



Fighting for the U.S. Cattle Producer!

R-CALF United Stockgrowers of America
P.O. Box 30715
Billings, MT 59107
Fax: 406-252-3176
Phone: 406-252-2516
Website: www.r-calfusa.com
E-mail: r-calfusa@r-calfusa.com

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Docket No. APHIS 2008-0093
Regulatory Analysis and Development, PPD
APHIS, Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

Via Overnight Mail and Facsimile: 301-734-8934

Re: R-CALF USA Supplemental Comments in Docket No. APHIS-2008-0093: Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Meat, Meat Byproducts, and Meat Food Products Derived From Bovines 30 Months of Age or Older

Dear Administrator:

R-CALF USA submits these supplemental comments to ensure that the U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) has reviewed critical information regarding APHIS' request for comments in Docket No. APHIS-2008-0093 (hereafter "APHIS' 2008 Notice") that has materialized after Nov. 17, 2008.

R-CALF USA submitted comments on APHIS' 2008 Notice on Nov. 17, 2008. The new information provided below is crucial to APHIS' 2008 Notice, and R-CALF USA respectfully requests that APHIS consider the following information prior to determining the disposition of this docket:

A. New OIG Report Reveals that BSE Mitigation Measures Critical to the Protection of Human Health have Not Been Properly Performed or Enforced

APHIS' 2008 Notice published at 73 Fed. Reg., 54083-54089 on Sept. 18, 2008, states APHIS' belief that ante-mortem inspections of cattle at the time of slaughter were critical to preventing human exposure to bovine spongiform encephalopathy (BSE). APHIS expressly states that "the removal of SRMs effectively mitigates the BSE risk to humans associated with cattle that pass both ante-mortem and post-mortem inspections (i.e., apparently healthy cattle)." 73 Fed. Reg., at 54086, col. 3 (emphasis added). An official report issued on Tuesday, Dec. 9, 2008, for an ongoing investigation by USDA's Office of Inspector General (OIG) regarding

Evaluation of FSIS Management Controls Over Pre-Slaughter Activities¹ reveals, *inter alia*, that this critical mitigation measure has not been performed properly in slaughter plants that slaughter cull cattle, which are inherently at higher risk for BSE. *See* Exhibit 1, at iii.

The OIG's investigation of pre-slaughter activities in slaughtering plants is ongoing (*see id.* at ii) and includes 10 slaughtering establishments (*see id.*, at ii) in addition to the Hallmark-Westland Meat Packing Co. (Hallmark) that was the subject of the largest recall in U.S. history (143 million pounds of meat), which resulted from the plant's violation of the BSE-related ban on the slaughter of non-ambulatory cattle. *See id.*, at i.

In its review of 10 of the 49 largest cull cow slaughtering plants (*see id.* at 6), the OIG found, *inter alia*, that:

- Shortcuts were taken at 4 slaughtering plants in ante-mortem inspections. *See id.*, at iv.
- FSIS inspectors did not comply with required inspection procedures and/or found that FSIS inspectors used inconsistent methods in performing ante-mortem inspections. *See id.* at 29-35.
- Non-veterinarians have performed ante-mortem inspection without formal training or direct supervision. *See id.*, at 25.

These violations of crucial BSE mitigation measures found in slaughtering plants that slaughter cattle that have an inherently higher risk for BSE demonstrates that APHIS has both understated the risk of BSE spreading and overstated the agency's ability to protect human health from BSE infection. A rule, as is this instant rule, that is based on regulations the agency has neither properly enforced, nor demonstrated that it can properly enforce, is arbitrary and capricious and should be withdrawn.

The OIG report, however, demonstrates that not only are ante-mortem inspections not being properly performed and/or enforced, but also, another mitigation measure crucial to the protection of human health – the removal of specified risk materials (SRMs) – is still not being performed properly, even at plants that slaughter cull cattle that have an inherently higher risk for BSE. The OIG's investigation found, e.g., that:

- “FSIS cannot effectively demonstrate that its verification of establishment controls and written procedures for the removal, segregation, and disposition of SRMs is adequate to detect noncompliance.” *Id.* at 47.
- FSIS' continues to be limited in its ability to review and analyze SRM noncompliance records. *See id.*, at 48-51.

¹ Audit Report, Evaluation of FSIS Management Controls Over Pre-Slaughter Activities, U.S. Department of Agriculture, Office of Inspector General, Great Plains Region, Report No. 24601-0007-KC, November 2008, attached hereto as Exhibit 1.

- FSIS inspectors did not always detect or document instances of non-compliance with SRM removal requirements. *See id.*, at 53.
- One slaughtering plant was not properly carrying out SRM removal. *See id.* at 55.
- Slaughtering plants were neither using dedicated equipment, nor properly cleaning equipment when they cut products that contained SRMs. *See ibid.*
- FSIS did not take consistent enforcement actions on SRM violations. *See id.*, at 57.

Based on the initial findings of this ongoing OIG investigation, it is clear that the optimistic assumptions critical to APHIS' 2008 Notice regarding the effectiveness of both ante-mortem inspections and SRM removal to protect human health are baseless. For these reasons, as well as for the reasons contained in R-CALF USA's Nov. 17, 2008, comments, the agency's Sept. 17, 2007, rule (which took effect Nov. 19, 2007) that allows the importation of over-30-month (OTM) cattle and beef from OTM cattle into the United States from Canada (Final OTM Rule)² should be immediately withdrawn.

B. New Research Undercuts APHIS' Assumption that there is a Substantial Species Barrier and that the United States' Basic Feed Ban is Insufficient to Protect Against Significant BSE Risk to Humans

An article published on Dec. 7, 2008, in the *Telegraph*³ indicates that research published in the journal *Lancet Neurology* has found that variant Creutzfeldt-Jakob disease (vCJD) is affected by genetic factors in patients, and that thousands of people may yet develop vCJD because of the length of time the disease can remain in the body without symptoms. This new research undercuts APHIS' assumption that there is a substantial species barrier that protects humans from vCJD. Instead, what APHIS assumed as a substantial species barrier may be a function of delayed symptoms in infected humans resulting from individual DNA make-up. The article states the research suggests that next wave of vCJD could be a "tidal wave or an imperceptible ripple."

The uncertainty regarding the human health effects of consuming meat from animals infected with BSE (as more fully described in R-CALF USA's Nov. 17, 2008, comments), combined with this new research that suggests the current vCJD outbreak may not be over but instead latent, strongly suggests that APHIS should at least be taking the precautions implemented elsewhere in the world. But APHIS is not. It continues to rely only on a rudimentary feed ban that scientists the world over consider to be a simply *partial* feed ban,⁴ while simultaneously exposing the U.S. cattle herd and U.S. consumers to a population of cattle and beef with the highest risk for disease – OTM cattle and beef from a country, Canada – that

² Bovine Spongiform Encephalopathy; Minimal-Risk Regions; Importation of Live Bovines and Products Derived from Bovines," (Final OTM Rule) published at 72 Fed. Reg., 53314-53379.

³ 'Second wave' of mad cow disease could hit Britain, scientists warn, Kate Devlin, Medical Correspondent, *Telegraph* (UK), December 7, 2008, attached hereto as Exhibit 2.

⁴ R-CALF USA's Nov. 17, 2008 comments on the Final OTM Rule provide evidence in support of this assertion.

has had a multi-generational exposure to BSE and that continues to detect BSE in its native cattle herd.

For the foregoing reasons, R-CALF USA urges APHIS to reaffirm its commitment to U.S. citizens and to the U.S. cattle industry to prevent the introduction of BSE into the United States by withdrawing the Final OTM Rule in its entirety.

Sincerely,

A handwritten signature in cursive script that reads "R. M. Thornsberry DVM". The signature is written in black ink and is positioned above the typed name and title.

R.M. Thornsberry, D.V.M.
President, R-CALF USA Board of Directors

Exhibits 1, 2