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U.S. Department of Agriculture
Food Safety and Inspection Service
Room 102, Cotton Annex
300 12th and C Street, SW
Washington, DC 20250-3700

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Leo McDonnell

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Docket Nos. 01-003P, RIN 0583-AC87
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03-038IF
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03-048N

In the Matter of Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle; Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems; Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter; Bovine Spongiform Encephalopathy Surveillance Program; Interim Final Rules and Notice.

Dear Administrator:

Thank you for the opportunity to comment on the Food Safety and Inspection Service's (Agency's) preliminary regulatory impact analysis (PRIA), Docket No. 01-003P, RIN 0583-AC87; Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle, Docket No. 03-025IF; Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems, Docket No. 03-038IF; Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter, Docket No. 01-033IF; and Bovine Spongiform Encephalopathy Surveillance

Program, Docket No. 03-048N, published by the Agency in the Federal Register on January 12, 2004 (April 7, 2004 in Docket No. 01-003P, RIN 0583-AC87), in response to the detection of a case of BSE in a cow imported from Canada.

The Ranchers Cattlemen Action Legal Fund - United Stockgrowers of America (R-CALF USA) is a non-profit association representing over 52,000 cattle producers, 8700 of which are voluntary, dues-paying R-CALF USA members and over 43,000 are members of R-CALF USA's 59 affiliated ranch and 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.

Regarding Docket No. 03-48N, Notice, Bovine Spongiform Encephalopathy Surveillance Program, R-CALF USA appreciates the Notice and supports the rule.

Regarding Docket No. 01-033IF, Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle during Slaughter, R-CALF USA supports the Interim Final Rule.

Regarding Docket No. 03-038IF, Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems, R-CALF USA supports the Interim Final Rule.

Regarding that portion of Docket No. 03-025IF that pertains to Requirements for the Disposition of Non-Ambulatory Disabled Cattle, R-CALF USA supports the Interim Final Rule.

With Respect to that portion of Docket No. 03-025IF that pertains to the Prohibition of the Use of Specified Risk Materials for Human Food (Rule) and Docket No. 01-003P, RIN 0583-AC87, the Food Safety Inspection Service's preliminary regulatory impact analysis (PRIA) for the above referenced dockets, R-CALF USA submits the following comments:

While R-CALF USA agrees that the Rule and PRIA are intended to further minimize potential human exposure to the BSE agent through the consumption of beef and beef food products and to restore exports of U.S. beef, R-CALF USA believes the implementation of the Rule and development of the PRIA was the result of the Agency's failure to consider the known facts of the BSE case that precipitated these actions. The Agency's actions are void of any consideration of more cost-effective and efficient alternatives with which to achieve the Agency's objectives. The Agency's actions are not likely to result in the achievement of the Agency's objectives without modification. And, the PRIA is particularly deficient in that it lacks a foundation in internationally accepted and science-based standards. The PRIA, therefore, is an inadequate analysis with which to maintain domestic confidence in the U.S. beef supply and is equally inadequate for purposes of encouraging foreign customers to resume U.S. beef exports.

1. The Agency's Rules and its PRIA are Overly Broad and Discriminate Against the U.S. Cattle Producer Rather than Targeting the Source of any possible BSE Contamination.

The Rule and PRIA acknowledge that the sole impetus for the Agency's implementation of the Rule was the finding of a BSE-positive cow in Washington State on December 23, 2003. However, BSE has never been found in native U.S. cattle. The Holstein cow found with BSE was confirmed to originate in Alberta, Canada. The Office International des Epizooties (OIE) removed the United States from its list of countries with native-born cases of BSE in early January 2004.[1] As such this is **NOT a United States problem – this is a Canadian problem**. The failure of the Agency to recognize and acknowledge the source of this BSE problem has effectively preempted the United States from implementing or even considering a far more effective strategy with which to prevent the introduction of BSE into the U.S. beef supply and cattle herd and to control and eradicate BSE from the Canadian cattle herd presently affected.

The Rule and PRIA fail to consider any alternative approaches to accomplishing the Agency's stated benefits of reducing human exposure to BSE infectivity and restoring beef exports. R-CALF USA members are extremely frustrated that USDA refuses to follow the time-honored disease control strategy that is central to USDA's BSE Response Plan. The BSE Response plan is predicated on containment. It calls for the rapid quarantine of the infected animal's herdmates.[2] The BSE-positive cow originated from the Canadian cattle herd. Its herdmates, therefore, are Canadian cattle. The USDA should have then, as it should now, immediately begin identifying the herdmates of the Canadian cattle herd that presently reside in the United States. These cattle should be permanently identified and quarantined, either in the U.S. or in Canada, to ensure that no herdmate from the Canadian cattle herd can introduce the BSE agent into the United States cattle herd or beef supply.

R-CALF USA has reviewed data maintained by the USDA Foreign Agricultural Service and has determined that since 1997, the year the United States' feed ban went into effect, the U.S. imported 8.1 million head of live Canadian cattle into the U.S. from Canada. However, 6.2 million of these cattle were imported directly for slaughter and another 1.6 million were feeder cattle destined for slaughter within 4-8 months. Since the U.S. border has been closed to live Canadian cattle for nearly a year, all these cattle have likely been purged from the U.S. food supply chain. This leaves approximately 437,000 head of Canadian cattle that may still reside in the U.S. Of these, 382,000 are dairy cattle and less than 55,000 are beef cattle.[3] It would appear that this is a manageable number of cattle as it represents less than one-half of one percent of the total U.S. cattle herd.

The Agency should work aggressively with state animal health officials to identify and subsequently mark these imported cattle with a permanent mark of origin to prevent the

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[1] 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, downloaded on May 7, 2004.

[2] Bovine Spongiform Encephalopathy (BSE) Response Plan Summary, U.S. Department of Agriculture, Animal Plant and Health Inspection Service and Food Safety and Inspection Service, available at http://www.aphis.usda.gov/lpa/issues/bse/bsesum.pdf, downloaded on May 7, 2004.

[3] U.S. Trade Statistics, United States Department of Agriculture, Foreign Agriculture Service, HS 10-Digit Imports, available at http://www.fas.usda.gov/ustrade/USTExHS10.asp?QI=, downloaded on January 2, 2004.

possibility that one of these animals may lose their Canadian export tag. In addition, the Agency would increase its protections of U.S. consumers by testing these imported animals for BSE at the time of slaughter while at the same time restricting the importation of live cattle and beef from countries with native cases of BSE.

In February 2004, R-CALF USA submitted initial comments regarding the Rule's mouthing provisions stating that while it appreciated many of the safeguards USDA has put in place, it believed the mouthing rule was inappropriate. R-CALF USA stated that in the unlikely event a BSE infected animal is found in native U.S. cattle, then perhaps this rule would have more validity. Until then, R-CALF USA encourages the Agency to help the U.S. cattle industry protect its greatest asset - the consumer, without harming the United States producer.

R-CALF USA's initial comments stated the mouthing rule was having a negative financial impact on producers and feeders. It described losses that were revealed by harvest sheets and sale barn receipts all across the nation in February 2004. At that time, cattle feeders were losing upwards of $200 per head for cattle considered close to 30 months of age, representing nearly a 20 percent loss per head. In May 2004, the discount for cattle at or approaching 30 months of age is estimated at approximately $125 per head. Cattle producers were also experiencing a decline in income in February on this type of animal of nearly $360 per head, resulting in a loss of almost 50 percent of the value of their cattle. In May 2004, the per head loss to cattle producers is estimated at approximately $200. Also in February, R-CALF USA calculated that potential industry wide losses due to the mouthing rule could exceed $1 billion in 2004 alone. This is a loss the United States feeder and producers cannot withstand.

U.S. producers are deeply disappointed that they must absorb the costs associated with a problem originating in Canada, and which problem could be readily contained and eventually eradicated in Canada if the Agency would direct its efforts toward the source of the problem. The Agency's strategy for protecting consumers and the U.S. cattle herd from the BSE agent must include an immediate and coordinated effort to identify the higher-risk Canadian cattle currently interspersed, albeit in small numbers, within the U.S. beef and dairy cattle herds.

2. The Notice of Availability and Request for Comment on Preliminary Regulatory Impact Analysis; Extension of Comment Period for Interim Rules (Agency Notice) Published in the Federal Register on April 7, 2004, and the Rule Fail to Acknowledge the Central Fact that the BSE Case Precipitating the Need for the Rules and the PRIA was Detected in a Cow that Originated Directly From the Importation of a Cow from the Canadian Cattle Herd.

It must be presumed that interested parties reviewing the Federal Register for BSE related notices, including the United States prospective beef export customers, are familiar with the internationally recognized and science-based disease risk categories and corresponding disease mitigation recommendations of the OIE. By failing to acknowledge the true origin of the BSE case detected in the state of Washington, the Agency unwittingly signaled the international community and any other interested party that the U.S. is among the countries known to have BSE. Because the U.S. met the OIE criteria for a "BSE Provisionally Free Country or Zone" prior to the BSE case in Washington State, and because the central fact that the BSE-affected

cow was an animal imported from Canada was omitted, interested parties would logically conclude that the U.S. had lost its eligibility for a "BSE Provisionally Free Country or Zone." Further, because it is common knowledge that the U.S. has not had its feed ban in effect for the requisite 8 years, a country situated as is the U.S. could achieve a no more favorable disease status than a "Country or Zone with a Moderate BSE risk" if it were to detect a BSE case within its native herd.

Under the OIE's disease mitigation recommendations for a "Country or Zone with a Moderate BSE Risk" the country would be required, when exporting fresh meat and meat products, to remove the brain, eyes, spinal cord, distal ileum or mechanically separated meat from skull and vertebral column, otherwise known as specified risk materials (SRMs) from cattle over 6 months of age in order to comply with the internationally accepted, science-based recommendations.[4]

However, the Rule does not contemplate this degree of disease mitigation as it only proposes the removal of SRMs from animals over 30 months of age. The PRIA, consequently, does not address the economic impact associated with the OIE recommended mitigation measures for a "Country or Zone with a Moderate BSE Risk."

The failure of the Agency to assert the U.S.'s continued eligibility for the OIE's "BSE Provisionally Free Country or Zone" status, along with its associated disinclination to publicly and officially acknowledge the Canadian origin of the BSE case detected in Washington State, has fostered unnecessary confusion, obfuscation, and ambiguity in the minds of both domestic and international consumers, which has greatly contributed to the perception by international customers that the U.S. beef supply may not be safe.

R-CALF USA urges the Agency to immediately adopt the internationally accepted and science-based standards established by the OIE; to immediately acknowledge that while the Canadian cattle industry can achieve a no more favorable OIE disease status than a "Country or Zone with a Moderate BSE Risk," the U.S. continues to meet the OIE standard of a "BSE Provisionally Free Country or Zone;" and to discontinue its efforts to rationalize its non-science based actions in contradiction to OIE standards. By doing so, the Agency will significantly enhance its ability to maintain the integrity of the U.S. beef supply for domestic and international consumers alike.

For a more detailed discussion on why the Agency's failure to adopt the internationally accepted and science-based standards of the OIE effectively renders the Agency's objective of assuring domestic consumers that the U.S. beef supply remains safe and concurrently encouraging foreign customers to resume U.S. beef exports untenable, see R-CALF USA's comments of January 5, 2004 and April 7, 2004 to the Animal Plant Health Inspection Service attached hereto as Exhibits 1 and 2, respectively, and incorporated herein.

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[4] Terrestrial Animal Health Code, 11th edition – 2003, Part 2, Section 2.3, Chapter 2.3.13., Article 2.3.13.16, Office International des Epizooties.

3. The Agency Notice and PRIA Fails to Consider the Increased Risk and Related Economic Impact Associated with USDA's Acceptance of Beef from a Country that Can Achieve a No More Favorable OIE Disease Status than a "Country or Zone with a Moderate BSE Risk," But Which Country Has Not Been Required to Comply with the Corresponding Internationally Accepted and Science-Based Disease Mitigation Recommendations of the OIE.

Part and parcel to its assurance that the U.S. beef supply is safe, the Agency states in the PRIA that "Countries that import beef products into the U.S. must have requirements that are equivalent to the new regulatory requirements by FSIS in response to the detection of a case of BSE in this country (9. CFR 327.2)." PRIA, Page 45. Notwithstanding the Agency's omission of the central fact that the BSE case discovered in this country originated directly from the importation of a cow from Canada, this requirement is woefully inadequate to ensure the safety of the U.S. beef supply, and it has no basis in internationally accepted science.

The OIE has established five science-based categories based on an exporting country's risk for BSE and then recommends science-based risk mitigation measures through an increasing degree of restrictions commensurate with the risks presented.[5] Thus the OIE recognizes that as a country's risk for BSE increases, the intensity of risk measures must also increase. However, not only does the Agency intend to ensure that countries that import future beef products into the U.S. have equivalent regulatory requirements as the U.S., apparently regardless of their internationally determined risk status, but the Agency is ignoring the fact that the U.S. has been allowing imports of beef from Canada, a country that can achieve a no more favorable OIE risk status than a "Country or Zone with a Moderate BSE Risk," for which the OIE recommends that SRMs be removed from all cattle over 6 months of age.[6] Canada, however, has been allowed to export beef to the U.S. since at least November 2003 without being required to implement the OIE's science-based risk mitigation measures.[7]

As a result of the Agency's failure to require Canada to implement the internationally accepted and science-based disease mitigation measures commensurate with Canada's risk status, the Agency has unnecessarily subjected domestic consumers to increased risk and has sent a detrimental signal to potential U.S. beef export customers that it does not embrace the internationally accepted and science-based recommendations of the OIE. Moreover, the USDA has proposed rules in November 2003 that would expand beef imports, and allow cattle imports from Canada without requiring the disease mitigation measures recommended by the OIE.

Even if it continues not to follow the OIE recommendation, the Agency has not justified its decision to require the removal of SRMs only in cattle less than 30 months of age. Clearly the recent cases of BSE detected in animals less than 24 months of age in Japan (both discovered after the establishment of the current OIE standards), and cases in younger animals elsewhere,

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[5] The OIE Standards on BSE: A Guide for Understanding and Proper Implementation, Press Release, Office International des Epizooties, Updated 09-Jan-2004, available at http://www.oie.int/eng/press/en040109.htm, downloaded on May 6, 2004.

[6] Terrestrial Animal Health Code, 11th edition – 2003, Part 2, Section 2.3, Chapter 2.3.13., Article 2.3.13.16, Office International des Epizooties.

[7] Low Risk Canadian Products, USDA – Animal Plant Health Inspection Service, April 19, 2004, see also Low Risk Canadian Products, USDA – Animal Plant Health Inspection Service, August 7, 2003.

should call into question the scientific basis for this requirement. Of course, this is all the more confusing to an industry representing a cattle herd in a country that meets the OIE criteria of a "BSE Provisionally Free country," which, by OIE's definition does not have SRMs in its herd.

4. The Agency has Misrepresented the Scope and Findings of the Harvard School of Public Health, Center for Risk Analysis (Harvard Analysis) thus Providing a False Assurance that a Scientific Assessment Regarding the Risk of Introducing BSE Into the U.S. has been Conducted and Incorporated in the PIRA.

The Agency's PRIA introduces the Harvard Analysis as both "an analysis and evaluation of the current measures implemented by the U.S. government to prevent the introduction and spread of BSE in the United States and to reduce the potential exposure to the BSE agent." [Emphasis added.] However, the scope of the Harvard Analysis, as described by its authors, is limited to an analysis "to evaluate 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." [Emphasis added.] Thus representations made in the PRIA suggesting that the Harvard Analysis provides scientific evidence that current measures are adequate to prevent the introduction of BSE in the U.S. cannot be supported. Further, such misrepresentations inure to the preemption of any serious consideration for the need to significantly strengthen the United States resistance to the introduction of BSE.

Previous misrepresentations by USDA suggesting that the Harvard Analysis assessed efforts to keep BSE out of the U.S. have been reported in January 27, 2004 and May 3, 2004 articles by Jim Barnett that appeared in the Portland Oregonian.[8] In three articles, Mr. Barnett documents how Harvard researchers had spent two years trying unsuccessfully to measure the risk that BSE might enter the U.S.[9] Barnett indicated that in an interview with George Gray, lead author and executive director of the Harvard risk center, researches simply assumed that BSE got in.[10]

The mischaracterization of the Harvard Analysis is particularly troubling given first the August 2003 relaxation of restrictions on the importation of Canadian beef products following the May 2003 discovery of a BSE-affected cow in Canada. Second, the further weakening of the United States resistance to the introduction of BSE that occurred during the period August 2003 through April 26, 2004. Third, the ongoing proposal by USDA to even further reduce the United States defenses by allowing most all beef products from Canada as well as live cattle. Fourth, the fact that the Agency's PRIA ominously mentions neither that products from a BSE-affected country are already entering the U.S. nor that USDA is working aggressively to allow a significant expansion of beef products and cattle from that country. And, finally, that these USDA actions to reduce our current health and safety standards are being taken without the

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[8] Jim Barnett, *Bush Officials Overstated Findings of Risk Study*, The Oregonian, January 27, 2004, http://www.oregonlive.com/news/oregonian/index.ssf?/base/front_page/1075208119170910.xml; Jim Barnet, *Harvard Study Couldn't Assess the Risk of Entry,* The Oregonian, May 3, 2004, http://www.oregonlive.com/search/index.ssf?/base/news/1083585412836 90.xml?oregonian?lcg; Jim Barnett, *U.S. Policy On Mad Cow in Question*, The Oregonian, May 3, 2004, http://www.oregonlive.com/search/index.ssf?/base/front_page/108358536383690.xml?oregonian?fpfp .

[9] *Id.*

[10] *Id.*

benefit of a scientific risk analysis with which to quantify or otherwise assess the increased risk to humans or to the U.S. cattle industry of introducing BSE into the U.S.

As demonstrated in the evaluation prepared by Dr. Louis Anthony Cox, Jr., a nationally recognized expert on risk analysis, the Harvard Analysis lacks many of the key elements of a valid risk assessment.[11] Little to no actual data was considered and, accordingly, the conclusions reached are expressed in vague, subjective terms.[12] And, such an analysis 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.[13]

It is disconcerting that the Agency's PRIA remains silent regarding any risks associated with immediate past, current, and impending expansions of beef products from Canada and, in the latter case, even live cattle imports. But more disconcerting is that the Animal and Plant Health Inspection Service (APHIS), the agency proposing to relax current health and safety standards, is justifying its actions not with scientific evidence, but rather by claiming that FSIS's requirement for the removal of SRMs from cattle over 30 months of age ensures that beef products from older cattle are risk-free, apparently without regard to whether the animal originates from a BSE provisionally free country or a country with moderate risk for BSE. This unscientific deduction is pronounced in APHIS's reopened proposed rule wherein it states based on FSIS policy that it is no longer necessary to restrict beef from Canada only from cattle under 30 months of age.[14] Likewise, APHIS has asserted that, because FSIS is not requiring removal of SRMs from U.S. cattle under 30 months of age, FSIS' action means that Canadian cattle under 30 months of age present minimal risk. These conclusions contradict, yet again, the internationally accepted and science based risk standards of the OIE.

R-CALF USA appreciates the opportunity to submit the foregoing comments.

Sincerely,

WILLIAM L. MILLER FOR

Leo McDonnell
President

[11] 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 contained in attached Exhibit 2 of these comments as Appendix A.
[12] Id. at 4.
[13] Id.
[14] 69 Fed. Reg. 10,635 (March 8, 2004).