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Dr. John R. Clifford, Deputy Administrator, Chief Veterinary Officer  
Animal Plant Health Inspection Service  
1400 Independence Ave. SW, Room 317-E  
Jamie L. Whitten Federal Building  
Washington, DC 20250

Dear Deputy Administrator Clifford,

We have a number of questions about your November 23, 2004 announcement that a cow, which had tested "not negative" in two runs of the Bio-Rad ELISA quick test for mad cow disease, was "indeed negative for BSE."<sup>1</sup> We are concerned because *New Scientist* reported last June that the false positive rate after such repeated testing is "around one in 100,000 for Bio-Rad."<sup>2</sup> We would appreciate a chance to meet with you this month to discuss the questions below.

1. You have indicated that the Biorad screening test was run twice and got a positive result both times. Were the two runs conducted by the same or different technicians? Did they use the same or different brain samples?
2. When the immunohistochemistry (IHC) test was conducted, what was the condition of the brain when it arrived at the National Veterinary Services Laboratory in Ames, Iowa? Did scientists note any deterioration?
3. How many slides were made and examined for the IHC test? Were they from only the obex, or other areas of the brain? Atypical strains of BSE have been found in Italy<sup>3</sup> and Japan<sup>4</sup> where the level of PrPres in the obex was low or non-

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<sup>1</sup> From <http://www.usda.gov/documents/NewsReleases/2004/11/0508.doc>

<sup>2</sup> MacKenzie, D. 2004. Second US cow tests positive for BSE. *New Scientist*, June 28, 2004. At <http://www.newscientist.com/news/print.jsp?id=ns99996080>

<sup>3</sup> Casalone, C. et al. 2004. Identification of a second bovine amyloidotic spongiform encephalopathy: Molecular similarities with sporadic Creutzfeldt-Jacob disease. *PNAS*, 101(9): 3065-3070.

detectable, unlike in traditional BSE. What portion(s) of the brain were examined?

4. Experienced technicians can sometimes disagree on the interpretation of IHC slides. Does one technician review the slides or more than one technician? If the latter, how many? Did they all agree on the conclusion?
5. The World Organization of Animal Health, known as O.I.E., recognizes use of immunoblotting (also know as Western Blot) as a further confirmation of the IHC test, and it is used in Japan and most European countries. USDA used the Western Blot test in December 2003 along with IHC to confirm the first case of mad cow disease in the United States<sup>5</sup>. In Japan<sup>6</sup> and Belgium<sup>7</sup> cows that tested positive on two quick tests (in both cases using a Bio-Rad test), negative on IHC, yet positive on Western Blot and are considered to be confirmed BSE cases. Was Western blot or any other technique besides IHC used to confirm or rule out a positive result on this November 2004 cow? If so, what was the result? If not used, why not?
6. Were all the procedures referred to in your March 15, 2004 announcement of protocols to confirm any suspect positives utilized, particularly the reference to use of "full battery of tests" that includes, but is not limited to IHC?<sup>8</sup> If not, what protocol was used and what is your rationale for the differences?

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<sup>4</sup> Yamakawa, Y. et al. for the Expert Committee for BSE Diagnosis, Ministry of Health, Labour and Welfare of Japan. 2003. Atypical proteinase K-resistant prion protein(PrPres) observed in an apparently healthy 23-month old Holstein steer. *Japan Journal of Infectious Disease* 56:221-222.

<sup>5</sup> From <http://www.ars.usda.gov/is/AR/archive/dec04/tse1204.htm>

<sup>6</sup> Yamakawa, Y. et al. 2003. op cit.

<sup>7</sup> De Bosschere, H., Roels, S. and E. Vanopdenbosch. 2004. Atypical case of bovine spongiform encephalopathy in an East-Flemish Cow in Belgium. *The International Journal of Applied Research*, 2(4). Accessed at <http://www.jarvm.com/articles/Vol2Iss1/DEBOSSCHERE.htm>

<sup>8</sup> In a technical briefing on the new BSE surveillance plan, Dr. Ron DeHaven clearly stated that USDA would use multiple tests that included IHC: "The Department at NVSL will continue to use the immunohistochemistry, or IHC, for quality control testing, and in addition if any of the rapid screen test comes back with a suspect positive then NVSL will use the IHC *as well as other tests necessary to confirm the results*. . . Let me say up front that we expect that there will be positive results on these screening tests, and that's just the nature of the beast. That's because screening tests by design are intended to be very sensitive and not to miss any positive animals. But with that high degree of sensitivity also comes the possibility for false positive test results. And again that's to be expected. any suspect test results will be sent to NVSL for confirmatory testing with *the full battery of tests*. That would include the IHC. From: <http://www.usda.gov/Newsroom/0106.04.html>

7. Does USDA still have brain material from the cow in question? If so, could it be sent to the World BSE reference laboratory in Weybridge, United Kingdom for IHC and Western Blot analysis to confirm the USDA finding? If not, why not?
8. Canadian press has reported that “Canadian authorities have been told that the cow, from Texas, didn’t have the metal ID tags that cows born here are given.”<sup>9</sup> Is this correct? What was the age of the cow and where had it lived?

We would like to request a meeting with you between now and the end of January about these questions, which are very important to consumer confidence in the safety of the food supply.

Sincerely,

Jean Halloran, Director

Michael Hansen, Ph.D.  
Senior Research Associate

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<sup>9</sup> From <http://edmonton.cbc.ca/regional/servlet/View?filename=ed-mad-cow20041122>