附件 1

Consumers Union®

May 1, 2012

Margaret Hamburg, Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Commissioner Hamburg:

USDA's announcement last week that a fourth case of bovine spongiform encephalopathy (BSE) has been identified in the United States, in a dairy cow in Central California, is a warning flag that current safeguards against BSE are not adequate and FDA should take additional steps to protect the health of animals and of the beef-eating public.

Consumers Union, the policy and advocacy arm of Consumer Reports, is concerned that if additional steps are not taken now, this deadly disease could circulate and amplify within U.S. cattle. FDA should immediately prohibit feeding bovine blood, poultry litter, and all brains and other "specified risk materials" to cows, as all of these could carry the BSE infective agent.

USDA has confirmed to news media that the current case is an "L-type" atypical strain of BSE.[1] FDA therefore must be especially vigilant, because this may well not be a "spontaneous" case, but rather may well have been infected through feed, and it may be particularly infectious in humans.

The L-type BSE strain has previously been identified in cattle in Europe[2] and in Canada.[3] This would suggest that the current case may have been contracted through feed.

Studies further suggest that the L-type BSE can infect humans, possibly even more easily than "classical" BSE. A study using humanized mice (mice genetically engineered to have brain prions like humans) suggested that L-type BSE could infect humans.[4] Another

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[1] Thompson, H. 2012. California BSE prion comes with a different twist. *Nature News Blog*, April 27. At: http://blogs.nature.com/news/2012/04/california-bse-prion-comes-with-a-different-twist.html

[2] Brown, P, McShane, LM, Zancusso, G and L Detwiler. 2006. On the question of sporadic or atypical bovine spongiform encephalopathy and Creutzfeldt-Jacob disease. *Emerging Infectious Diseases*, 12(12): 1816-1821. At: http://wwwnc.cdc.gov/eid/article/12/12/pdfs/06-0965.pdf

[3] Dudas, S et al. 2010. Molecular, Biochemical and Genetic Characteristics of BSE in Canada. *PLOS* One, At: http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0010638

[4] Kong, Q, et al. 2008. Evaluation of the human transmission risk of an atypical bovine spongiform encephalopathy prion strain. *Journal of Virology*, pp. 3697-3701.

also shown that either mice[12] or sheep[13] infected with BSE can transmit the disease to other mice or sheep via blood transfusion. Since milk replacer is fed to weaning animals, which appear to be more susceptible to BSE than older animals, FDA, as a preventive measure, should prohibit bovine blood products in cattle feed.

FDA should ban all ruminant brains, spinal cords, and other "specified risk materials" from animal feed, regardless of the age of the ruminant these materials come from.

As a further safeguard, FDA should prohibit all brains, spinal cords and other potentially risky "specified risk materials" in animal and pet food. In 2008, FDA banned brains and spinal cords from cattle older than 30 months, in animal and pet food. This ban was too narrow; it should include a broader range of risky materials, such as tonsils and eyes, including all the tissues FDA banned for human consumption in 2004.[14] Risky materials from younger cattle also should be prohibited in animal and pet food. In the United Kingdom, BSE has been found in at least 49 cows under 30 months of age.[15] Therefore FDA should extend the ban on risky materials to include such materials from all cattle, regardless of age.

We would appreciate having an opportunity to discuss these recommendations with you and your staff. Thank you for your consideration.

Sincerely,

Michael Hansen, Ph.D.
Senior Scientist

Jean Halloran
Director, Food Policy Initiatives

cc USDA Secretary Tom Vilsack

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and J.W. Ironside. 2004. Preclinical vCJD after blood transfusion in a *PRNP* codon 129 heterozygous. *Lancet,* 364: 527-528.

[12] Taylor, D.M., Fernie, K., Reichl, H.E. and R.A. Somerville. 2000. Infectivity in blood of mice with a BSE-derived agent. Letter to the Editor. *Journal of Hospital Infection*, 46: 78-79.

[13] Hunter, N., Forster, J., Chong, A., McCutcheon, Parnham, D., Eaton, S., MacKenzie, C. and F. Houston. 2002. Transmission of prion diseases by blood transfusion. *Journal of General Virology*, 83: 2897-2905.

[14] FDA. 2004. Interim Final Rule on Use of Materials Derived from Cattle in Human Food and Cosmetics. 69 FR 134, pp. 42256-42274. At: http://www.gpo.gov/fdsys/pkg/FR-2004-07-14/html/04-15881.htm

[15] http://vla.defra.gov.uk/vla/vla_ati_020205.htm