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December 27, 2004

The Honorable Ann Veneman
Secretary
United States Department of Agriculture
1400 Independence Ave., SW
Washington, DC 20250

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

Via E-mail and Overnight Delivery

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

Dear Secretary Veneman and Administrator DeHaven:

R-CALF USA is disappointed to learn through unofficial channels that the United States Department of Agriculture's Animal and Plant Health Inspection Service (USDA-APHIS) has chosen not to consider R-CALF USA's Second Submission of Supplemental Comments for Docket No. 03-080-1: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities (Second Submission of Supplemental Comments) prior to publishing the agency's final rule in the Federal Register. Notwithstanding this decision, R-CALF USA hereby submits its Third Submission of Supplemental Comments for Docket No. 03-080-1: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities (Third Submission of Supplemental Comments).

R-CALF USA offered its constructive, Second Submission of Supplemental Comments in recognition of the evolving BSE-related scientific research that continually challenges the now outdated assumptions underpinning the USDA-APHIS proposed rule issued over one year ago. In the context of BSE research, which began only around 1986, the agency's refusal to consider the scientific developments over the past eight months effectively blocks from the agency's

view some of the most important scientific discoveries regarding the epidemiology of BSE. This despite the fact that R-CALF USA provided the agency with complete copies of nine recent scientific reports within its Second Submission of Supplemental Comments, which affords the agency with immediate and ready access to this critical information. The agency's rejection of this critical information is a serious oversight that could well imperil the health and safety of U.S. and international consumers and the U.S. cattle industry.

R-CALF USA is committed to ensuring the health and safety of U.S. and international beef consumers and the welfare of the U.S. cattle industry. Toward this end, R-CALF USA submits the following supplemental comments so USDA-APHIS will have the most recent and relevant scientific and factual information with which to base its final decision regarding Docket No. 03-080-1:

1. A study published in December 2004 shows how prions cross the human intestinal epithelial cell barrier, a finding that undercuts several key assumptions that were the basis for the USDA-APHIS proposed rule.

An article published December 15, 2004, in the *Journal of Neuroscience* adds another piece of information to the Bovine Spongiform Encephalopathy (BSE) puzzle that has evaded scientific explanation since BSE was first discovered in European cattle in the mid-1980s. This new research supports the theory that BSE resulted from the transmission of sheep scrapie to cattle as BSE and is subsequently transmitted to humans as variant Creutzfeldt – Jakob disease (vCJD).¹ But more importantly, the article describes the process by which prions cross the generally impermeable and highly selective epithelial barrier of the human intestinal tract.

Scientists at Case Western Reserve University, a leading research center for transmissible spongiform encephalopathies (TSEs) and prions, have identified ferritin, which is present in meat, particularly beef, as the likely carrier protein that co-transport prions across the intestinal epithelial cell barrier.² The researchers suggest ferritin may be only one such carrier protein.³ More research is needed to identify other potential carrier proteins to prevent a carrier state across species, either by transport “. . . to sites where it may undergo conformational ‘adaptation’ with time . . . ; or in the case of livestock, lie dormant until ingested by a susceptible host.”⁴ The implication is that apparently healthy livestock could be carriers, which disseminate prions through a variety of means. This, the researchers found, could pose a potential threat to the population.⁵

The implications of this finding should be carefully considered by USDA-APHIS before relaxing regulatory restrictions on importing cattle and beef from countries known to have BSE present in their cattle herds. Other research previously submitted by R-CALF USA to USDA-APHIS, as

¹ R. Mishra, S. Basu, Y. Gu, X. Luo, W. Zou, R. Mishra, R. Li, S. Chen, P. Gambetti, H. Fujioka, N. Singh, Protease-Resistant Human Prion Protein and Ferritin Are Cotransported Across Caco-2 Epithelial Cells: Implications for Species Barrier in Prion Uptake from the Intestine, *The Journal of Neuroscience*, 24(50): 11280-11290 (Dec 15, 2004), attached hereto as Attachment A.

² *Id.* at 11289.

³ *Id.* at 11290.

⁴ *Id.*

⁵ *Id.*

well as an article regarding prions in tongue that is attached to these comments, has shown that prions accumulate in muscle tissue, i.e. meat.⁶ USDA must address the very real possibility that consumption of meat containing BSE prions will result in a significant risk of exposure to humans. Removal of Specified Risk Materials (SRMs) does not address this problem, as the meat itself is the source of infectious prions.

The proposed USDA-APHIS rule does not address the potential that other proteins residing in cattle could be carriers of BSE, and by extension, the host cattle as well. The proposed rule does not provide for any measures that would prevent consumers from being exposed to BSE prions from asymptomatic, BSE-infected cattle. Testing all Canadian cattle at slaughter for BSE would identify infected animals within the sensitivity of testing technology; however, given the limits of current tests, only animals over 20 months of age could be adequately screened. Somewhat ironically, if USDA-APHIS adopted a requirement that all Canadian cattle be tested, older animals, which could be screened with more confidence, could well pose a lower risk to consumers than younger animals that USDA-APHIS proposes to allow to be imported into the United States. Therefore, until testing technology allows for detection of prions in younger animals, the safest course would be to maintain the current regulations, which ban the importation of cattle and beef from countries where BSE exists.

2. Recently published research shows prion infection of the tongue, a finding that further undercuts several key assumptions that were the basis for the USDA-APHIS proposed rule.

Another piece of the BSE puzzle was revealed in July 2004 when scientists published research findings in the *Journal of Virology* that indicate prion infection of skeletal muscle cells and the epithelial layer in the tongue can be established following the spread of the prion agent from nerve terminals and/or axons that innervate the tongue. The researchers stated:

Our data suggest that ingestion of meat products containing prion-infected tongue could result in human exposure to the prion agent, while sloughing of prion-infected epithelial cells at the mucosal surface of the tongue could be a mechanism for prion agent shedding and subsequent prion transmission in animals.⁷

The researchers acknowledge they have not identified prion infectivity in bovine tongues, but they qualify this condition as likely resulting from a lack of sensitivity in the infectivity bioassays used in previous investigations, which may not detect low levels of the prion agent. The researchers believe their findings have implications for intraspecies transmission of animal prion diseases.⁸

⁶ See E. Mulcahy, J. Bartz, A. Kincaid, R. Bessen, Prion Infection of Skeletal Muscle Cells and Papillae in the Tongue, *J. Journal of Virology*, Vol. 78 No. 13, 6792 -6798 (July 2004) attached hereto as Attachment B.

⁷ Ellyn R. Mulcahy, Jason C. Bartz, Anthony E. Kincaid, Richard A. Bessen, Prion Infection of Skeletal Muscle Cells and Papillae in the Tongue, *Journal of Virology*, Vol. 78, No. 13: 6792-6798 (July 2004), attached hereto as Attachment B.

⁸ *Id.* at 6797.

This new research undercuts several key assumptions that were the basis for the proposed rule. First, it is apparent that USDA-APHIS' assumption that beef tongue is unlikely to be infected even in an animal with BSE, and therefore tongue should be imported freely, is incorrect. Second, the agency's assumption that the misformed prions thought to cause BSE are limited to parts of cattle designated as SRMs is inaccurate or overly simplistic. Clearly these prions can migrate out of nervous system material and into muscle tissue in the tongue. Third, the researchers suggest there is a plausible route of migration of BSE from one live animal to another, through sloughing of the epithelial layer of the tongue into saliva.⁹ This points to a potential risk that USDA-APHIS has assumed does not exist – the risk that Canadian cattle infected with BSE could infect U.S. cattle when imported and co-mingled with the U.S. herd, regardless of how effective the U.S. and Canadian feed bans are.

3. December 2004 news reports originating in Canada collaborate pre-existing evidence that demonstrates Canada has not adequately enforced its meat-and-bone meal (MBM) feed ban, up to and including 2004.

In mid-December 2004, a Canadian journalist for *The Vancouver Sun* (*The Sun*) reported that the Canadian government had conducted “secret” tests that revealed Canadian cattle feed labeled as “vegetable-only” was contaminated by animal parts.¹⁰ The tests reportedly showed that a majority of Canadian feed labeled as containing vegetable matter only in fact contained animal parts as well. The article identified the source of the test results as “. . . internal Canadian Food Inspection Agency documents – obtained by *The Sun* through the Access to Information Act. . .”¹¹ The article named Sergio Tolusso, feed program coordinator for the Canadian Food Inspection Agency (CFIA) as the author of a government memo who described the test results as “worrisome,”¹² and who reportedly said “. . . the agency [CFIA] doesn’t have a clear idea of how much cattle remains have been fed to other cattle.”¹³ The findings of the study reported by *The Sun* include, “Of the 28 domestic feed samples tested by the agency, 20 had undeclared animal protein in them – 71 percent of all the samples.”¹⁴

Alarming, the article suggests that United States authorities knew at least as early as the summer of 2003 that Canada was negligent in its MBM feed ban enforcement. The article stated that in the summer of 2003, U.S. authorities “turned-back seven separate shipments of vegetable feed from Canada because they were contaminated with animal parts.”¹⁵ If this allegation is correct, then many decision-makers in the United States, including USDA-APHIS officials who believed that Canada has been in full compliance and should be designated a minimal risk

⁹ Ellyn R. Mulcahy, Jason C. Bartz, Anthony E. Kincaid, Richard A. Bessen, Prion Infection of Skeletal Muscle Cells and Papillae in the Tongue, *Journal of Virology*, Vol. 78, No. 13: 6792-6798 (July 2004), at 6797, attached hereto as Attachment B.

¹⁰ Chad Skelton, Secret Tests Reveal Cattle Feed Contaminated by Animal Parts Mad Cow Fears Spark Review of ‘Vegetable-only’ livestock feeds, *The Vancouver Sun*, December 16, 2004, available at: <http://www.canada.com/vancouver/vancouversun/news/story.html?id=892f5a65-1b99-4b84-8359-6629bbd1f419>, attached hereto as Attachment C.

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

region, as well as members of the consuming public, may have been seriously misled. Not only was USDA-APHIS silent regarding any known violations by Canada of the Canadian MBM feed ban in its October 2003 risk analysis concerning the risk of importing ruminant and ruminant products from Canada into the United States, but USDA-APHIS made repeated claims within its risk analysis that no known violations had occurred:¹⁶ USDA-APHIS stated in its October 2003 risk analysis:

(c) The region [Canada] has a ban on the feeding of ruminant protein to ruminants that appears to be an effective barrier to the dissemination of the BSE infectious agent in place, and compliance with the ban appears to be good.¹⁷

(c) The region [Canada] has implemented a ban on the feeding of ruminant protein to ruminants that appears to be an effective barrier to the dissemination of the BSE infectious agent. There is no evidence of significant non-compliance with the feed ban.¹⁸

Canadian government authorities inspect rendering facilities, feed manufacturers and feed retailers to ensure compliance with the feed ban (CFIA 2003a). Rendering facilities are regulated under an annual permit system, and compliance with the regulations is verified through at least one inspection each year. Feed manufacturers or mills, feed retailers, and farms have been inspected on a routine basis. These inspections have revealed that the level of compliance is good, and there is no evidence of significant noncompliance with the feed ban (CFIA 2003a).¹⁹

As noted previously, Canada has maintained an effective mammalian-to-ruminant feed ban, with requirements similar to the feed ban in place in the United States (DHHS), since 1997. Since compliance with the feed ban appears to have been good (CFIA 2003a), it is unlikely that the animal recently confirmed with BSE ingested contaminated feed during the period covered by the ban. This suggests that the ban has been effective. All of these actions will further reduce the already minimal risk of the spread of BSE.²⁰

The Sun article links the United States' discovery of the summer 2003 Canadian feed ban violation to the "secret," nationwide testing program Canada initiated for both domestic and imported animal feed in 2004.²¹

¹⁶ Risk Analysis: BSE Risk from Inportation of Designated Ruminants and Ruminant Products from Canada into the United States, United States Department of Agriculture Animal and Plant Health Inspection Service Veterinary Services, October 2003, attached hereto as Attachment D.

¹⁷ *Id.* at 11.

¹⁸ *Id.* at 13.

¹⁹ *Id.*

²⁰ *Id.* at 15

²¹ Chad Skelton, Secret Tests Reveal Cattle Feed Contaminated by Animal Parts Mad Cow Fears Spark Review of 'Vegetable-only' livestock feeds, *The Vancouver Sun*, December 16, 2004, available at: <http://www.canada.com/vancouver/vancouversun/news/story.html?id=892f5a65-1b99-4b84-8359-6629bbd1f419>, attached hereto as Attachment C.

The Sun article further reveals the results of the CFIA's investigation of Canada's commercial feed meals. It indicates that Canada has approximately 550 commercial feed mills, and several hundred of those mills were inspected with the following results:

However, the report notes that seven mills had "major non-compliance issues" involving things like proper labeling and record-keeping.²²

And three mills were failing "to prevent the contamination of ruminant feeds with non-ruminant feeds containing ruminant meat and bone meal" – the exact type of contamination that can spread BSE.²³

Two of those three mills successfully recalled their contaminated product, but the report notes that in one case, some of the feed was sent out and consumed by cattle.²⁴

USDA-APHIS fully understands why Canada's compliance with its feed ban is critically important in protecting against the spread of BSE: "The primary source of BSE infection is commercial feed contaminated with the infectious agent,"²⁵ USDA-APHIS stated in its October 2003 risk analysis. And, USDA-APHIS acknowledged the results of the Harvard Center for Risk Analysis when it referenced the Harvard study's conclusion:

The study concluded that the most effective U.S. measure preventing BSE spread is the feed ban instituted by the Food and Drug Administration (FDA) in 1997 (DHHS) to prevent recycling of potentially infectious cattle tissues.²⁶

This information indicates that a key assumption of USDA-APHIS' assessment of the risks of resuming trade in Canadian cattle and beef—that Canada's food ban will prevent isolated cases of BSE in the Canadian herd from being spread to other Canadian cattle—is not supported by the facts. Obviously, the agency will want to consider this critical information because, again, it indicates the agency's assumptions formulated over a year ago no longer may be valid.

Given the tremendous importance associated with Canada's compliance with its MBM feed ban to the question of whether USDA-APHIS can allow the importation of Canadian cattle and beef into the United States from Canada without endangering the U.S. cattle industry, the validity of the aforementioned claims raised by *The Sun* must definitively be determined before USDA-APHIS proceeds with its rulemaking proposal.

²² Chad Skelton, Secret Tests Reveal Cattle Feed Contaminated by Animal Parts Mad Cow Fears Spark Review of 'Vegetable-only' livestock feeds, *The Vancouver Sun*, December 16, 2004, available at: <http://www.canada.com/vancouver/vancouversun/news/story.html?id=892f5a65-1b99-4b84-8359-6629bbd1f419>, attached hereto as Attachment C.

²³ *Id.*

²⁴ *Id.*

²⁵ Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States, United States Department of Agriculture Animal and Plant Health Inspection Service Veterinary Services, October 2003, at 16, attached hereto as Attachment D.

²⁶ *Id.* at 32.

- 4. In December 2004, The National Joint Council of Food Inspection Locals lodged a complaint against USDA alleging failure to implement adequate controls and delegate the critical authorization necessary to properly enforce BSE risk mitigation measures and export requirements – failures that could compromise U.S. and international consumer confidence in U.S. beef, thereby harming the U.S. cattle industry.**

In R-CALF USA's first submission of comments regarding the instant USDA-APHIS rule, Docket No. 03-080-1, dated January 5, 2004, R-CALF USA provided evidence that USDA-APHIS' existing rules are not sufficiently robust to protect the U.S. cattle industry and United States consumers from the introduction of BSE.²⁷ R-CALF USA further provided evidence in those comments that USDA-APHIS has not adequately enforced its existing BSE regulations, thereby subjecting the United States cattle industry and United States consumers to unnecessary risk.²⁸ In R-CALF USA's Second Submission of Supplemental Comments on this USDA-APHIS rule dated December 9, 2004, R-CALF USA provided evidence showing that Canada has already demonstrated it cannot adequately ensure that products exported to the United States are compliant with U.S. BSE-related regulations.²⁹ At the very least, the foregoing submissions provide evidence demonstrating that the USDA-APHIS rule fails to consider known compliance complications with both its current BSE regulations and its proposed regulations.

We presume USDA-APHIS is also aware of the letter this month from the chairman of the National Joint Council of Food Inspection Locals (NJC), the union which represents federal government meat inspectors. The NJC letter detailed reports by inspectors that they have limited ability to enforce current BSE-related regulations and that they have observed many instances where export requirements of Mexico were not being met for products originating from cattle over 30 months of age. The letter included the following complaints:

1. plant employees are not correctly identifying and marking all heads and carcasses of animals over 30 months old. Therefore, plant employees and government personnel further down the line are unaware that numerous parts should be removed as SRMs and these high risk materials are entering the food supply.
2. on line Inspectors are not authorized to take actions when they see plant employees sending products that do not meet export requirements past the point on the line where they can be identified and removed.³⁰

Additionally, the NJC argues that USDA's Food Safety Inspection Service (FSIS) has not established any qualifications or training requirements for plant employees charged with meeting

²⁷ R-CALF USA comments in Docket No. 03-080-1: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, January 5, 2004, at 10-11.

²⁸ *Id.* at 11-13.

²⁹ R-CALF USA's Second Submission of Supplemental Comments for Docket No. 03-080-1: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 9, 2004, at 15-16.

³⁰ Charles S. Painter, Chairman, National Joint Council of Food Inspection Locals, American Federation of Government Employees, Letter to Mr. William Smith, Assistant Administrator for Field Operations, USDA-Food Safety Inspection Service, December 8, 2004, attached hereto as Attachment E.

certain BSE risk mitigation requirements and that frontline inspectors have been told “. . . not to intervene when they see that the export requirements of Mexico are not being met.”³¹

Taken together, the previous and immediate evidence described above that demonstrates USDA-APHIS and USDA-FSIS have not or are not properly discharging their obligations under current BSE regulations and are intentionally avoiding opportunities to mitigate the risk of BSE transmission and exposure strongly suggests that APHIS, FSIS and other inspection agencies cannot be expected to properly implement the more complicated and risky provisions contained in the agency’s proposed rule. For this reason alone, USDA-APHIS should immediately withdraw its proposed rule. Moreover, this calls into question the key APHIS assumption that regulations requiring SRM removal would be sufficient to ensure that consumers are not exposed to BSE infectivity potentially found in Canadian cattle.

Sincerely,

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

Bill Bullard
CEO

³¹ Charles S. Painter, Chairman, National Joint Council of Food Inspection Locals, American Federation of Government Employees, Letter to Mr. William Smith, Assistant Administrator for Field Operations, USDA-Food Safety Inspection Service, December 8, 2004, attached hereto as Attachment E.