

PolicyPennings by Dr. Daryll E. Ray

# Creekstone BSE case: Latest rulings and a "new test" development

The discovery of bovine spongiform encephalopathy (BSE), often referred to as Mad Cow Disease, in the US cattle herd in December 2003 resulted in precipitous drop in US beef exports. In order to reclaim its share of those export markets, Creekstone Farm Premium Beef decided in early 2004 to test each cow it slaughters for BSE.

Creekstone ordered the test kits from Bio-Rad Laboratories only to be told that USDA approval was needed for the sale of the kits. Creekstone then contacted the USDA to obtain permission to purchase the test kits, only to be denied. The USDA wrote, "allowing a company to use a BSE test in a private marketing program is inconsistent with USDA's mandate to ensure effective, scientifically sound testing for significant animal diseases and maintain domestic and international confidence in U.S. cattle and beef products."

The USDA claimed its authority to deny Creekstone permission to use the tests comes from a 1913 law, the Virus-Serum-Toxin Act (VSTA), which makes it "unlawful...to prepare, sell, barter, or exchange...or to ship or deliver for shipment...any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous products intended for use in the treatment of domestic animals." The USDA contends that the rapid BSE test Creekstone wanted to purchase is an analogous product.

Creekstone filed suit against the USDA in district court on three counts: 1) the USDA had no authority to make regulations restricting the use of products, 2) BSE testing is not being used in the treatment of domestic animals because they have already been slaughtered when the test is used, and 3) the USDA denial is arbitrary and capricious, a violation of the Administrative Procedures Act.

The district court ruled against Creekstone on the first count agreeing with the USDA that it had the authority to make the regulations it used in denying Creekstone's request. With regard to the second count, the court agreed that the USDA cannot regulate BSE testing because there is no known cure for BSE and the testing can only be done post-mortem. No decision was made on Creekstone's third argument.

Both sides appealed the district court's March

29, 2007 ruling to the District of Columbia Circuit Court of Appeals. Seventeen months later on August 29, 2008 the appeals court released its opinion ruling that the district court was correct in affirming the USDA's rule making authority in this instance. As to the second count, the appeals court overturned the district court's reasoning that, given its use is targeted testing of high risk animals, the USDA authority to regulate the test kits is reasonable and can restrict their use.

The case was then sent back to the district court to rule on the third count to determine whether or not USDA's actions were arbitrary and capricious.

In the same time period that this ruling was promulgated by the appeals court, Canadian researchers, Sharon LR Simon et. al., announced the discovery that BSE can be detected in live animals using urine to detect the presence of BSE in an animal and the length of time the animal has been infected. The results of their research have been published in Proteome Science in an article titled, "The identification of disease-induced biomarkers in the urine of BSE infected cattle," [www.proteomesci.com/contents/6/1/23](http://www.proteomesci.com/contents/6/1/23).

If their preliminary findings result in a test that can be made on live animals, it seems likely that some beef producers would want to use it to certify that their herd is BSE-free.

With that news and the ruling of the appeals court, it would seem that the issue of BSE testing of animals, alive or dead, is alive and well.

The next two things to watch for are 1) the district court judgment on Creekstone's "arbitrary and capricious" argument and 2) whether or not the Canadian researchers can transform their laboratory analysis into a reliable and economical test that can be put on the market.

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