



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 Europe² 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

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.

study showed oral transmission to a primate.⁵ The mouse study also found shorter incubation periods than for classical BSE, making it a more “virulent” strain.⁶

Therefore, to ensure that this, or any other type of BSE, does not circulate in animal feed, we urge FDA to take additional steps to ensure feed safety. Ideally FDA should prohibit feeding of all mammal material to food animals. Specific measures that should be taken immediately are outlined below.

FDA should ban the feeding of poultry litter (chicken coop floor wastes) to cattle.

It is surprising to many consumers that in intensive livestock production facilities, pigs and chickens are fed the rendered remains of slaughtered cows, and dairy and beef cows are fed the rendered remains of pigs and chickens, as well as chicken coop floor wastes. Feeding poultry litter to cows in particular creates an opportunity for BSE to spread, because poultry knock a certain amount of their feed on to the floor.

An estimated two billion pounds of poultry litter—floor wastes that include feces and feathers as well as uneaten feed—is fed to cattle every year.⁷ As former FDA Commissioner Dr. Lester Crawford stated in 2003, “There is a possibility that chickens waste so much feed that the litter can contain up to 30% meat and bone meal.”⁸ This translates to 600 million pounds of meat and bone meal—which can come from cattle—that may be fed to cattle every year.

If the BSE infectious agent were present when this cow-protein containing floor waste is fed back to cows, then the BSE infectious agent could be passed along. Given that BSE has been shown to still be present in U.S. cattle as of 2012, FDA should, as a preventive measure, prohibit the risky practice of feeding poultry litter to cattle. In 2009, 13 organization, including Consumers Union petitioned FDA to ban poultry litter as feed for cattle (e.g., Docket No. FDA-2009-P-0405-0001).⁹ FDA should grant this petition.

FDA should ban feeding of bovine blood products to cattle.

The FDA allows bovine blood products to be fed back to cattle. Much of this, in the form of bovine plasma or red blood cells, may be used as calf milk replacer.¹⁰ We now know that blood can contain the infectious agent. Two people in the United Kingdom are believed to have contracted a human form of the disease, vCJD, from blood transfusion.¹¹ Studies have

⁵ Mestre-Frances N et al. 2012. Oral transmission of L-type bovine spongiform encephalopathy in primate model. *Emerging Infectious Diseases*, 18(1): 142-145.

⁶ Kong et al. Op cit.

⁷ Hileman, B. 2003. Guarding against mad cow disease. *Chemical and Engineering News*, 81(31): 32-34. At: http://www.organicconsumers.org/madcow/america_mad_cow.cfm

⁸ Ibid.

⁹ FACT (Food Animal Concerns Trust). 2009. Petition to FDA to ban use of poultry litter as animal feed. At: <http://www.regulations.gov#!documentDetail:D=FDA-2009-P-0405-0001;oldLink=false>

¹⁰ See: <http://www.extension.org/pages/17563/application-of-new-technologies-in-functional-proteins-for-feeding-calves>

¹¹ Llewelyn, C.A., Hewitt, P.E., Knight, R.S. et al. 2004. Possible transmission of variant Creutzfeldt-Jakob disease by blood transfusion. *Lancet*, 363: 417-421. and Peden, A.H., Head, M.W., Ritchie, D.L., Bell, J.E.

also shown that either mice¹² or sheep¹³ 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,

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Senior Scientist

Jean Halloran
Director, Food Policy Initiatives

cc USDA Secretary Tom Vilsack

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