

From: Tony Corbo [tcorbo@fwwatch.org]

Sent: Friday, August 11, 2006 9:41 AM

To: FSIS RegulationsComments

Subject: Food & Water Watch Comments re: Harvard BSE Risk Assessment Update -- Docket No. FSIS-2006-0011

August 11, 2006

Docket Clerk

U.S. Department of Agriculture

Food Safety and Inspection Service

300 12th St. SW

Room 102 Cotton Annex

Washington, DC 20250

RE: Docket No. FSIS-2006-0011

Dear Sir or Madam:

On behalf of the non-profit consumer organization Food & Water Watch, I welcome this opportunity to comment on the Harvard Risk Assessment of Bovine Spongiform Encephalopathy (BSE) Update.

I would like to open our comments by quoting from an article that appeared in a trade journal in February 2004, just after the International Review Panel made its recommendations to Secretary Veneman about U.S. efforts to control the spread of BSE.

“Kihm was the most critical of the (Harvard) risk assessment, saying that it was a “nice model” but that it doesn’t reflect reality. ‘Infection in this part of the world is circulating,’ Kihm said. ‘10 years ago I wouldn’t have believed it, but now it’s a fact.’”

Food Chemical News, February 9, 2004, page 13.

This statement by the chairman of the panel highlights the fact that BSE is present in U.S., and any assessment of the risk of BSE in this country must adequately reflect that. But while the Food Safety and Inspection Service has instituted some measures to keep contaminated meat from entering the human food supply, the overall safety net still contains gaping holes that makes the most recent revision of the Harvard Risk Assessment just as unrealistic as the one it replaced.

1. Removal of specified risk materials

On January 12, 2004, FSIS instituted an interim final rule that called for the removal of specified risk materials (SRMs) from all slaughtered cattle over 30 months old. We have a number of

concerns about this rule.

First, the actual implementation by slaughtering facilities has been inconsistent. Records we obtained through a Freedom of Information Act request in 2005 show that numerous slaughter facilities across the country were not complying with the interim final rules during the year after they were released.^[1]^[1] Because of procedures implemented by the Agency that hamstring the ability of FSIS inspectors to enforce the SRM removal rules, we believe that American consumers are being exposed to greater risk from BSE-contaminated meat entering the human food supply. In light of the analysis performed by FSIS staff that there is a direct relationship between the effectiveness of SRM removal and the amount of risk of BSE-contaminated meat entering the food supply,^[2]^[2] we believe that the Agency needs to empower its inspection staff to play a greater role in enforcing the regulations.

We also call your attention to an affidavit prepared by attorney Felicia Nestor who has documented the problems with SRM risk removal under the current FSIS regulatory framework. (See <http://www.foodandwaterwatch.org/food/felicianestoraffidavit.pdf>).

Furthermore, the International Review Panel recommended the removal of all SRMs from cattle 12 months and older.^[3]^[3] We believe that the FSIS standard of removal of SRMs from cattle over 30 months leaves too much risk for BSE to enter the human food supply in light of the fact there have been younger animals in other parts of the world that have been diagnosed with BSE.

2. BSE Prions Found in other Organs

While the conventional wisdom has been that BSE prions are found only in the central nervous system of infected animals, recent research indicates that BSE prions can migrate to other organs such as the liver and spleen.^[4]^[4] Limiting the risk assessment discussion to SRMs may be too restrictive to truly assess the magnitude of the risk to both the animal and human populations.

3. The Downer Ban

There are mixed signals coming from USDA on the policy of banning non-ambulatory cattle from being slaughtered for the human food supply. Secretary Mike Johanns has indicated in several different forums over the past 20 months that he is re-evaluating the policy of banning downer cows from being accepted at slaughter facilities. As recently as July 20, 2006, the Secretary stated that he is still studying the issue.^[5]^[5] Yet, his Under Secretary for Food Safety has argued that the downer ban has been instrumental in removing the risk of BSE entering the human food supply.^[6]^[6] This continued ambivalence is very worrisome and a change in policy could punch a major hole in the Harvard Risk Assessment model, which assumes that the downer ban will continue.

4. The BSE Surveillance Program

The recent announcement by Secretary Johanns that the agency would drastically scale back the BSE surveillance program is very alarming for a number of reasons. Even when the agency was doing significantly more tests, the program was far from adequate. Because the testing program is voluntary, it does not give a representative picture of how prevalent the disease is in the U.S. herd. Another weakness has been documented by the USDA's Inspector General's office, which criticized the program's sampling protocols.[\[7\]](#)[\[7\]](#) Finally, we are very concerned about the lack of consistent protocols used to test tissues from suspect animals, and the influence exercised by top administrators at the Animal and Plant Health Inspection Service (APHIS) to dissuade agency scientists from using all available tests to confirm BSE in tissue samples.[\[8\]](#)[\[8\]](#)

These design flaws, combined with a reduced amount of testing, significantly weaken the ability of the surveillance program to provide an accurate picture of the extent of BSE in the U.S. The updated risk assessment should reflect the limited ability of the surveillance program to detect the disease, but currently does not.

5. Still No Change in the Feed Ban Regulations

Despite an announcement in January 2004 by the Secretary of Health and Human Services and Commissioner of the Food and Drug Administration (FDA) that the agency would tighten the restrictions on animal feed, [\[9\]](#)[\[9\]](#) nothing has been done by FDA reduce the risk of BSE-contaminated feed entering the animal food supply. While the agency did propose a rule in October 2005 to provide a "90% solution" for mitigating the remaining risk in the animal feed supply, no final rule has been issued – even though FDA officials promised the publication of that rule by July 1, 2006.[\[10\]](#)[\[10\]](#) Consequently, the U.S. cattle population is being exposed to a greater risk of BSE with regulations that have not been updated since 1997. The updated risk assessment does not factor in the persistent weakness in the feed rules.

6. Imported Cattle

We believe that USDA has been premature in re-opening cattle trade with Canada, especially since it is becoming increasingly apparent that Canada has had difficulty in enforcing its feed ban. Within the past year, Canada has reported two cattle with BSE that were born after 1997, when the Canadian feed ban was instituted. The most recent case is most troublesome since the cow was only 50 months old – born in 2002, years after the rules that would supposedly prevent the disease went into effect.[\[11\]](#)[\[11\]](#) USDA re-opened trade for live cattle under 30 months of age in 2005; it was on the verge of re-opening trade for cattle over 30 months of age until the most recent BSE case was discovered in Canada.[\[12\]](#)[\[12\]](#) Until Canada can prove that it can effectively enforce its animal feeding regulations, we believe that the United States should stop all cattle trade with that country.

The updated risk assessment does not adequately address the risk presented by cattle from

Canada.

7. The Dormancy of variant Creutzfeldt-Jakob Disease (vCJD)

According to scientists in Great Britain, Europe could experience a “second wave” of vCJD cases in the future since the disease can lie dormant in humans for decades after they have consumed BSE-contaminated meat.^[13]^[13] While there have been no reported cases of indigenous vCJD cases in the United States, we believe the possibility remains since the food safety net has been riddled with holes for decades.

Should you have any questions regarding our comments, please feel free to contact me at (202) 797-6550.

Sincerely,
Wenonah Hauter
Executive Director

^[1]^[1] <http://www.foodandwaterwatch.org/publications/reports/bse-non-compliance-record-analysis/pdf>

^[2]^[2] http://www.fsis.usda.gov/News_&_Events/Slides_Dessai_072506/index.asp

^[3]^[3] http://www.aphis.usda.gov/lpa/issues/bse/US_BSE_Report.pdf

^[4]^[4] <http://www.medicalnewstoday.com/medicalnews.php?newsid=19660>

^[5]^[5] <http://www.usda.gov/wps/portal/usdahome?contentidonly=true&contentid=2006/07/0256.xml>

^[6]^[6] http://in.today.reuters.com/news/newsArticle.aspx?type=worldNews&storyID=2006-07-26T033440Z_01_NOOTR_RTRJONC_0_India-261031-1.xml&archived=False

^[7]^[7] <http://www.usda.gov/oig/webdocs/50601-9-final.pdf> and <http://www.usda.gov/oig/webdocs/50601-10-KC.pdf>

^[8]^[8] Testimony of USDA Inspector General Phyllis Fong before the House Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations, March 1, 2006, p. 255.

^[9]^[9] <http://www.hhs.gov/news/press/2004pres/20040126.html>

^[10]^[10] Bloomberg News. “Mad-Cow Feed Rules to be Tightened in U.S. in 2006,” February 16, 2006.

^[11]^[11] <http://www.inspection.gc.ca/english/corpaffr/newcom/2006/20060713e.shtml>

^[12]^[12] <http://www.cbsnews.com/stories/2006/07/28/health/main1845458.shtml>

^[13]^[13] See <http://www.sciencedaily.com/upi/index.php?feed=Science&article=UPI-1-20060520-11280900-bc-britain-madcow.xml>