

Creekstone Farms Premium Beef v. USDA
Civ. Action No. 06-544 (JR)
Plaintiff's Summary Judgment Reply and Opposition

EXHIBIT 10

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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CREEKSTONE FARMS PREMIUM BEEF, LLC,)	
)	
Plaintiff,)	
)	
vs.)	Civil Action No. 06-544 (JR)
)	
UNITED STATES DEPARTMENT OF AGRICULTURE)	
and MIKE JOHANNNS, IN HIS CAPACITY AS THE)	
SECRETARY OF AGRICULTURE,)	
)	
Defendants.)	
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DECLARATION OF LINDA A. DETWILER, D.V.M.

Linda A. Detwiler, D.V.M., certifies and states as follows:

1. I am currently a consultant on animal health issues specializing in transmissible spongiform encephalopathies (TSEs) and the emergency response to those diseases. I received a Bachelor of Science Degree in dairy science from Delaware Valley College of Science and Agriculture and Doctor of Veterinary Medicine from the Ohio State University, College of Veterinary Medicine. From 1985 until 2003, I was employed by the United States Department of Agriculture (USDA), specifically as a veterinarian in the Veterinary Services division of the Animal and Plant Health Inspection Service (APHIS). Beginning in 1985, I was actively involved with the USDA's scrapie control program. Scrapie is a Transmissible Spongiform Encephalopathy (TSE) in the same family as Bovine Spongiform Encephalopathy (BSE) and has been documented as a disease entity since the 18th century. My work with scrapie started before BSE was identified as a disease anywhere in the world. I began working on BSE prevention measures for APHIS in the late 1980's as a member of the TSE Working Group (formerly known

by different names). I became the coordinator of the TSE working group in 1996 and held this position until May 2002. I left APHIS in August 2003.

2. I have served on numerous TSE advisory committees around the world, including committees for: Argentina; the Azores; the European Union; the United Kingdom; the World Organization for Animal Health or OIE; and the World Health Organization. I have also authored or been a co-author of a number of publications regarding TSEs (A list of my published work is included in my curriculum vitae attached as Attachment A).

3. To date, surveillance conducted in the United States has found the level of BSE in the national herd to be very low. Numerous actions have been taken by the USDA and other government agencies to prevent the entry and recycling of BSE in the United States. These have been essential in preventing an epidemic as experienced by the United Kingdom. There are however, still some vulnerabilities within the country's cattle production and animal feed processing systems. The recirculation of BSE in a national herd requires a source of agent and the maintenance of exposure. Both of these conditions currently exist in the U.S. Potential sources of infection may come from existing domestic BSE cases, previously imported Canadian cattle and feed, as well as cattle and or feed products from other countries of the world with a BSE risk. The U.S. has an incomplete feed ban with exceptions that allow the possibility for cattle to be exposed to the BSE agent.

4. **Source of the Disease - Domestic Cases of BSE:** The USDA, APHIS website states, "The enhanced surveillance program, which ran from June 1, 2004 through August 20, 2006, was a one-time effort to determine the prevalence of BSE in the United States. The analysis concluded that the prevalence of BSE in the United States is less than 1 case per million adult cattle". (See http://www.aphis.usda.gov/newsroom/hot_issues/bse/bse_test_results.shtml -

accessed November 3, 2006.) Given that the adult cattle population in the United States is approximately 42 million head, the estimated total number of BSE cases should be a number less than 42.

5. **Source of the Disease - Imported cases of BSE from Canada:** Between January and August 2006, Canada has detected five cases of BSE after conducting a total of 37,452 tests. *See* <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/bseesbindexe.shtml>. Three of these five infected cattle were most likely exposed to the BSE agent by consuming feed that was contaminated between three to five years after the Canadian government initiated its original feed ban. Between 1996 and 2003, the United States imported millions of cattle from Canada. Like the BSE positive animals found in Canada this year, it is possible that some of the cattle exported from Canada to the United States would also have been exposed to and become infected with BSE. A past illustration of this is the BSE-infected cow found in Washington State in December 2003, which had been imported from Canada in 2001.

6. The seventh BSE case detected in Canada in a native cow was confirmed on July 13, 2006. The cow was born in April 2002. *See* <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2006/7investe.shtml>. It is thought that most cattle are infected with BSE during the first year of life. Thus this cow, which was 50 months old when it was tested for BSE provides substantial evidence that the BSE agent was circulating in the Canadian animal production system until at least 2002-2003. (The Canadian Food Inspection Agency report regarding the BSE-infected 50 month old cow is attached to this declaration as Attachment B.) Cattle exposed in Canada and exported to the United States during this time may not yet have progressed through the incubation period to

display clinical signs of the disease. If any are infected and subsequently slaughtered and rendered, they would be another source of BSE to the U.S. animal feed supply.

7. **Source of the Disease - Risk from Other Countries:** To protect the livestock and poultry industries in the US from such diseases as Foot and Mouth Disease, Rinderpest, Classical Swine Fever, etc., APHIS does not allow live animals or products into the U.S. until a careful evaluation has been conducted. This evaluation takes into consideration the veterinary infrastructure, disease occurrences, surveillance, prevention and control measures. In this regard, BSE is unique in that USDA, APHIS allows trade until there is an actual finding of disease in a country or until the agency conducts an assessment and determines that a risk exists. Consequently, unless APHIS is actively conducting evaluations, trade may continue with countries that have significant risk of BSE in their cattle herds. At present the U.S. does not have BSE import restrictions for live ruminants and ruminant products from countries such as Estonia, Chile and Mexico which carry a European Union Geographical BSE Risk (GBR) rating of III (likely to have the disease but not detected). There are other countries of the world that have not been evaluated by APHIS and may have a much higher risk level than countries with prohibitions. The U.S. policy is also in conflict with Canada which rates countries prior to allowing trade.

8. **Potential routes of exposure to BSE:** FDA regulations still allow high- BSE-risk tissues, which are known as specified risk materials (SRMs), to be used in animal (other than ruminant) feed. These SRMs provide a potential source of infectivity in the feed supply. Although these materials are prohibited in feed for ruminants, the FDA feed ban still allows the possibility for cattle in the U.S. to be exposed to BSE through the following routes:

- i. Feeding of materials currently subject to legal exemptions from the ban (*e.g.*, poultry litter, plate waste, etc.)

- ii. Cross feeding (the feeding of non-ruminant rations to ruminants) on farms; and
- iii. Cross contamination between non-ruminant and ruminant feed

9. In the United States poultry litter can be fed to cattle. There are two potential sources of risk from poultry litter. Poultry litter not only consists of digested feed but also of feed which spills from the cages. As a consequence, the practice of feeding litter back to cattle is innately non-compliant with a ruminant to ruminant feed ban if the poultry themselves are being fed ruminant protein. Given that ruminant protein can no longer be fed to ruminants in the United States and that most, if not all, countries will no longer import North American ruminant meat and bone meal (MBM), an even larger part of poultry diets may now be ruminant MBM. Consumption of the spilled feed with the litter provides a direct link to back to cattle.

There is no reason to expect that TSE infectivity would be inactivated by passage through the poultry gut, and only a slim possibility that composting would reduce infectivity. Thus poultry feces are another potential route of transmission back to cattle. Evidence for this comes from rodent experiments where infectivity was demonstrated in the feces after being fed: “Laboratory experiments show that mice orally challenged with scrapie have detectable infectivity that passes through the gut. Gut contents and fecal matter may therefore contain infectivity, and it is noted that in experimental oral challenges in cattle conducted in the UK, feces must be treated as medical waste for one month following the challenge. It is concluded that digestive contents and fecal material from livestock or poultry currently being fed with MBM potentially contaminated with BSE should not be used as a feed ingredient for animal feed.” *See Proceedings: Joint WHO/FAO/OIE/ Technical Consultation on BSE: public health, animal health and trade, Paris, 10-14 June 2001; Alan Dickinson, personal communication.*

10. Ruminant tallow is also exempted from the current feed ban. Tallow contains protein impurities that could be a source of TSE infectivity. International standards specify that the maximum level of insoluble impurities be .15% in weight. In the United States there are no FDA regulations which require a maximum level of insoluble impurities in tallow used for animal feed.

11. Plate waste is not limited to meat (muscle tissue). For example, cuts that include a portion of the spinal cord or that are contaminated by cord or ganglia during preparation could contain high levels of infectivity if derived from a TSE infected animal late in the preclinical stage of infection. At best this material would be exposed to normal cooking temperatures. USDA, APHIS experience with the Swine Health Protection Act has revealed that plate waste also includes uncooked trimmings and bones. Although the current FDA regulation requires the plate waste be treated again. However FDA does not require a treatment which would render a TSE agent inactive. Potential sources of infectivity delivered through plate waste would include both bovine and sheep tissues. Although sheep scrapie is not known to be a risk for human consumption, it is one of the possible origins of BSE. The sheep scrapie agent is known to be widely dispersed throughout the body of a sheep. There are relatively high titers in lymphoid as well as nervous tissue.

12. The UK epidemiology has clearly shown that BSE contaminated feed is the primary if not sole vehicle for the transmission of typical BSE to cattle. Moreover, results from the United Kingdom's attack rate study indicate that it does not take much exposure to transmit BSE to cattle. Recent results from the attack rate study which is still in progress have found that 0.1 g of brain transmitted BSE by the oral route to 3 cows out of 15 thus far, and 0.01 and

0.001gr of brain have transmitted BSE to 1 cow out of 15 respectively. (Danny Matthews, DEFRA presentation at TAFS meeting, Washington, DC April 2004).

Rendering may reduce infectivity but it does not eliminate it. *See* Taylor, DM, Woodgate, SL, Atkinson, MJ, Inactivation of the bovine spongiform encephalopathy agent by rendering procedures, *Veterinary Record*, Vol. 137, pp. 605-610 (1997); Taylor, DM, Woodgate, SL, Fleetwood, AJ, Cawthorne, RJG, The effect of rendering procedures on scrapie agent, *Veterinary Record*, Vol.141, pp 643-649 (1995); Schreuder, BEC, Geertsma, RE, van Keulen, LJM, van Asten, JAAM, Enthoven, P, Oberthür, RC, de Koeijer, AA, Osterhaus, ADME, Studies on the efficacy of hyperbaric rendering procedures in inactivating bovine spongiform encephalopathy (BSE) and scrapie agents, *Veterinary Record* 142, 474-480 (1998). Given that BSE can be transmitted to cattle via an oral route with just 0.001 gram of infected tissue, it may not take much infectivity to contaminate feed and keep the disease recycling. This is especially true in countries like the U.S., which does not require companies to have dedicated lines and equipment to manufacture and process feed for ruminants and non-ruminants.

In addition, epidemiological investigations in European countries have shown that cross feeding and cross contamination on farm can be a significant vehicle for continued BSE transmission even after feed bans are well established. Cross feeding is the practice of feeding meal for poultry or pigs or pet food (which can legally contain ruminant MBM) to cattle on the same farm. This is usually due to simple human error or negligence. Hoinville, LJ, Decline in the incidence of BSE in cattle born after the introduction of the 'feed ban', *Veterinary Record*, 134(11): 274-5 (Mar 12, 1994); Hoinville, LJ, Wilesmith, JW, Richards, MS, An investigation of risk factors for cases of bovine spongiform encephalopathy born after the introduction of the 'feed ban', *Veterinary Record*, 136(13): 312-8 (Apr 1, 1995); Doherr, MG, Hett, AR, Rufenacht,

J, Zurbriggen, A, Heim, D, Geographical clustering of cases of bovine spongiform encephalopathy (BSE) born in Switzerland after the feed ban, *Veterinary Record*, 151(16): 467-72 (Oct 19, 2002); Glatzel M, Abela E, Maissen M, Aguzzi A., Extraneural pathologic prion protein in sporadic Creutzfeldt-Jakob disease, *New Engl. J Med.*, 349(19):1812-20 (Nov 6, 2003); Stevenson, M. A., Wilesmith, J. W., Ryan, J. B. M., Morris, R.S., Lockhart, J. W., Lin, D. & Jackson, R. (2000) Temporal aspects of bovine spongiform encephalopathy in Great Britain: individual animal-associated risk factors for the disease. *Vet. Rec.* 147, 349-354.

13. FDA, Center for Veterinary Medicine reports that compliance with the existing feed ban is high. This high level of compliance primarily reflects the actions of the rendering and feed mills. The statistics do not include much data reflecting the compliance level on the farm. There are hundreds of thousands of farms in the U.S. Many of these have multiple species. That is, they raise cattle, pigs, chickens etc., on the same premises. The sheer number of farms makes it very difficult to assure compliance on farm and to adequately cover all farms by inspection. Even if the rendering industry and feed industry were to maintain 100% compliance at their facilities, if a producer inadvertently feeds rations made for chickens (containing bovine MBM) to their cattle, they negate a perfect compliance rate higher in the chain. Recent data from the Harvard BSE risk assessment suggest that the level of misfeeding on farms plays a significant role in the ability of the infectious agent to recycle. In fact George Gray, principal investigator for the study, stated that if, in the United States, misfeeding were to occur at a level of 15%, the R0 would be over 1, indicating that the BSE level would not be declining. (George Gray presentation at the Meeting on BSE Prevention in North America: An Analysis of the Science and Risk; January 27, 2005, Washington, DC.) The level of misfeeding on farms is not known.

14. Human error is extremely difficult to prevent, and managing the risk through enforcement is problematical when confronted with the extreme logistical challenges of on farm monitoring. In January 2004 the FDA proclaimed that it would take actions to strengthen the feed ban. To date no actions have been taken.

15. **Wider distribution of infectivity in animal tissue:** By the end of 2004, there was increasing evidence in species other than cattle that peripheral nerves and muscle have infectivity. In some of these species, studies indicate that the agent migrates to the brain and spinal cord, replicates to high levels in the CNS and then spreads centrifugally from the spinal cord back down through the spinal neurons to the junction of the nerves and muscle into the muscle cells themselves. [Bosque PJ, Ryou C, Telling G, Peretz D, Legname G, DeArmond SJ, Prusiner SB](#), Prions in skeletal muscle, Proc Natl Acad Sci USA, 99(6):3812-7 (Mar 19, 2002); [Glatzel M, Abela E, Maissen M, Aguzzi A](#), Extraneural pathologic prion protein in sporadic Creutzfeldt-Jakob disease. N Engl J Med., 349(19):1812-20 (Nov 6, 2003); [Bartz JC, Kincaid AE, Bessen RA](#), Retrograde transport of transmissible mink encephalopathy within descending motor tracts, J Virol., 76(11):5759-68 (June 2002); [Andreoletti O, Simon S, Lacroux C, Morel N, Tabouret G, Chabert A, Lugan S, Corbiere F, Ferre P, Foucras G, Laude H, Eychenne F, Grassi J, Schelcher F](#), PrP^{Sc} accumulation in myocytes from sheep incubating natural scrapie, Nat Med, 10(6):591-3 (Jun 2004), Epub (May 23, 2004); [Mulcahy ER, Bartz JC, Kincaid AE, Bessen RA](#), Prion infection of skeletal muscle cells and papillae in the tongue, J Virol., 78(13):6792-8 (Jul 2004); [Thomzig A, Schulz-Schaeffer W, Kratzel C, Mai J, Beekes M](#), Preclinical deposition of pathological prion protein PrP^{Sc} in muscles of hamsters orally exposed to scrapie, J Clin Invest, 113(10):1465-72 (May 2004); [Thomzig A, Kratzel C, Lenz G, Kruger D, Beekes M](#), Widespread

PrPSc accumulation in muscles of hamsters orally infected with scrapie, EMBO Rep, 4(5):530-3 (May 2003).

16. A recent German study examined nerves and muscle from a cow naturally infected with BSE and found that infectivity was present in several peripheral nerves. Bushmann, A, and Groschup, M, Highly Bovine Spongiform Encephalopathy-Sensitive Transgenic Mice Confirm the Essential Restriction of Infectivity to the Nervous System in Clinically Diseased Cattle, J Infect Diseases, 192: 934-42 (Sep 1, 2005). The method of detection was bioassay in bovinized transgenic mice that show the same or greater sensitivity to transmission of BSE as cattle. This research concurs with findings by Japanese scientists that BSE infectivity is present in peripheral nerves at least in the clinical stage of disease.

17. There is increasing evidence that the pathogenesis of BSE might not be entirely different from TSEs in other species in that at the point of clinical disease there is peripheral involvement. The current USDA regulations prohibiting certain SRMs from food for humans do not require removal of these peripheral tissues. Thus if BSE infected cattle are passed for slaughter and there is infectivity from peripheral nerves, there may be additional contamination of edible products. To date the pathogenesis studies appear to indicate that the most extensive peripheral involvement is after agent replication in the brain. Thus removing cattle that test positive for BSE from the food chain would greatly reduce or eliminate this risk. Currently USDA does not test or allow testing of animals that pass both antemortem and postmortem inspection.

18. The updated Harvard Risk Assessment assumes that USDA inspectors by visual inspection alone would be able to detect 95% of the cases of BSE which can still walk and 85% of those which are down. These cattle would then be prevented from being passed for slaughter

(http://www.fsis.usda.gov/PDF/BSE_Risk_Assess_Report_2005.pdf). The assessment did not provide data to support these assumptions. In fact, actual data from the United Kingdom and other European countries provided by one of the reviewers suggest that these assumptions considerably overestimate the ability of inspectors to identify BSE. In the United Kingdom, the country with the most cases of BSE in the world, inspectors have only identified half of the BSE cases prior to slaughter. Testing has identified the other half. Reviewer one states, “So it seems as if only approximately 50% of clinical cases may be detected at ante-mortem inspection at abattoirs in the UK at present, and even then they are still only identified as “risk animals” rather than as BSE suspects.”

(http://www.fsis.usda.gov/PDF/BSE_Risk_Assess_Appendix_4_2005.pdf) The experience in most countries that have gone from testing only “at risk” cattle to the testing of all cattle above a certain age has confirmed this, identifying more cases of BSE.

19. Cattle that do not display outward signs of BSE may still test positive for BSE. There are many reported cases of positives in BSE screening tests even though the animal tested did not have detectable clinical signs of BSE. As outlined above there are circumstances where testing could provide another level of safety.

20. There are precedents that demonstrate that voluntary testing by the industry may be conducted successfully. The government of Switzerland did not mandate the testing of all “healthy” cattle presented for slaughter. They did allow their industry to fund testing programs. Tests had to be conducted at laboratories approved by the government, done according to government approved protocols and products could not be labeled as “BSE-free”.

21. The government may argue that testing cattle that pass antemortem and postmortem inspection at slaughter may not be a wise expenditure of public funds, in light of

other health priorities competing for these dollars and the apparently low level of disease.

Private voluntary testing is not harmful to cattle and would not interfere with the management of the disease if done per government specification. In fact, if private testing were to find a case of BSE this would provide additional information to the government. Data from surveillance provides essential information for determining future public policy.

22. Although uncommon, BSE has been detected in cattle less than 30 months old in the United Kingdom, Germany, Poland, and Portugal. (*See* www.defra.gov.uk/animalh/bse/statistics/bse/age.htm; http://ec.europa.eu/food/food/biosafety/bse/bse45_en.pdf; http://ec.europa.eu/food/food/biosafety/bse/annual_report_2002_en.pdf; http://ec.europa.eu/food/food/biosafety/bse/annual_report_tse2005_en.pdf; http://ec.europa.eu/food/food/biosafety/bse/annual_reps_en.htm.) In 2003, the Japanese government detected two BSE-positive animals under the age of 24 months, although those cases are still in the process of being confirmed.

23. The chances of detecting BSE in “at risk” cattle tested in the US, while certainly greater than the chances of detecting BSE in cattle that appear normal, is still very low, given the detection limits of rapid screening tests and the very low level of infectivity currently present in the U.S. herd.

24. Currently, in the U.S. the poultry industry is allowed to conduct testing for reportable avian influenza, although that disease is extremely rare in commercial poultry operations. The industry has announced this testing as occurring prior to slaughter and providing a measure of food safety. *See* <http://www.state.de.us/deptagri/pressrel/2006/010506 NCC.pdf>. Most if not all of the pre-slaughter avian influenza tests currently conducted in the U.S. are for

antibodies indicating past exposure. In reality that does not guarantee they are free from early infection.

I declare under penalty of perjury that the foregoing is true and correct.

A handwritten signature in black ink, appearing to read "Linda A. Detwiler". The signature is fluid and cursive, with a large loop at the end.

Executed on October 30, 2006.

Linda A. Detwiler, D.V.M.

ATTACHMENT A

Linda A. Detwiler, D.V.M.

Curriculum Vita

LINDA A. DETWILER

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EDUCATION

1984 - DVM - The Ohio State University College of Veterinary Medicine, Columbus, Ohio.

1980 - BS, Summa Cum Laude - Dairy Science - Delaware Valley College of Science and Agriculture, Doylestown, PA.

EXPERIENCE

January 2006 - Present – Assistant Director, Virginia-Maryland Regional College of Veterinary Medicine, University of Maryland, Center for Public and Corporate Veterinary Medicine

August 2003 - Present

Private Animal Health Consultant:

Specializing in the Transmissible Spongiform Encephalopathies (TSEs), Emergency Preparedness (TSEs, Avian Influenza), Biosecurity (Avian Influenza) and Import/Export Animal Product Issues.

Clients –Food and Pet Food Companies, Pharmaceutical Companies, Agricultural Production Associations, Foreign, US and State governments.

May 2002 – August 2003 Veterinarian in Charge - New Jersey, USDA, APHIS, Veterinary Services

Supervisor - Dr. Ulysses Lane (919-716-5570)

-Oversee all Veterinary Services programs in the state of New Jersey. Primary programs include avian influenza surveillance and control in the live bird markets, foreign animal disease response, endemic disease control and eradication programs, import/export activities (three port locations), and swine health protection,. Responsible for the New Jersey Area budget and supervision of all employees.

1996-May 2002 - Senior Staff Veterinarian, Emergency Programs Staff, USDA, APHIS, VS Supervisor - Dr. Joseph Anelli (301-734-8073)

-Coordinates APHIS surveillance, prevention and education activities for Bovine Spongiform Encephalopathy (BSE). Provides technical advice on the Transmissible Spongiform Encephalopathies (TSEs) for USDA, the public, industry groups, foreign governments, etc. Acts as media spokesperson for APHIS activities in regards to the TSEs in national and international arenas. Serves on national and international TSE advisory committees. Coordinated the development of a national BSE response plan. Authors publications, articles, decision memos, etc. on TSEs.

1988-July 1997 - Veterinarian in Charge - New Jersey, USDA, APHIS, Veterinary Services Supervisor - Dr. Thomas Holt (518-453-0103)

-Oversee all Veterinary Services programs in the state of New Jersey. Primary programs include avian influenza surveillance and control in the live bird markets, import/export activities (three port locations), swine health protection, foreign animal disease response, endemic disease control and eradication programs. Responsible for the New Jersey Area budget and supervision of all employees.

June 1990 - 1992 - Senior Staff Veterinarian, Miscellaneous Diseases Staff, USDA, APHIS, VS Supervisor - Dr. William Ketter (301-734-8093)

-Responsible for disease control programs involving small ruminants with the primary emphasis on scrapie. Played an integral part in developing the current scrapie program through the process of Negotiated Rulemaking.

1987-1988 - Assistant Veterinarian in Charge - New England, USDA, APHIS, VS Supervisor - Dr. William Smith (508-865-1421)

-Supervised field staff of 21 veterinarians and animal health technicians. Responsible for oversight of the day-to-day field activities of VS programs in the six New England states. Acted in the capacity of the Area Veterinarian in Charge in his absence.

1985-1987 - Section Veterinary Medical Officer, USDA, APHIS, VS, Ohio Area Supervisor - Dr. William Nape (614-469-5602)

-Responsible for the VS program activities of a 21 county section in central Ohio. Primary programs in this section included animal welfare activities, scrapie control and eradication, pseudorabies, brucellosis and tuberculosis field work. Coordinated all the scrapie activities for the state of Ohio. Assigned to be the Acting Veterinarian in Charge in West Virginia. Detailed to New Jersey during outbreaks of HPAI and NDV.

1984-85 - private food animal practice, Mount Gilead, Ohio

ADDITIONAL ACTIVITIES

- * Member of the TSE Food Safety Foundation, Switzerland (TAFS) since 2002
- * Past member of USDA, APHIS' TSE Working Group since 1990 (Member 1990 to August 2003; Coordinator 1996-2002)
- * Chair Working Group on BSE in sheep, Consultation of OIE, WHO, FAO, Paris (2001)
- * Chair Working Group on Animal Health, PAHO/WHO Consultation on Bovine Spongiform Encephalopathy (BSE) - Scientific Basis for Policy Decisions in the Americas (April 2001)
- * Chair European Union Working Group on BSE in Sheep (2000-01)
- * Co-chairperson of the World Health Organization's Consultation on Public Health and Animal TSEs (1999)
- * Consultant to the Azorean government on TSE prevention and surveillance (1998-01)
- * Serves on TSE Advisory Committee to Argentina
- * Serves on various European Union TSE Working Groups (ie. Surveillance, BSE Risk Assessment)
- * Served on United Kingdom SEAC BSE and Sheep Working Group
- * Served on US Food and Drug Administration TSE Advisory Committee
- * Serves on Office of International Epizootics Ad Hoc Committee on TSEs
- * Testified at a House of Representatives subcommittee hearing on USDA preventative activities regarding BSE.
- * Provided briefings to House and Senate AG Committees on BSE and its potential zoonotic risk
- * Served on the combined industry/government BSE committee in the early 1990's through present.
- * Involved with the sheep industry in their efforts to control scrapie since 1985
- * Represented the USDA at a World Health Organization meeting on the TSEs (1991)

HONORS and AWARDS

- * USDA's Secretary of Agriculture Group Honor Award for Chronic Wasting Disease Management (2003)
- * Ohio State University College of Veterinary Medicine Outstanding Alumnus (2002)
- * USDA's Secretary of Agriculture Team Honor Award for the role of the Transmissible Spongiform Encephalopathy Working Group (2001)
- * Delaware Valley College President's Award (2001)
- * Honorary Diplomat of the American Veterinary Epidemiology Society (1998)
- * USDA's Secretary of Agriculture Honor Award for Personal and Professional Excellence (1998)
- * APHIS, Veterinary Services Award - most outstanding contribution to the organization (1998)
- * Delaware Valley College Centennial Award - given to 100 alumni from the college's first 100 years, who have shown outstanding leadership and accomplishments in their profession (1997)
- * Conferee of the 1996 USDA's "Unsung Hero Award."
- * Award for exemplary leadership nationally and internationally in support of scrapie activities (1992)

- * Delaware Valley College's "Most Outstanding Alumnus" in Animal Science (1990)
- * Kellog Fellow at Resources for the Future (1990)
- * APHIS Administrator's Award for contribution to the animal welfare program (1987)
- * AVMA Auxiliary Award for Outstanding Service to the College and Community (1984)

PUBLICATIONS

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Detwiler, L. A. (1997) Epidemiological studies and research undertaken in the Americas In Epidemiological studies and research on transmissible spongiform encephalopathies *Overview, conclusions and recommendations of Meeting of the OIE Ad hoc Group on transmissible spongiform encephalopathies, Paris, 8-9 October 1996*, 16-24.

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SIGNIFICANT CONFERENCE PRESENTATIONS

International Meeting on TSEs: Impact on Animal and Human Health, Heidelberg, Germany (23-24 June 1992) Scrapie Control in the United States

Third International Sheep Veterinary Conference, Edinburgh, Scotland (27 June 1993) "Scrapie Control"

International Meeting on TSEs, Berlin, Germany (December 1993) "Scrapie Surveillance and Control"

47 th Annual Meeting of the European Association for Animal Production, Lillehammer, Norway (25-29 August 1996) "Scrapie: An overview of the disease with an emphasis on control"

Meeting of the Mercusor Countries on the TSEs, Buenos Aires, Argentina (June 1996) "BSE Surveillance and Prevention in the United States"

International Symposium on Spongiform Encephalopathies: Generating Rational Policy in the Face of Public Fear, Georgetown University, Washington, DC. (12-13 December 1996) "Scrapie Overview" and "BSE Surveillance and Prevention in the United States"

Canadian Sheep Producers Meeting, Ontario Veterinary College, Canada (18-19 October 1996) "Scrapie: The disease and US Program"

NMHCC's Transmissible Spongiform Encephalopathies: Toward Risk Assessment and Management, Washington, DC. (25 February 1997) "USDA Prevention Activities in Response to BSE"

American Association of Animal Science Annual Meeting, Nashville, TN, USA (31 July 1997) "BSE Prevention and Surveillance in the United States"

North American Veterinary Conference, Orlando, Florida, USA (10-14 January 1998) "BSE - View from the US Perspective" and "BSE: What would a practitioner see?"

JIFSAN's Workshop on TSE Risks in Relation to Source Material, Processing and End-Product Use, College Park, Maryland, USA (8-9 June 1998) "Sourcing Considerations For Sheep, Goat and Other Animal Material"

World Sheep Congress, Pomona, California, USA (18 July 1998) "An overview of the TSEs with an emphasis on scrapie and scrapie control"

American Veterinary Medical Association Annual Meeting, Baltimore, Maryland, USA (26 July 1998) "An Update on Scrapie"

Singapore Veterinary Annual Meeting, Singapore (7 November 1998) "An Overview of the TSEs with an emphasis on BSE"

International Symposium on Prion Diseases, Tübingen, Germany (23-25 September 1999) Panel Discussion on TSE Surveillance

National Pharma Meeting, Washington, DC (1 November 1999; 3 October 2000) An update on BSE and its impact on the pharmaceutical industry.

WHO Consultation Public Health and the Animal TSEs, Geneva, Switzerland (1-3 December 1999) Scrapie Control: Principles, Practice and Experience.

International Gelatine Manufacturer's Meeting, Palm Springs, California (23 March 2000) BSE: An Update.

United Kingdom Scrapie Information Group Meeting, London, England (2 May 2000) Scrapie Control in the United States.

Global Beef Information Forum, Frankfurt, Germany (7 November 2000) An overview of TSEs with an Emphasis on BSE.

Food Safety 2000, Oporto, Portugal (11 November 2000) Measures to Prevent BSE from Entering the United States.

Pan American Health Meeting, Montevideo, Uruguay. (April 2001) BSE Surveillance: An Overview

International Life Sciences Institute, Cancun, Mexico (January 2002): An Update on the Science of the Transmissible Spongiform Encephalopathies

Ensminger International Short Course, Thailand (February 8, 2002) BSE Prevention Methods

TSE Diagnostic Workshop, Buenos Aires, Argentina (May 2002) Sampling procedures for BSE and scrapie

Miner Institute 2nd International Symposium on BSE, Fukuoka and Tokyo, Japan (July 2002) Prevention of BSE and other foreign animal diseases in the United States

International Conference on methods for the control of scrapie, Oslo, Norway (May 2003) The History of Scrapie Control

American Association of Bovine Practitioners, Columbus, Ohio (September 2003) Bovine Spongiform Encephalopathy

Association of Medical Laboratory Immunologists, Baltimore, Maryland (August 2004) BSE: An Update

Canadian Veterinary Conference, Banff, Alberta, Canada (October 2004) TSEs: An Update

USDA Outlook Forum, Crystal City, Virginia (February 2005) Science and the Consumer: Making and Implementing Policy

Midwest Veterinary Conference, Columbus, Ohio (February 2005). TSEs: An Update; Emerging Diseases of Public Health Significance (Avian Influenza, SARs, Monkeypox, Nipah)

Global Feed and Food Congress, Sao Paulo, Brazil (July 2005) The Food Industry and BSE: Public Health and Economic Impacts

United States Animal Health Association, Minneapolis, Minnesota (November 2006) Atypical BSE: What does it mean?

ATTACHMENT B

Canadian Food Inspection Agency
Report on the Investigation of the Seventh Case of Bovine Spongiform Encephalopathy (BSE) in Canada



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REPORT ON THE INVESTIGATION OF THE SEVENTH CASE OF BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) IN CANADA

Background

On July 2, 2006, a dairy cow on a farm in northern Alberta died due to complications related to mastitis. The following day, a private practitioner sampled the cow under Canada's National BSE Surveillance Program. Brain samples from this animal were sent to the Alberta Agriculture, Food and Rural Development (AAFRD) Laboratory, where they were screened for BSE using a Bio-Rad rapid test. The preliminary test results received on July 6, 2006 did not rule out BSE. In accordance with the prescribed testing protocol, the test was repeated on July 7 and produced a second reaction. Brain samples were then sent to the National Centre for Foreign Animal Disease in Winnipeg, where BSE was confirmed by the SAF immunoblot and immunohistochemistry (IHC) procedures on July 13, 2006. The staining pattern from the confirmatory IHC tests supported the notion that this animal seemed to have been detected at an earlier stage of BSE incubation. Had the animal succumbed to BSE and not to an unrelated disease, it may have been some time before BSE symptoms would have been noted. The carcass was secured from the farm, transferred to the AAFRD laboratory and incinerated. No part of the carcass entered the human food supply or animal feed chain.

The CFIA immediately initiated an epidemiological investigation based on the most recent World Organization for Animal Health (OIE) recommended BSE guidelines. Specifically, the CFIA investigated:

- the birth cohort (all cattle born in the same herd as, and within 12 months of the birth of the BSE-positive animal);
- the feed cohort (all cattle which, during their first year of life, were reared with the BSE positive animal during its first year of life, and which investigation showed consumed the same potentially contaminated feed during the period); and
- feed to which the animal may have been exposed early in its life.

At the time that this cow was confirmed to have BSE, it was not in milk production. With respect to the milk this cow produced prior to the detection of the disease, scientific research indicates that BSE is not transmitted through cow's milk, even if the milk comes from a cow with BSE. Therefore, milk and milk products are considered safe and no action on such products was required.

Animal Investigation

The positive cow was confirmed to be a purebred dairy animal born on April 22, 2002, and was 50 months old at the time of death. It was born and lived its entire life on the index premises. The producer reported the duration of illness was two days, during which the animal displayed signs of toxic mastitis, and, despite treatment, became non-ambulatory (downer) and died. The following day, a private practitioner attended the premises to perform a post-mortem examination, which revealed the likely cause of death was toxic septicaemia attributable to the acute mastitis. Because the animal met the inclusion criteria of Canada's National BSE Surveillance Program, arrangements were made to forward appropriate samples for laboratory evaluation.

The investigation revealed that the positive cow had one male calf born during the two years prior to her death (born March 17, 2005). Based on advances in science, the OIE (Terrestrial Animal Health Code 2006) no longer recommends regulatory action with respect to calves of BSE positive cows. The hypothesized increased risk to calves born within 24 months of the onset of clinical signs in dams with BSE is not supported by ongoing research and analysis of data. Therefore, the CFIA has amended its policy regarding such calves and will no longer require their destruction. However, the CFIA will trace calves born to a positive female in respect of current export certification requirements requested by importing countries.

The index farm was a dedicated dairy operation. The birth and feed cohort was determined to comprise 172 animals that, along with the positive animal, were born or raised on the farm. The trace-out investigation of the cohort located 38 live animals on the index premises and in other herds to which they had been sold. The majority of these animals were euthanized and their carcasses disposed of by incineration, in accordance with OIE recommendations. Because testing of cohort animals is not required by OIE recommendations and has proven to be of little epidemiological value in Canada's and other countries' experience, the CFIA has discontinued the practice of testing the cohort animals. Four animals have been retained under quarantine for a short period to allow for calving or collection of valuable genetic material. As BSE is not contagious, these animals do not represent a risk of horizontal transmission to other animals. Once these animals are euthanized, their carcasses will be destroyed and excluded from the food and feed chains, as per OIE guidelines. The following is the disposition of the remaining 134 animals in the cohort:

- 113 animals were traced and confirmed to have died or been slaughtered (two animals had previously been tested under Canada's National BSE Surveillance Program with negative results);
- 13 animals were traced and presumed to have died or been slaughtered; and
- Eight animals were determined to be untraceable because of inadequate records.

The trace-out investigation is complete.

Feed Investigation

The feed investigation focussed on the critical period of susceptibility during the first year of life and encompassed all potential avenues of direct exposure to prohibited material as well as potential areas of cross contamination. Compliance with the regulatory requirements of the 1997 feed ban was assessed throughout the investigation.

Investigation at the birth farm revealed that laying hens, rabbits, cats, a horse, a dog and possibly some goats were present during the time of interest. Feed products for these species were purchased in bags and stored in original packaging in the same building as bagged products for dairy animals. The rations for the layers and rabbits did not contain prohibited material and were manufactured in a facility free of prohibited material. The cat and dog food products are presumed to have contained prohibited material but were understood to be fed as intended and away from the dairy animals. The horse and goats were not fed commercial horse or goat products.

All feed products to which the BSE positive animal had access were intended for feeding to ruminants. These consisted of farm-grown or purchased grains and forages, and feed products from three different commercial suppliers. On-farm mixing equipment consisted of a stationary mixer used to combine forages with commercial products for lactating animals and those over two months of age.

For the first two months of life, the BSE positive animal was housed by itself in a single calf hutch and fed colostrum, milk or milk replacer and a commercially prepared 20% Calf Starter. The milk replacer and calf starter were manufactured in facilities that did not receive, store or use prohibited material.

From two to six months of age, the animal was housed in an outdoor group pen with animals of similar age and fed a 16% Heifer Grower (for approximately six weeks), followed by an 18% Calf Starter (until reaching about six months of age), and forages (hay and silage). Other feed products available at this age were canola meal and, possibly, free choice mineral.

From six to fourteen months of age, the calf was fed a farm-mixed ration consisting of barley silage, canola meal, and commercial dry cow/heifer premix.

Other commercial products used on the farm included two different rations for the lactating cows and one for dry cows. These products were not fed to the index animal prior to 14 months of age, although the same mixer was used for both the index animal and the lactating cows. Various salt blocks and miscellaneous types of bagged products from facilities not handling prohibited material were used as well.

Three different commercial suppliers were identified through the on-farm feed investigation. Investigations at the primary supplier of the calf products (manufactured the 20% and 18% Calf Starters which were fed for approximately 4 or 5 of the first 6 months of life) confirmed it to be free of prohibited material. This facility was dedicated free of prohibited material for more than ten months before manufacturing feeds during the time frame of interest. Feeds from this facility were delivered to the index farm in dedicated, company-owned trucks.

Investigations at the other two facilities-that did receive, store and use prohibited material during the period of interest-confirmed that all feed product formulations for the index farm (16% Heifer Grower, 2 different lactation rations, lactation and dry cow/heifer premixes) were not manufactured using prohibited material. Therefore, the remainder of the investigation focused on production practices and the records for manufacture and delivery of feeds specific to the index animal.

Both manufacturing facilities received prohibited material from the same rendering plant implicated in previous BSE investigations. Both facilities had procedures in place to comply with the 1997 feed ban. However, a review of production records revealed that one of these facilities failed to document a flush of equipment used to pellet 2.08 tonnes of commercial 16% Heifer Grower ration. The equipment had previously been used to pellet a feed containing prohibited materials for non-ruminants. This entire load of commercial Heifer Grower ration was delivered to the index farm (on May 25, 2002) and used in the feeding of the index animal and others on the premises at the time. An enforcement investigation into feed mill activities is underway.

Canola meal from the second facility is believed to have been fed to the index animal for a period of about two weeks when it was two to three months of age. Production records from this facility, while not pointing to any instances of potential cross contamination of this feed, were incomplete and did not allow for the desired level of certainty. The procedural error associated with the 16% Heifer Grower ration makes that feed the most likely source of infection.

Considering the feeding regime on the farm and specific production records reviewed, the most likely source of exposure to BSE infectivity appears to be the heifer ration referred to above, which could have become contaminated by prohibited material from the non-ruminant ration produced immediately before it. Because of incomplete or absent documentation, the possibility of cross-contamination during transportation being a contributing factor could not be ruled out.

Investigation Overview

Since detecting BSE in May 2003, Canada has significantly increased its targeted testing of cattle in high-risk categories (including animals which die on-farm). This effort is directed at determining the level of BSE in Canada, while monitoring the effectiveness of the suite of risk mitigating measures in place. Canada's National BSE Surveillance Program continues to demonstrate a very low level of BSE in Canada, with seven positive animals detected among over 117,000 targeted tests conducted since 2003. Such detections demonstrate the effectiveness and integrity of Canada's surveillance system; the level of awareness existing at all levels of the animal and meat production systems; the value of financial reimbursement provided for sampling and carcass disposal; and the commitment of Canadian producers and veterinarians to eliminating this disease. Canada's surveillance program fully respects OIE guidelines.

The detection of this case at an early stage demonstrates the highly sensitive and robust nature of Canada's BSE surveillance program. This animal was detected and diagnosed with BSE during a pre-clinical phase of the disease. The normal disease course to expression of clinical signs in this animal would be expected to have included an additional three to six months of incubation followed by an additional one to two months of clinical expression prior to being recognized as symptomatic of BSE and targeted for testing. Had an unrelated disease not hastened her entry into the surveillance stream, this animal would most likely have demonstrated clinical signs sometime between 54 and 56 months, not significantly different from the age range of previous cases.

It is important to recognize that the incubation period seen internationally ranges from 21 months of age to 216 months of age and is thought to be a function of the age of an animal when exposed and the dose of exposure. With an age range of 50 months to 180 months or more, Canada's cases are consistent with international data suggesting low dose exposures.

The location of Case 7's birth farm in northern Alberta and the possible relationship with a previously identified source of prohibited material make this occurrence consistent with the previously identified geographic cluster.

Other Relevant Information

Regarding the nature and effectiveness of Canada's ruminant feed ban, it is recognized that any potential BSE infectivity entering the beginning of the animal feed supply chain requires management throughout a complex feed and animal production system. As such, the current framework of the ban provides limited potential opportunities for prohibited animal proteins to contaminate feeds for ruminants, particularly when errors are made during mixing and manufacturing in multi-purpose facilities. Given the nature of the ban and these opportunities, the detection of BSE cases in Canadian cattle born after the implementation of the ban is consistent with the experiences of other countries that have detected a small number of domestic cases of BSE in recent years. International experts have agreed that the proactive implementation of the 1997 mammalian to ruminant feed ban in Canada has been a critically important factor in limiting the spread and preventing the amplification of BSE in the feed system.

Since the year 2000, the CFIA has significantly increased the frequency of inspections of the animal feed system. For example, the inspection frequency for commercial feed mills has increased from once per year to twice per year for all mills and is being increased further, to up to four times per year for higher risk facilities. Internal and external reviews have been conducted to assess inspection activities and the ban's effectiveness. Both the United States Department of Agriculture (USDA) and Canadian Food Inspection Agency's (CFIA) reviews in 2005 concluded that the ban, as designed, implemented and currently applied, is providing an effective barrier that is contributing to reducing the risk of BSE.

In 2005, the CFIA received additional funding to increase inspection and enforcement activities associated with the ban and to work toward implementing enhancements to the existing feed ban proposed by the CFIA in December 2004. Throughout 2005-06, additional inspection staff have been recruited, trained and deployed to augment feed ban-related programs.

Inspection activities are focussed on renderers, commercial feed manufacturers, retail and on-farm locations. Currently, there are approximately 30 renderers, 515 feed mills, 1300 retailers and over 100,000 farms (ruminants) in Canada. Approximately 115 new staff are working in this area. This is in addition to the approximately 70 cross-utilized inspection staff who worked in the program in the year 2000. These new inspection resources are deployed on a risk basis with emphasis on facilities that receive, store, use and distribute prohibited material.

Regulations to enhance Canada's feed ban were announced on June 26, 2006. The most important enhancement will require the removal of specified risk material (SRM) from all animal feeds, pet food and fertilizer. The enhancement will significantly accelerate Canada's progress toward eradicating BSE from the national cattle herd by preventing more than 99% of any potential BSE infectivity from entering the Canadian feed system. For further information, please see the fact sheet, "[Canada's Enhanced Feed Ban](http://www.inspection.gc.ca/english/anima/feebet/rumin/enhrene.shtml)", available at <http://www.inspection.gc.ca/english/anima/feebet/rumin/enhrene.shtml>.

The safety of beef produced in Canada is assured by public health measures enacted in 2003, following the first detection of BSE in Canada. The removal of SRM from all animals slaughtered for human consumption in Canada is the most effective single measure to protect consumers in Canada and importing countries from exposure to BSE infectivity in meat products.

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Date Modified:
2006-08-24


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