and increased imports would only exacerbate the already precarious position of U.S. producers.

Change in the supply of beef has long been recognized as an important factor affecting prices for live cattle. Nearly 40 years ago Congress recognized that increased imports of beef were having a negative effect on domestic beef prices and hence on the U.S. cattle industry. Quoting from the Senate Finance Committee’s report which accompanied the Meat Import Act of 1964, Congress observed:

“Th[e] price data strongly suggests imported meat has played an important part in creating the distressed market conditions in the cattle industry. The pressure on domestic prices of low-priced, foreign imported beef discourages sale of domestic livestock and

⁶⁴ Chuck Lambert, Chief Economist, NCBA, *Beef Today*, (Sept. 1997).

⁶⁵ See Sparks Companies Inc., “Potential Impacts of the Proposed Ban on Packer Ownership and Feeding of Livestock”, A Special Study, (March 18, 2002) at 37 (“In general, prices decrease 1% for each 0.6% increase in beef production (consumption = production for beef).”)

⁶⁶ United States Trade Deficit Review Commission, Report of “The U.S. Trade Deficit: Causes, Consequences and Recommendations for Action,” (November 14, 2000), Chapter 2 – Republican Commissioners’ Views – Causes, at 26, Obtained from the Internet at www.ustrdc.gov/reports/finalrept-contents.html.

⁶⁷ U.S. Agricultural Imports Head Higher, *Agricultural Outlook* (U.S. Dept. of Agriculture), August 2000, at 5.

encourages their return to the range where they produce new calves and add more weight, thus intensifying the problems confronting the American cattlemen. . . . On the basis of information presented to the committee, . . . your committee has concluded that beef imports have contributed heavily to the depressed conditions in the livestock industry”⁶⁸

In particular, trade with Canada in the years before the first BSE discovery in a Canadian cow was a virtual one-way street marked by a progressively increasing supply of price-depressing Canadian beef and cattle shipments that increasingly overshadowed the relatively small volumes of U.S. beef or cattle exports to Canada.

The United States – Canadian Free Trade Agreement (USCFTA) was implemented in 1989,⁶⁹ and this agreement was completely phased in on January 1, 1998.⁷⁰ The North American Free Trade Agreement (NAFTA) went into effect on January 1, 1994, and incorporated the USCFTA.⁷¹ The terms of the USCFTA were folded into NAFTA. Prior to the USCFTA, imports of Canadian cattle into the United States basically remained flat and averaged 368,000 head per year from 1978 to 1988.⁷² Following the implementation of the USCFTA, imports of Canadian live cattle into the United States increased substantially. As noted by the USDA in 1989, U.S. imports of Canadian cattle began a “fluctuating, but generally strong upward trend” with imports that year totaling 585,000 head.⁷³ During the five years preceding 2003, imports of Canadian cattle have averaged 1,251,217 head annually.⁷⁴

Due to alleged sanitary threats, U.S. exports of live cattle to Canada are restricted. But a post-NAFTA agreement, the Northwest Pilot Program, has led to increased exports of U.S. cattle to Canada when certain sanitary conditions are

⁶⁸ S. Rep. No. 88-1167, (1964), reprinted in 1964 U.S.C.C.A.N. at 3074.

⁶⁹ U.S. Department of Agriculture, Foreign Agricultural Service, *FAQ's Regarding U.S. Cattle and Beef Imports from Canada*, available at <http://www.fas.usda.gov/dlp/Canada/questions.htm>, retrieved on February 11, 2003.

⁷⁰ U.S. Department of Agriculture, Economic Research Service, *Effects of North American Free Trade Agreement on Agriculture and the Rural Economy*, WRS-02-1, July 2002, at v.

⁷¹ *Id.*

⁷² U.S. Department of Agriculture, Foreign Agricultural Service, *FAQ's Regarding U.S. Cattle and Beef Imports from Canada*, available at <http://www.fas.usda.gov/dlp/Canada/questions.htm>, retrieved on February 11, 2003, at 2.

⁷³ *Id.*

⁷⁴ *Source*: Livestock, Dairy and Poultry Outlook Reports, U.S. Department of Agriculture, Economic Research Service.

met. U.S. shipments of live cattle to Canada grew from 40,000 head in 1996 to 349,536 head in 2000.⁷⁵ While U.S. exports of live cattle to Canada have increased slightly following NAFTA, averaging 224,199 head annually during the five years preceding 2003, imports of live cattle into the United States from Canada greatly overshadow export gains by the United States.⁷⁶ The United States cattle trade deficit with Canada averaged 1,027,018 head annually for the five years preceding 2003.⁷⁷

U.S. imports of beef from Canada increased markedly in the years following the implementation of the USCFFTA, growing from 222.4 million pounds in 1990⁷⁸, to 823 million pounds in 1998⁷⁹, to 1.1 billion pounds in 2002.⁸⁰ During the five years preceding 2003, the average annual amount of beef imported from Canada was 933 million pounds.⁸¹

During this same period of time (1990-2002), U.S. exports of beef to Canada essentially remained flat with the United States shipping 191 million pounds in 1990,⁸² 261 million pounds in 1998,⁸³ and only 241 million pounds in 2002.⁸⁴ During the five years preceding 2003, the average annual amount of beef exported to Canada was 248 million pounds.⁸⁵ The United States beef trade deficit with Canada averaged 685 million pounds annually for the five years preceding 2003.

⁷⁵ U.S. Department of Agriculture, Economic Research Service, *Effects of North American Free Trade Agreement on Agriculture and the Rural Economy*, WRS-02-1, July 2002, at 57.

⁷⁶ Source: Livestock, Dairy and Poultry Outlook Reports, U.S. Department of Agriculture, Economic Research Service.

⁷⁷ *Id.*

⁷⁸ Table 45c, U.S. Beef Imports from Canada, Redmeat Yearbook, U.S. Department of Agriculture, Economic Research Service, available at <http://www.ers.usda.gov/data/sdp/view.asp?f=livestock/94006/>, retrieved on April 6, 2004.

⁷⁹ *Id.*

⁸⁰ Livestock Dairy and Poultry Outlook, LDP-M-17, U.S. Department of Agriculture, Economic Research Service, March 23, 2004, at 22, available at <http://www.ers.usda.gov/publications/ldp/Mar04/LDPM117F.pdf>, retrieved on April 6, 2004.

⁸¹ Source: Livestock, Dairy and Poultry Outlook Reports, U.S. Department of Agriculture, Economic Research Service.

⁸² Table 53b, U.S. Beef Exports to Canada, Redmeat Yearbook, U.S. Department of Agriculture, Economic Research Service, available at <http://www.ers.usda.gov/data/sdp/view.asp?f=livestock/94006/>, retrieved on April 6, 2004.

⁸³ *Id.*

⁸⁴ Livestock Dairy and Poultry Outlook, LDP-M-17, U.S. Department of Agriculture, Economic Research Service, March 23, 2004, at 22, available at <http://www.ers.usda.gov/publications/ldp/Mar04/LDPM117F.pdf>, retrieved on April 6, 2004.

⁸⁵ Source: Livestock, Dairy and Poultry Outlook Reports, U.S. Department of Agriculture, Economic Research Service.

The period preceding Canada's first BSE case described by the USDA as reflecting "more normal market conditions" was far from normal. From 1999 to 2004, the United States cattle herd fell from 98.5 million head to 94.9 million head,⁸⁶ while the Canadian cattle herd increased from 12.8 million head to 14.7 million head.⁸⁷ Thus, during this protracted period of U.S. herd constriction in the face of a mounting global trade deficit, the majority of which is attributable to Canadian imports, Canada was expanding its production capacity and was poised to continually capture an increasing share of the U.S. market, thereby supplanting the U.S. production capacity with foreign product.

15. Profits to Beef Packers, But Not to Cattle Producers

The U.S. beef sector has undergone significant changes in recent years. The U.S. beef packing industry has become heavily concentrated with just four firms controlling a combined 80 percent of the market.⁸⁸ Benefits to U.S. live cattle producers in the form of expanded markets for beef abroad have been heavily outweighed by the ability of packers to use imported cattle and beef to drive down prices received in the U.S. cattle market. This situation is most notable with the dramatic increase in imports of live cattle and beef from Canada following the implementation of the USCFTA/NAFTA.

16. Concentrated Packer Sector Has Benefited from Increased Cattle and Beef Imports

Packers are able to capture benefits from both increased imports and exports. Packers add value to live cattle and/or beef carcasses through processing and sell the resulting boxed beef and other beef products on a margin basis. To the extent that packers have access to an expanded supply of inventories, *i.e.*, a new source of imported inventories, packers are afforded new alternatives for sourcing lower-cost inventories. Lower inventory costs mean higher profits for

⁸⁶ United States and Canadian Cattle, U.S. Department of Agriculture, National Agricultural Statistics Service, Mt An 8 (2-99), available at <http://usda.mannlib.cornell.edu/reports/nassr/livestock/uscc/uscc0299.txt>, retrieved on April 7, 2004.

⁸⁷ United States and Canadian Cattle, U.S. Department of Agriculture, National Agricultural Statistics Service, Mt An 8 (2-99), available at <http://usda.mannlib.cornell.edu/reports/nassr/livestock/uscc/uscc0204.txt>, retrieved on April 7, 2004.

⁸⁸ Richard J. Sexton, *Market consolidation poses challenges for food industry*, California Agriculture, Vol. 56, No. 5, September-October 2002, at 146.

margin operators like packers and, therefore, packers have an economic incentive to seek new sources of lower cost inventories.

In addition, packers benefit from oversupply conditions as oversupplies lower domestic live cattle prices, hence the cost of their inventories. As discussed previously, the live cattle industry is highly sensitive to changes in the available supply of both beef and live cattle, a function of the perishable nature of both beef and live cattle. Thus, the very factors that benefit packers -- lower prices for live cattle and increased availability of beef supplies -- result in harm to cattle producers as cattle producers receive lower prices for their cattle, and their live cattle markets respond negatively to increased supplies.

This situation helps to explain how there is a negative correlation between profit margins at the packing and feeding stage, with the feeding stage representing the final phase of the live cattle industry, as was found in the 2002 study by Sparks Companies, Inc.⁸⁹ Although the packer is the customer of the live cattle producer, the packer is in direct competition with the producer over the price paid for live cattle. Unfortunately, the structural changes that have occurred within the U.S. cattle market, *i.e.*, the unprecedented concentration of the packing industry,⁹⁰ have afforded packers the ability to distort the outcome of that competition, and imports are a significant contributor to this distortion.

Thus, to the extent that reopening the Canadian border increases imports of cattle and beef, such imports will have a direct impact on the prices that cow-calf operators and ranchers receive for their cattle. Bear in mind as well that the cattle industry has been through and is continuing to experience an unprecedented eight-year period of contraction and liquidation, and higher relative prices are needed in order to rebuild the precariously diminished production capacity of this important domestic industry.

17. The Lack of Relationship between Live Cattle Prices and Retail Beef Prices

Consumers have not experienced a reduction in the price of retail beef that a competitive market would predict when the input costs associated with the final

⁸⁹ *See id.* at 24.

⁹⁰ U.S. General Accounting Office, *Economic Models of Cattle Prices: How USDA Can Act to Improve Models to Explain Cattle Prices*, GAO-02-246, March 2002 at 51. In reference to beef packer concentration, the GAO stated, "[N]o other manufacturing industry showed as large an increase in concentration since the U.S. Bureau of the Census began regularly publishing concentration data in 1947. . ."

product are drastically reduced, i.e., lower priced cattle resulting from increased imports. This fact is readily apparent upon review of the long-term data compiled by the USDA's Economic Research Service.

During the 10-year period from 1993 to 2002, live cattle prices fell from \$.77 per pound to \$.67 per pound, a \$.10 per pound price decrease, representing a loss to producers of \$125 per animal.⁹¹ This represents a 12 percent cattle price decrease over 10 years.

During this same 10-year period, choice beef retail values increased from \$2.93 per pound to a near record \$3.32 per pound, a \$.39 per pound retail price increase, representing an increased food cost to consumers of \$195 per live animal equivalent.⁹² This represents a 13 percent retail beef price increase over 10 years.

The following is an excerpt from the July 16, 2002 written testimony of Herman Schumacher, Director, R-CALF USA, before the United States Senate Committee on Agriculture, Nutrition, and Forestry Hearing on the Proposed Ban on Packer Ownership of Livestock and USDA's Enforcement of the Packers and Stockyards Act:

Let me close by saying the producers in North Dakota, South Dakota, Nebraska, and many other western states are suffering from a severe drought. My grandfather weathered droughts in South Dakota because he had a competitive market with which to recover a fair value for his cattle. The last severe drought we went through in our state was 1988. We culled our herd and sold cull cows for \$50 per cwt. Retail beef prices that year were \$2.50 per pound. In today's drought we are selling our cull cows into a market that will only return \$35 per cwt (\$180 less per head than in 1988). But today's retail beef prices are \$3.31.

⁹¹ Economic Research Service-USDA, Choice Beef Values and Spreads and All-Fresh Retail Value, obtained from the Internet at <http://www.ers.usda.gov/Briefing/FoodPriceSpreads/meatpricespreads/beef.xls>, on March 12, 2003.

⁹² Id. See also Retail Price Spreads, Redmeat Yearbook, 1970-2000, United States Department of Agriculture – Economic Research Service, available at <http://www.ers.usda.gov/data/sdp/view.asp?f=livestock/94006/>, downloaded on March 31, 2004.

The following is a quote from Leo McDonnell, Jr., President, R-CALF USA excerpted from the December 28, 2002 news release issued by R-CALF USA:

The fed cattle to retail spread for the previous three years has averaged \$1.50 per pound. This year the fed cattle to retail spread just though October averaged \$1.90 per pound. If prices were reflective of retail value, then we should have seen fed cattle in the \$80 per cwt range instead of the present \$60 per cwt range.

Thus the USDA's assumption that consumers would benefit from lower priced cattle resulting from increased Canadian imports is not supported by the preponderance of relevant data compiled by the USDA's Economic Research Service. Instead, this data shows the price consumers pay for beef has little or no relation to the price producers receive for their cattle. The chart attached at Exhibit C depicting the relationship between live cattle prices and retail prices reveals that this lack of relationship is not an anomaly, but rather, it is a persistent trend manifest since 1979.

18. The Proposed Rule Does Consider Not Recent Government Subsidies to the Canadian Cattle Industry

Moreover, the USDA failed to recognize or otherwise mention the costs of the significant government price support Canada has provided to assist its cattle industry in responding to BSE. The following government programs are listed on the Canadian Food Inspection Agency Website:

Canadian BSE Recovery Program:	\$520 million
Work Sharing Program:	\$9.4 million
Producers Assistance 2003:	Unknown
Cull Animal Program:	\$200 million
Transitional Industry Support Program:	\$930 million
Business Risk Management Transition Funding:	\$1.2 billion ⁹³

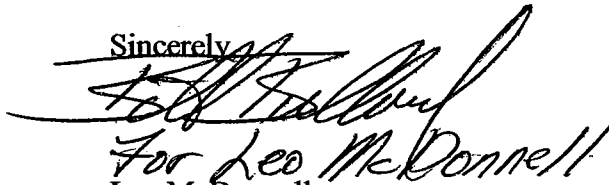
Further, the USDA failed to consider the potential impact these government support programs may have in affording Canadian cattle and beef a subsidy-related advantage upon entry into the United States market.

⁹³ http://www.agr.gc.ca/cb/index_e.php?s1=b&s2=2004&page=bse-esb

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R-CALF USA appreciates the opportunity to submit these comments to APHIS.

Sincerely

A handwritten signature in black ink, appearing to read "Leo McDonnell", written in a cursive style.

Leo McDonnell
President

EXHIBIT A

**Evaluation of the Adequacy and Appropriateness of Risk Analysis Used
by the U.S. Department of Agriculture Animal and Plant Health
Inspection Service in Support of Proposal to List Canada as a Bovine
Spongiform Encephalopathy Minimal Risk Region**

Louis Anthony Cox, Jr., Ph.D.

INTRODUCTION

This document assesses USDA's October 2003 report¹ titled: "Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States" (the "Risk Analysis"), and the February 2004 "Explanatory Note"² to the Risk Analysis, as a basis for USDA's proposed regulatory action³ (the "Proposed Rule").

In brief, since the discovery of a cow with bovine spongiform encephalopathy ("BSE") in Canada in May 2003, USDA has prohibited importation of ruminants and most ruminant meat products from Canada. Under the Proposed Rule, USDA proposes to allow the importation of certain ruminants and ruminant products from Canada, creating a new regulatory category of "BSE minimal-risk regions," and designating Canada as such a region.

As discussed in detail below, the Risk Analysis does not provide a thorough, data-driven assessment of the risks posed by importing live ruminants and ruminant products under the Proposed Rule. Nor does it contain key pieces of a standard risk analysis, including key conclusions, that are needed to guide well-informed risk management decision-making. For example, the Risk Analysis incorporates little or no actual data or explicit, objective calculations from published data. Accordingly, the conclusions reached are expressed in vague, subjective terms. Such an analysis is simply not adequate to inform (or support) a fact-based decision on whether to take an action that could have a significant impact on animal or human health. At best, the Risk Analysis provides an interesting overview of some of the general risk issues involved in importing animals and meats with BSE, and the safeguards in the Proposed Rule intended to reduce those risks. To fully understand the risks, a more thorough, detailed, and methodologically valid risk analysis is essential.

¹ Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States, USDA, APHIS, October 2003.

² Explanatory Note. Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States, USDA, APHIS, February 2004.

³ 69 FR 62386 (November 4, 2003).

COMMENTS

1. The USDA has not presented an appropriate risk assessment that supports its proposed action. Its Risk Analysis presents opinions, judgments, and conjectures rather than relevant data and results of transparent and sound quantitative analysis.

Although the USDA has named its supporting document a “risk analysis,”⁴ this document does not (a) conform to standard definitions and concepts for risk assessments or (b) provide the essential information required to inform rational risk management decision-making on this critical issue. It does not provide high-quality risk analysis information suitable for supporting the proposal to import certain live ruminants and ruminant products from Canada. Among others, it does not answer these two key questions:

- (a) *What is the probable change in human health risk (i.e., frequency and severity of adverse human health effects) that would be caused by each alternative risk management option considered (e.g., reopening the US to less restricted imports of Canadian ruminants vs. imposing different types of restrictions vs. keeping the status quo); and*
- (b) *How certain is the change in human health risk that would be caused by each proposed risk management action?*

These questions, and the analogous questions for animal health, are usually considered to be essential components of a health risk assessment. For example, a Joint FAO/WHO Expert Consultation defines risk characterization (corresponding approximately to what USDA terms “Risk Estimation”) as the “integration of hazard identification, hazard characterization [i.e., dose-response or exposure-response relation] and exposure assessment into an estimation of the **adverse effects likely to occur in a given**

⁴ Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States, USDA, APHIS, October 2003.

population, including attendant uncertainties.”⁵ The U.S. Food and Drug Administration (FDA) has also used this definition⁶ and it is widely shared in the food safety and risk analysis community. Further, the Codex Alimentarius Commission, uses a similar definition: **“The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.”⁷** Characterizing the risks for different risk management interventions is thus traditionally expected to provide information about likely animal and/or human health effects (frequencies and severities of adverse consequences) for each, thus providing a basis for well-informed decision-making. The USDA Risk Analysis does not provide *any* quantitative or substantive qualitative estimation of the frequency and severity of adverse health effects from the different decision alternatives (beyond undefined adjectives such as “low”, offered without any clear, explicit interpretation or any explicit, verifiable derivation from data).

The crucial “Risk Estimation” section of the USDA Risk Analysis occupies less than half of a page.⁸ It does not present *any* (qualitative or quantitative) information about the likely frequency or severity of adverse human or animal health effects for different risk management interventions (i.e., the usual components of a health risk assessment), but instead opines: “that the animals and animal products under consideration in this analysis are of low or minimal risk in view of the certification requirements that will be implemented.” *But no definition of “Low or minimal risk” is given, so it is impossible to know how to interpret this result.*

“Low or minimal risk” can mean any number of things, such as:

- The smallest we can think of (i.e., zero)

⁵ <http://www.fao.org/docrep/w8901e/w8901e06.htm> (emphasis added).

⁶ <http://www.foodsafety.gov/~dms/lmriskgl.html>. USDA FSIS also repeats the definition in footnote 5.

⁷ <http://www.fao.org/DOCREP/005/Y2200E/y2200e07.htm> (emphasis added).

⁸ Risk Analysis at page 35.

- The smallest risk found among a subset of countries that we want to trade with
- The smallest we can reasonably expect to achieve without spending a lot more money
- The probability of infecting more than 10 people per year is less than 10%
- The probability that Canadian imports, taken in conjunction with current and expected future US conditions, will initiate a widespread epidemic is less than 1%
- The risks are acceptably small, as judged by criteria such as no more than 1 excess fatality per million lifetimes with confidence of at least 95%

“Low or minimal risk” might mean any of these things, or none of them, or perhaps something else entirely. It is too vague to be clearly understandable and useful for purposes of rational risk assessment.” Without a specific definition of what the terms used in its conclusion mean, USDA’s conclusion is, at best, not much more informative or useful than a vague reassurance, along the lines of: “We think it’s very probably ok,” without any independently verifiable justification or derivation from data being presented. This is inadequate as the final output of a “risk analysis.”

The Risk Estimation section of USDA’s Risk Analysis concludes: “In summary, VS considers the risk of BSE-imported animals or animal products entering the United States from Canada and exposing U.S. livestock through feeding of infected materials to susceptible animals, to be low.”⁹ This appears to be no more than an opinion (or, perhaps a risk management policy judgment, if “low” is defined as “acceptable to import”) that is not supported by or explicitly derived from stated facts and data using clear definitions and subsequent analysis via openly published formulas. It does not appear to be based on any documented calculations that integrate factual outputs from the hazard identification (or release), exposure assessment, and consequence steps, as risk assessment traditionally requires. In short, it is not clear that this conclusion actually follows from available facts and data in any transparent, verifiable way, or that it is based on substantive risk analysis as opposed to policy judgments, opinion, or hope.

⁹ Risk Analysis at page 35.

In summary, it is not clear what USDA's "Risk Estimation" conclusions mean in terms of human or animal health impacts, or how they are derived from or supported by factual evidence and objective data. The resulting qualitative reassurances do not constitute an adequate "Risk Analysis", as the essential components of what is usually meant by risk analysis are missing.

2. The USDA has misrepresented and misused the “Harvard Study” in support of its proposed action.

The “Risk Estimation” section of the Risk Analysis¹⁰ states that its conclusions “are consistent with the 2001 Harvard study, which found that the measures taken by the US government and industry make the United States robust against the spread of BSE, should it be introduced into the country.” This overstates what the Harvard Center for Risk Analysis (HCRA) model (the “Harvard Study”)¹¹ actually found. While that study indicated that its *base case assumptions* implied a high degree of robustness against the spread of BSE, it also clearly indicated that there is enough uncertainty about the validity of these assumptions so that no single, unambiguous set of conclusions can be drawn with very high confidence. The Harvard Study took care to document the sensitivities and crucial assumptions, including unvalidated ones, in its analysis. It explicitly stated that “a true validation of the simulation model described in this report is not possible.” It described its base case results as probably being reasonable and plausible, but did not claim that they are correct, or assert that they are suitable for use in this rulemaking or applicable to the definition and characterization of Canada as a minimal-risk region.

The original Harvard Study was prepared in 2001 for a totally different purpose than to serve as analytic support for the importation of live ruminants and ruminant products from Canada. It was also prepared prior to the recent identification of the Canadian and

¹⁰Risk Analysis at page 35.

¹¹ Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States, Joshua T. Cohen, et. al., Harvard Center for Risk Analysis, November 26 2001, Revised October 2003.

US BSE cases in 2003. Even though the authors of the Harvard Study have recently updated their analysis, none of the simulation runs or analyses was specifically appropriate for the action that the USDA now proposes. None claimed to model the current situation in Canada. USDA does not explain how the Harvard Study, which did not use Canadian data, can even be used as an analytic tool to support reclassifying Canada's risk status. At best, the Harvard Study should be viewed as a first-cut "screening" risk analysis, whose conclusions suggest the need for additional refined risk analyses.

Moreover, as stated in the HCRA report: "Because the feed and MBM parameters include the three parameters that had the greatest univariate impact on the number of additional infected cattle (see Figure 4-1), it is not surprising that assigning worst case values to all the parameters in this set has a substantially greater impact on the number of additional infected cattle. **Assigning worst case values to all of these parameters simultaneously results in an R_0 value exceeding unity at the 75th percentile.** ... We did not simulate the scenario in which all parameters are simultaneously assigned their worst-case values for three reasons. First, the results described in the preceding paragraph indicate that **assigning worst case values to two of the three sets of parameters (demographic assumptions and MBM production, feed production, and feed practice parameters) is sufficient to change the predicted behavior of the agricultural system.**"¹²

The practical implications of this technical passage are as follows. " R_0 value exceeding unity" is the condition for a single new BSE case to be able to start an epidemic, i.e., it is the *opposite* of the base-case, in which a single new BSE case is expected to cause less than one additional new case, and thus imported cases eventually die out. (This reversal of qualitative conclusions from Imported BSE cases will probably die out to Imported BSE cases will probably start an epidemic is what is meant by "sufficient to change the predicted behavior of the agricultural system.") Thus, assigning even a subset of

¹² Harvard Study, line 3465 (emphasis added).

parameters non-baseline values that are within the range that the HCRA team judged as being possible, reverses the reassuring baseline conclusion cited by USDA in the Risk Analysis, instead leading to the conclusion that the US could be sensitive to, rather than robust against, imports of BSE. We believe that this should be of paramount interest to decision makers.

The HCRA report further explains that: “The base case assumes that 94.9999% of cattle remains are sent to prohibited rendering plants, 5% are sent to mixed plants, and 0.0001% are sent (incorrectly) to non-prohibited plants.”¹³ But it later notes that, due to lack of direct, real-world experience with importing BSE-infected cattle, **“a true validation of the simulation model described in this report is not possible.”**¹⁴ Moreover, the HCRA report finds that: “The sensitivity analysis results indicate that the predicted number of additional cattle infected is particularly sensitive to the assumed proportion of prohibited MBM that is mislabeled and the assumed proportion of properly labeled prohibited feed that is incorrectly fed to cattle (i.e., the assumed error rate of only 0.0001% above.) **Predicted human exposure is likewise sensitive to these parameters.** It is also sensitive to the assumed number of ID50s in the carcass of an animal with full blown BSE, and to a lesser extent to several parameters related to the slaughter process.”¹⁵ Being “sensitive” to these assumptions, in this case, means that if error rates are higher than those assumed, BSE-infected cattle imports will have a greater potential to start a US epidemic or to have severe adverse consequences than the base case estimates. In short, the Harvard Study shows that if reassuring base case assumptions are made, reassuring results are produced; while if pessimistic assumptions are made, potentially severe consequences are produced. Which set of assumptions is correct is not known, but both are considered possible. USDA’s paraphrase does not emphasize that the Harvard Study can be used to predict catastrophic as well as reassuring US consequences of BSE imports based on parameter values considered to be possible, and perhaps not extremely unlikely.

¹³ Harvard Study, line 2420.

¹⁴ Harvard Study, line 3125 (emphasis added).

¹⁵ Harvard Study, line 3306 (emphasis added).

