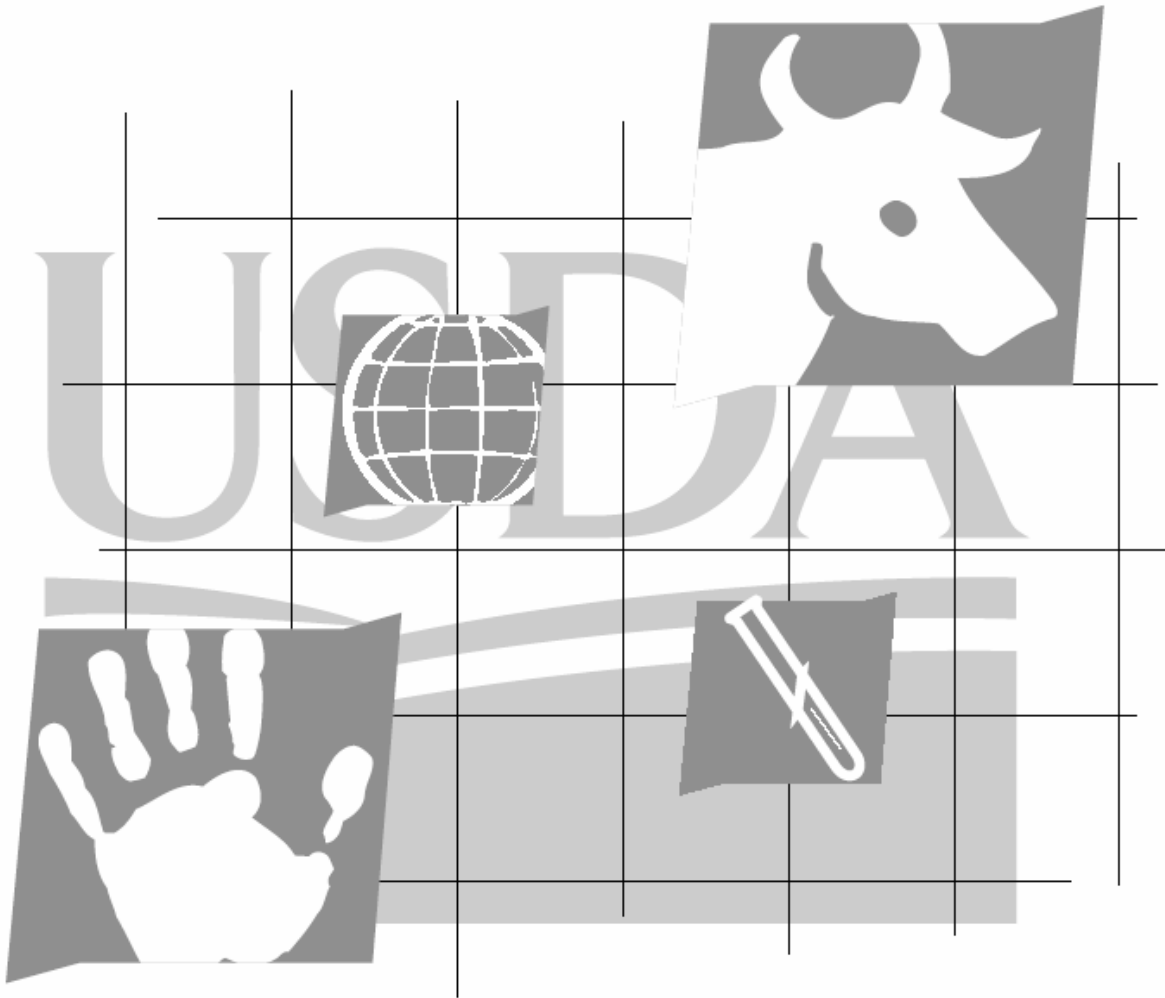




**U.S. Department of Agriculture's
Summary of the Epidemiological
Findings of North American
Bovine Spongiform Encephalopathy
Positive Cattle**



April 2005

Table of Contents

1 Executive Summary 5

2 Introduction 6

2.1 Objectives of mission 7

2.2 Overview of the cattle industry in Canada 7

3 Description of the four indigenous North American BSE positive cattle 10

3.1 Case #1 10

3.1.1 History and signalment 10

3.1.2 Trace back investigation to birth herd 10

3.1.3 Disposition of herd mates/birth cohorts/other cohorts 10

3.1.4 Disposition of dam and calves 11

3.1.5 Trace forward feed investigation 11

3.1.6 Trace back of possible feed sources of exposure 11

3.2 Case #2 11

3.2.1 History and signalment 11

3.2.2 Trace back investigation to birth herd 12

3.2.3 Tracing birth cohort 12

3.2.4 Disposition of herd mates/birth cohorts/other cohorts 13

3.2.5 Disposition of dam and calves 13

3.2.6 Feed Investigation 13

3.2.7 Rendered material follow up: 14

3.3 Case #3 14

3.3.1 History and signalment 14

3.3.2 Location, tracing, and animal demographics 14

3.3.3 Disposition of calves 15

3.3.4 Feed investigation 15

3.4 Case #4 16

3.4.1 History and signalment 16

3.4.2 Location, tracing, and animal demographics 16

3.4.3 Feed investigation 16

3.5 Summary of epidemiological investigations and potential ‘point source’ of exposure 16

4 General Summary of Canada’s response to BSE 17

4.1 Importation 17

4.2 Animal feed exclusions 18

4.3 Surveillance 20

5 BSE Epidemiology of Alberta, Canada 20

5.1 Background epidemiology of the Alberta area 20

5.2 Risk profile of a BSE case 21

5.3 Active and intensive surveillance in Alberta 21

5.4 Cluster concept 22

6 Theories regarding the origin and development of BSE in Canada 22

6.1 Geographic distribution of cattle in Canada 23

6.2 Origin Assessments 23

6.3 Rendering 23

6.4 Feed ban implementation and implications of feeding practices 23

6.5 Clustering hypothesis..... 23

6.6 Generations of exposure 24

6.7 Epidemiological implications to the United States..... 24

7 Conclusions related to the objectives of the mission..... 25

7.1 Point source of the infection 25

7.2 Investigation into other cattle of concern 25

7.3 Feed evaluation 26

Abbreviations

APHIS	Animal and Plant Health Inspection Service
BSE	Bovine spongiform encephalopathy
CCIA	Canadian Cattle Identification Agency
CEAH	Centers for Epidemiology and Animal Health
CFIA	Canadian Food Inspection Agency
CJD	Creutzfeldt-Jakob disease
CWD	Chronic wasting disease
FDA	Food and Drug Administration
ITS	Import Tracking System
MBM	Meat and bone meal
NCFAD	National Center for Foreign Animal Diseases
OIE	Office International des Epizooties (World Organization for Animal Health)
PPQ	Plant Protection & Quarantine
TSE	Transmissible spongiform encephalopathy
USDA	United States Department of Agriculture
UK	United Kingdom
VS	Veterinary Services

1 Executive Summary

On January 24, 2005 four USDA, Animal and Plant Health Inspection Service (APHIS) epidemiologists traveled to Canada to thoroughly review the Canadian epidemiological investigations of the four confirmed cases of bovine spongiform encephalopathy (BSE) in North America. The team evaluated the possibilities of any common links between these cases, and also evaluated the likelihood of higher risk animals or feed exposure to the United States.

The investigation team did not conclusively identify a point source of potentially contaminated feed common to all four BSE cases. However, there are feed exposure links between 3 of the cases, an association that is difficult to dismiss. The team concluded that all four cases appear to have resulted from the consumption of feed contaminated with infected bovine tissues during the early part of the animal's life (when they are most susceptible) and either prior to or soon after implementation of the Canadian feed ban. The information available strongly suggests a localized exposure of BSE, based on the relatively small geographical location, the temporal association, and the clustering of all four cases.

The team evaluated whether higher risk animals may currently be present in the United States. In the epidemiological investigations of all cases, cattle of concern were those identified within the 4 birth cohorts: animals born within one year before or after each case. Of the 859 potential cattle of concern initially identified, six cattle were eliminated as part of the birth cohort, 11 are considered untraceable, four are still alive in Canada and under observation by the Canadian Food Inspection Agency (CFIA), 809 are either dead or slaughtered, and 29 are believed to have entered the United States. Of the 29 believed to have entered the United States, 18 (62 percent) were definitively identified and either depopulated or confirmed slaughtered.

Approximately 40,000 breeding cattle came into the United States from the Alberta region between 1994 and 1998, with about 18,000 of those entering during 1997 to 1998. These cattle could represent another group of higher risk animals, as profiled by CFIA. Normal aging and attrition would be expected to have removed the majority of these cattle from the population. An age distribution model for United States cattle indicates that less than three percent of these animals would be expected to remain in the United States herd at this time.

The investigation team documented the importation of suspect ruminant-origin meat and bone meal from a local renderer in Alberta, Canada into the Pacific Northwest of the United States in early 1997. An investigation with the importer determined that none of this product was manufactured into ruminant feed. A vast majority of the product was exported directly to Asia, and any remaining product was incorporated into poultry feed.

Some of the data suggest that the Northwest region of the United States could be considered within a broadly defined movement area that could be at higher risk of exposure to BSE. While this region has historically imported a substantial number of cattle from western Canada, and a small portion of high-risk meat and bone meal was shipped to the area, the U.S. feed ban and other mitigations have effectively minimized the risk of transmission or amplification of the BSE agent.

2 Introduction

Bovine spongiform encephalopathy is an incurable, invariably fatal degenerative neurological condition of cattle that was first diagnosed in the United Kingdom (UK) in 1986. Since that initial diagnosis, BSE has been identified in 20 other European countries and in non-European countries such as Japan, Israel, Canada, and in the United States from an imported cow. Clinical signs of BSE may initially be subtle and confined to behavioral manifestations such as nervousness or aggression. As the disease progresses, other signs may include head rubbing, ataxia, weight loss, falling, decreased milk production, and muscle fasciculation.

BSE belongs to a group of diseases called transmissible spongiform encephalopathies (TSE) that include such agents as scrapie in sheep, chronic wasting disease (CWD) of cervids, and Creutzfeldt-Jakob disease (CJD) in humans. Although the causative agent of BSE has not been fully characterized, the protein-only or prion theory has dominated the scientific literature. The current theory is that TSEs develop when prion proteins, found on the surface of nerve cells in the brain, change into an abnormal shape and accumulate within the nerve cells. This abnormal prion then induces normal prions to change to the aberrant form and further replicate, thereby behaving as an infectious agent.

BSE is believed to be primarily acquired via the oral route when cattle consume feed that contains the abnormal protein (prion). Animal feed becomes contaminated when BSE-infected animals are rendered into a protein source that is subsequently incorporated into the manufacturing of ruminant feed and fed back to cattle. Tissues of greatest risk of containing the BSE agent include the brain, spinal cord, eyes, dorsal root ganglion, other neurological tissue, and the distal ileum. The oral infectious dose can be very small – in cattle, the ingestion of only 10 milligrams of infected brain material may cause BSE. In addition, one study reported that the possibility of maternal transmission of the agent to calves born to infected dams during the later stage of disease cannot be ruled out. The incubation period of BSE has a wide range in cattle, two to eight years, with an average of five to six years, and is inversely proportional to the infectious dose.

BSE is diagnosed by the histopathological review of brainstem (the obex) and by immunohistochemistry to detect the abnormal prion protein; there is no ante mortem diagnostic testing available. In addition, there is no effective treatment for BSE. Prevention of the disease is based on prohibiting the consumption of the infectious agent by susceptible cattle.

One of the concerns of BSE infection in cattle is its zoonotic potential. A novel variant of CJD (called vCJD), initially reported in the UK in 1996, has been associated with the consumption of BSE-infected tissue. Activities to address and prevent BSE infection in cattle have been a direct response to protect public health.

On May 20, 2003, Canada reported its first indigenous case of BSE. Following receipt of this notification, the United States Department of Agriculture (USDA) immediately prohibited the importation of all live ruminants, ruminant meat, ruminant meat products, and other ruminant protein products from Canada. In November 2003, USDA published a proposed rule that would

allow importation of certain ruminant products from minimal risk regions under specified conditions. This rule proposed to list Canada as a BSE minimal risk region.

On December 29, 2004, USDA announced a final rule that established conditions under which the United States will allow imports of certain live ruminants and ruminant products from regions with effective BSE prevention and detection measures. Canada was the first country recognized as a minimal-risk region; therefore, it was to be eligible to export certain live ruminants and ruminant products to the United States beginning March 7, 2005. On March 2, a Montana District Court ruled to temporarily enjoin implementation of the rule.

Canada subsequently reported two additional cases of BSE on January 2 and 11, 2005. USDA, in cooperation with the CFIA, sent two technical teams to Canada in January 2005 to thoroughly evaluate the epidemiology of the four North American BSE cases and Canada's ruminant-to-ruminant feed ban program.

2.1 Objectives of mission

Four USDA, Animal and Plant Health Inspection Service (APHIS) epidemiologists traveled to the CFIA headquarters office in Ottawa during January 24 to 28, 2005. The objectives were three-fold: 1) to thoroughly review the Canadian epidemiological investigations of the four confirmed cases of BSE in Alberta and evaluate the possibility of a point source exposure involving contaminated feed to explain them; 2) to evaluate the likelihood that other related high risk cattle (if any) from Canada are currently present in the United States; and 3) to evaluate any feed issues that may have resulted in a possible exposure to United States cattle. To accomplish these objectives, the epidemiology team met with CFIA officials to obtain detailed information on the various aspects of the investigations. This report will detail the findings of the epidemiological review.

2.2 Overview of the cattle industry in Canada

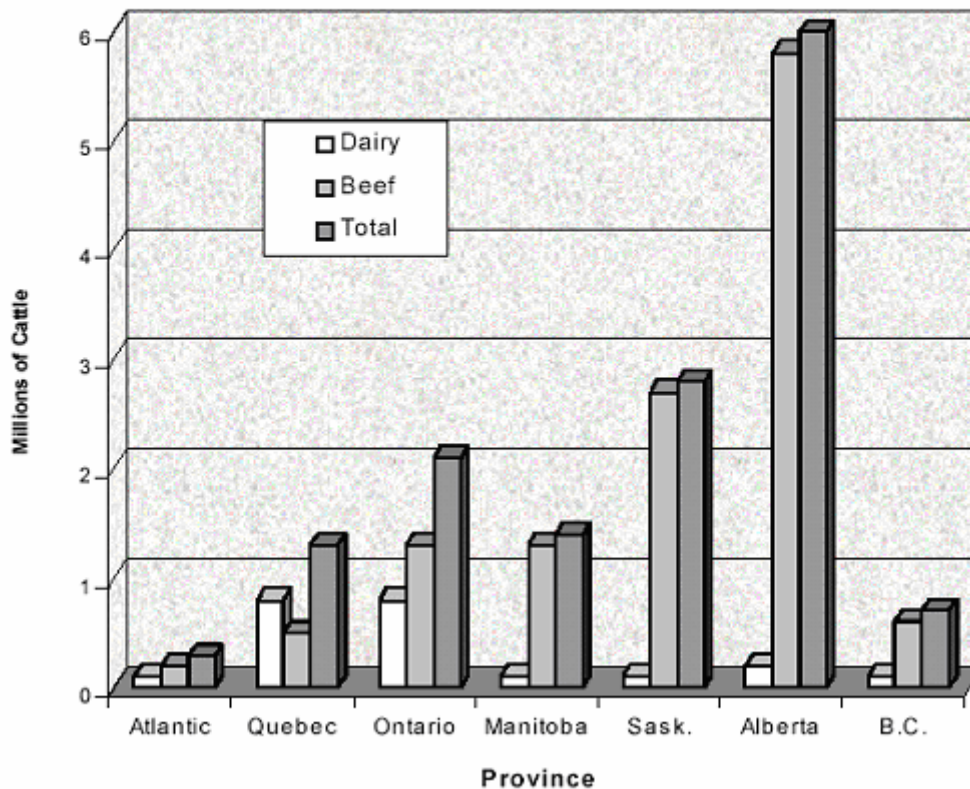
Agriculture and agri-food is one of the most important sectors of Canada's economy. It is the second largest manufacturing sector, the source of one in seven Canadian jobs, and is valued at \$130 billion. During the time period January 2000 to July 2001, the cattle population ranged from 12.8 million head to 14.6 million head; the majority consisting of beef animals (range of 82.7 percent to 85.2 percent) annually. According to CanFax Research Services (www.canfax.ca) the cattle population on July 1, 2004 had increased slightly to a total of 16.7 million head. Approximately 5.5 million head are over 24 months of age. The cattle population decreases by roughly 2 million head during the winter months due to culling to reduce feed costs.

The dairy cattle population in Canada is proportional to the human population in each Province and is concentrated in Quebec and Ontario; the primary breed is Holstein (91 percent). Roughly 81 percent of Canada's dairies are located in these two Provinces. Other dairy breeds in Canada include Ayrshire, Jersey, Brown Swiss, Guernsey, Canadienne, and milking shorthorn. On average, dairy cattle are culled at 5 years of age.

About 70 percent of Canada's beef cattle are located primarily in the western Provinces of Alberta and Saskatchewan (see Figure 1). The major beef breeds are Hereford, Angus, Charolais, Simmental and Limousin. To prevent newborn calves from being subject to the cold

winter weather, most cow/calf ranches in Canada breed their cows in June or July so the calves are born the following March and April. Most beef cattle are slaughtered at 18 months of age; prior to that they are generally forage fed over the winter and put out to pasture in the spring. In 2002, over 50 percent of the beef cattle produced in Canada were exported, primarily to the United States (70 percent), Mexico and Asia.

Figure 1: Distribution of Cattle in Canada



The bulk of Canadian cattle (96 percent) are slaughtered at federally-inspected plants; the remaining slaughter occurs at provincially-inspected plants. Roughly 85 percent of all cattle are slaughtered at a young age, approximately 18 months of age. Over 70 percent of the beef slaughtered in federally-inspected plants occurs in Alberta. In 2000, approximately 1.1 million young beef animals and 174,000 cull cows were exported to the United States for slaughter.

In addition to the exported slaughter animals mentioned above, during the time period 1997 to 2002, at least 871,144 live breeder and feeder cattle were exported to the United States per data from CFIA.

The manufacture, sale, and importation of feed is regulated by CFIA. From 2001 specific data obtained from the Canadian census, there were 583 feed mills; 24,130 on-farm feed mills; and almost 250,000 farms nationally. In Canada, over 96 percent of farms rear one production animal type; therefore, the possibility of on-farm feed cross-contamination due to multiple

species is minimal. In 1997, the feed mills located in Ontario, Quebec, and the Atlantic regions produced 71 percent of the total feed manufactured in Canada; western Canada produced 29 percent. With the large number of cattle in western Canada, it is likely that most feed is mixed on the farm. Based on the census data, 58 percent of the estimated on-farm feed mills were located in western Canada.

In 1997, the 32 rendering facilities throughout Canada were operating under an annual permit system to specifically address the risks associated with the feeding of ruminant protein to ruminants. In Alberta in 2004 there were six renderers throughout the Province.

Three types of permits are issued to allow the manufacture of meat and bone meal (MBM): non-prohibited material only (12), prohibited material only (7), and both non-prohibited and prohibited material manufacture (13). Between two to three million tons of inedible by-products are processed by these renderers annually. Four types of rendering processing systems are used: continuous cooker, continuous preheat/press/evaporator, batch cooking rendering, and continuous multi-stage evaporator. The first three of these systems may reduce BSE infectivity (from 1.0 to 3.1 log) but cannot be relied upon to completely inactivate the prion. The continuous multi-stage evaporator system (also referred to as a 'low temperature/vacuum' system) does not reduce infectivity.

The source of rendered product must be described in an import permit application. Canada imported MBM for the manufacture of livestock feeds primarily from the United States during the time period 1988 to 2001. Australia and New Zealand also provided some MBM to Canada but in much smaller quantities. The sole source of imported MBM was from the United States in 1988 to 1993 and in 2001. Australia or New Zealand or both countries contributed product in 1994 to 2000. Denmark and Germany were minor sources of non-ruminant MBM in 1997; however, both countries provided product for aquaculture use only.

Exportation of animal and vegetable protein sources from Canada into the United States may have occurred, particularly in the southern areas of the Provinces, but generally minimal product movement would occur if the value of the Canadian dollar was strong. Other conditions such as drought and feed availability may have also encouraged the movement of product from the United States into Canada and vice versa.

In Canada, the following five acts and regulations are relevant to the prevention and control of BSE:

- *Health of Animals Act and Regulations*
- *Meat Inspection Act and Regulations*
- *Feeds Act and Regulations*
- *Agriculture and Agri-Food Administrative Monetary Penalties Act and Regulations*
- *Foods and Drug Act*

The *Health of Animals Act and Regulations* mandated a national animal identification system for cattle and bison on January 1, 2001 that is managed by the Canadian Cattle Identification Agency (CCIA). An ear tag identification is applied to the animal once it leaves the farm of

origin and provides individual animal identification and herd-of-origin trace-back. This program is an integral component of the overall BSE strategy for Canada.

In November 1990, the Minister of Agriculture named BSE a reportable disease. Also in 1990, Canada placed all cattle imported from the UK and Ireland since 1982 in a monitoring program. Additional measures implemented included a ban on further importation of cattle from these countries. In December 1993, one imported cow that was residing in Alberta at the time showed clinical signs consistent with BSE; the diagnosis was confirmed at the Central Veterinary Laboratory (the international reference lab for BSE) in Weybridge, Great Britain. In response to the 1993 case, all cattle in Canada related to the index case were destroyed and all other remaining UK imports were removed or destroyed.

3 Description of the four indigenous North American BSE positive cattle

3.1 Case #1

3.1.1 History and signalment

Case # 1 was a black Angus cow, approximately six years of age (born in March 1997), when it was presented to a provincially-inspected abattoir in Grande Prairie (within the Peace River District of northern Alberta) on January 31, 2003. The animal was nonambulatory at presentation and condemned upon postmortem examination due to a finding of pneumonia. The animal met the criteria for BSE surveillance at that time and its head was sent to the Alberta provincial laboratory for BSE testing. It was subsequently revealed that the animal had experienced a period of abnormal behavior while on the farm. Since the carcass had been condemned it was not processed for human food and was sent to a local renderer in Edmonton. Meat and bone meal was produced and sent to various feed mills in the distribution area of the renderer for incorporation into pet food and poultry meal. The cow's hide was sent to a processor in Edmonton.

A preliminary diagnosis of BSE was made on May 16, 2003 by the Alberta provincial laboratory and was confirmed by the CFIA's National Centre for Foreign Animal Disease on May 18 and by the Central Veterinary Laboratory on May 20, 2003.

3.1.2 Trace back investigation to birth herd

The infected cow had been part of an 80 cow herd located in northern Alberta during the six months immediately prior to slaughter. The index cow was initially described solely as a "black cow" at slaughter; therefore, CFIA had to use DNA testing to positively identify the birth herd of the index cow. The birth herd (n=247) was ultimately traced to a town that straddles the provincial border between Saskatchewan and Alberta (due east of Edmonton); the location of birth of the index animal was actually in the Province of Saskatchewan.

3.1.3 Disposition of herd mates/birth cohorts/other cohorts

Cattle that may have spent time in herds with the infected cow during its lifetime, including cattle that had moved out of those herds before the infected cow was identified, were destroyed; a total of more than 2,700 animals were euthanized. Of these, more than 2,000 cattle were over 24 months of age and were tested for BSE with negative results in all cases. All animals that were part of the birth herd (247) were depopulated during the course of the investigation.

Through additional investigative processes, three additional farms were quarantined when investigation could not preclude the exposure of 63 head of cattle to feed destined for poultry. The animals were culled and tested negative.

3.1.4 Disposition of dam and calves

Subsequent to DNA confirmation of the herd of origin of the clinical case, it was determined that her dam was deceased. Of the two calves born to the affected animal in the two years prior to her onset of clinical signs, one was located and euthanized (parentage was confirmed using DNA analysis) and the other was confirmed to have gone to slaughter.

3.1.5 Trace forward feed investigation

The carcass of the index case was traced to its direct allocation into pet food and poultry meal with subsequent distribution across 1,800 farm sites. Visits were paid to the renderer and all feed mills that could have received product from the affected animal. These visits confirmed adherence to the ruminant feed ban legislation (implemented in 1997) on product receipt, segregation, labelling, and distribution.

As part of the trace-forward investigation into the processing of the remains of the BSE-infected cow, it was determined that rendered material from the cow may have been used in the production of dry dog food. The CFIA issued an information notice that included a listing of the potentially contaminated product and reminded livestock producers not to mix dog food into cattle or other animal feeds.

3.1.6 Trace back of possible feed sources of exposure

Two possible sources of MBM exposure were identified among the multiple herds initially associated with the index cow. One MBM source was a feed concentrate and the other was a high energy feed block. Although investigations of the feed mill records and compounding formulae confirmed that MBM incorporation in both products was discontinued in 1997 upon implementation of the MBM feed ban, it has been determined that products containing MBM were still available on farms subsequent to implementation of the ban at renderers and feed mills.

A single renderer, Renderer A, serviced the geographic area encompassing the birth herd of the infected animal. Multiple feed mills that could have produced supplements of the nature described above were in this same distribution area and most likely would have received their MBM from this renderer.

3.2 Case #2

3.2.1 History and signalment

On December 9, 2003, a nonambulatory 6.5 year old Holstein cow (date of birth: April 9, 1997) arrived at a slaughter plant in Washington State; the 'downer' status was attributed to complications from calving 10 days prior. As part of the APHIS BSE surveillance efforts, a brain sample was obtained and submitted to National Veterinary Services Laboratories in Ames, Iowa for testing. The carcass passed post-mortem inspection and was processed as usual. Offal, including potential high-risk material was sent to inedible rendering.

On December 23, 2003, USDA, APHIS announced a preliminary diagnosis of BSE in this animal. On December 25, 2003, the Central Veterinary Laboratory in Weybridge confirmed the diagnosis.

The United States' approach to this occurrence was a complete trace of progeny, birth cohort, and feed cohort in accordance with World Organization for Animal Health (also known as the Office International des Epizooties or OIE) guidelines. The Canadian approach to this case included a comprehensive investigation of animal tracing (both trace-back and trace-forward) along with feed investigations.

3.2.2 Trace back investigation to birth herd

APHIS, in collaboration with CFIA, traced the birth of the BSE-index cow to a dairy farm in Alberta, Canada, approximately 30 miles southwest of Edmonton. Thus, the BSE-positive cow was not indigenous to the United States but rather was a cow imported from Canada.

Tracing of the index animal's history by USDA and CFIA determined that the index cow was included in a shipment of 81 cattle exported on September 4, 2001, through the port of Oroville, Washington, to a dairy cattle finishing location in south-central Washington state. At the finishing premises, three animals were retained; seven animals were moved to a heifer raising operation 30 miles away; and 70 animals, including the index case, were purchased and relocated on October 16, 2001 to a dairy farm 50 miles south (the United States index herd location) from the finishing site.

The producer/owner of the index dairy farm had a total of roughly 4,000 head at 2 separate dairy locations; one location, where the index animal resided, housed around 1,700 head and the other, roughly 7.5 miles away, housed 2,300 head.

3.2.3 Tracing birth cohort

The animals subject to culling under OIE guidelines were those animals born one year before and one year after the index case and are collectively known as the birth cohort. Therefore, the trace-out investigation centered on animals born between April 1996 and April 1998. CFIA concluded that 57 animals were born into the birth herd in Canada from April 1996 to April 1998. Twenty-seven of these animals were traced and confirmed dead, 25 animals (including the index case) were exported to the United States, two animals were untraceable, and three animals continued to reside in Alberta. These three animals were humanely destroyed and all tested negative for BSE.

A related premises near the index herd in Canada, a commingled beef herd, also had 57 animals born during April 1996 to April 1998. These animals might have been exposed to small amounts of potentially contaminated feed through common management practices, which include the sharing of feed. Of these 57 animals, 48 were dispersed and nine, still on the farm, were destroyed. All nine tested negative for BSE. The 48 dispersed animals were determined to be among 86 head sold to numerous buyers. Eighty of these cattle were traced and confirmed slaughtered, two were untraceable and four cows were traced into a herd of 150 head. The four cows commingled with the herd of 150 may or may not be part of the birth cohort and their risk

of exposure is low. CFIA continues to monitor these four animals and recently reported that all four are still on the premises; one has calved and the remaining three are in calf.

In summary, CFIA euthanized and tested a total of 12 head of cattle; all animals tested negative for BSE.

3.2.4 Disposition of herd mates/birth cohorts/other cohorts

Additional investigations in the United States located a total of 255 “animals of interest” (animals that were or could have been from the source herd in Alberta, Canada) that were identified on 10 premises in three States in the Pacific Northwest (Washington, Oregon, and Idaho). All 255 animals were depopulated and examined for the presence of BSE, and all results were negative.

3.2.5 Disposition of dam and calves

A total of five calves were born to the index animal; two while she was in Canada and three while in the United States. However, per the OIE guidelines, the progeny born within the two years prior to the onset of illness (December 2001 to December 2003) are considered the highest risk animals and therefore should be located and euthanized. The index cow’s two most recent calves were traced and located: a heifer, born on November 9, 2002, was located on the index herd premises in Washington, euthanized, and tested negative for BSE; and a bull calf, born on November 29, 2003, was located at a nearby bull calf rearing facility. The heifer was included among the 255 “animals of interest” group as mentioned previously. Since the bull calf entered the rearing facility without any identification and could not be positively identified, all calves on the premises were euthanized (n=449). No BSE testing of the bull calves occurred because they were all younger than the minimum age recommended for testing.

The dam of the index cow was determined to have been on the same Canadian export certificate and entered the United States with the index cow in 2001; her age was listed at 11 years. At the time of the BSE-positive diagnosis of the index case in December 2003, her dam would have been 13 years old. The dam was not definitively located and is unlikely to still be alive.

3.2.6 Feed Investigation

The CFIA staff determined that only three commercial sources of protein were available to dairy cattle on the birth herd premises: 26 percent Calf Starter, a 20 percent Protein Supplement block, and a 15 percent Dairy Ration.

In general, calf starters do not intentionally contain any MBM and therefore it is unlikely that this product was contaminated with infected bovine tissue. However, the manufacturer of the calf starter did handle MBM and products containing MBM from Renderer A at the same time they manufactured the calf starter. The last documented purchase of this product by the birth herd producer was December 20, 1996; the producer indicated that the consumption of this product would have occurred prior to the birth of the index case in early April 1997.

The 20 percent Protein Supplement block manufacturing process was also reviewed by CFIA investigators. According to records of the manufacturer, the last documented purchases of this product by the producer were March 4, 1997 and March 13, 2001. The source of MBM for this

product is unknown since production records and formulation records were unavailable in 2001 for products retailed in 1997. The producer mentioned that one tub (block) would have been placed in the dry cow pen in March 1997 and would have been consumed prior to the addition of the index cow into that pen (mid-May 1997).

The producer reported that a 15 percent Dairy Ration was the sole commercial source of protein for lactating cattle on his premises. Renderer A supplied the MBM to a feed mill in Edmonton for the manufacture of 32 percent Equalizer Pellets. Records indicate that the equalizer supplement pellets would have been made with MBM prior to July 11, 1997 and without MBM after July 18, 1997. The pellets were then shipped to a feed manufacturer for incorporation into a 15 percent Dairy Ration. The Dairy Ration was purchased by the producer of the birth cohort premises at regular intervals every seven to 14 days; therefore, the index case had potential to be exposed to this ration post-weaning in late April 1997.

3.2.7 Rendered material follow up

The Food and Drug Administration (FDA) is the agency responsible for tracing rendered animal material. Over 2,000 tons of MBM and other by-products that could have been derived from the carcass of the infected animal were located and contained; none entered the animal feed manufacturing process.

3.3 Case #3

3.3.1 History and signalment

On December 17, 2004 a private veterinary practitioner collected and submitted a brain specimen from an 8-year-old Holstein cow that had been previously treated for “waxing and waning” neurological signs of posterior paresis; the specimen was BSE-positive on the BIO-RAD rapid test used at the Provincial TSE laboratory in Edmonton, Alberta. The diagnosis was confirmed by immunohistochemistry on January 2, 2005 by the National Center for Foreign Animal Diseases (NCFAD) in Winnipeg, Canada. No part of the cow entered the human food chain. Pending confirmation of the specimen and in accordance with Canada’s BSE surveillance program, the entire carcass was initially secured and retained on the index premises. Once the diagnosis was confirmed at the NCFAD, the carcass was removed and transported to a laboratory in southern Alberta for incineration.

The index cow was born October 5, 1996 on a beef and dairy premises in northern Alberta, approximately 85 miles northwest of Edmonton. At the time of her neurological condition and subsequent specimen submission, her index herd location was approximately 43.5 miles northwest of Edmonton, Alberta.

3.3.2 Location, tracing, and animal demographics

The birth herd cohort (October 5, 1995 to October 5, 1997) was a mixed herd with both beef and dairy animals initially believed to be comprised of 38 dairy breeders, 55 dairy feeders, 27 beef steer calves, and 21 beef heifer calves (total=141). When the 55 dairy feeders were further investigated, six animals were eliminated because they did not meet the cohort definition, thus leaving 49 feeders in a total birth cohort of 135 animals.

Of those 135 animals, 127 were accounted for with reasonable or greater confidence as being dead or slaughtered. Four additional animals were believed to have gone to the United States, and four others could not be definitively traced and could have gone to the United States.

The eight cattle that could have entered the United States were investigated by APHIS Veterinary Services (VS) personnel. Of the eight, four were either confirmed or highly likely to have entered the United States for slaughter. Two additional cows may have entered the United States and, if so, would have been slaughtered. The remaining two cattle were either very unlikely to have entered or cannot be traced based on limited identification information.

3.3.3 Disposition of calves

Prior to the onset of neurological clinical signs, the cow had given birth to a stillborn calf in November of 2004 and had a history of calving difficulty although she had delivered a live bull calf in 2003. The calf born in 2003 went to slaughter at a local facility on December 15, 2004 for the owner's consumption; however, the meat was not consumed and was still retained in the freezer as determined during the investigation. A third calf (a heifer) had been born to the index case in February 2002 and was sold to a feedlot and slaughtered in March 2004.

3.3.4 Feed investigation

Feed tracebacks indicated four sources of feed from October 1996 to December 1997 that were delivered to the birth herd cohort premises in northern Alberta.

1. Co-op dealer, who provided layer feed, salt blocks, fortified blocks, pet food, and minerals to the birth herd premises. These were unlikely to have been a source of suspect MBM.
2. A second feed dealer received material from a feed manufacturer in Alberta. This dealer sold both calf starter and a heifer ration that contained "Equalizer" supplement to the birth cohort premises. The "Equalizer" did contain MBM from Renderer A and was delivered to the index premises on Sept. 16, 1995; Oct. 3, 1995; and May 29, 1996. The feed manufacturer purchased MBM products from distributors in Edmonton and Wataskawin; these distributors had purchased MBM directly from Renderer A.
3. A third source was a feed manufacturer in Alberta that received MBM from Renderer A on February 28, 1997 and provided heifer rations containing MBM (32 percent supplement). The manufacturing date was most likely May 1997 and was shipped in June 1997. CFIA suspects that this is the likely source of contaminated/suspect feed. This Renderer A MBM shipment date is also associated with both the January 2003 and Washington State cases.
4. A fourth feed mill provided both 14 percent and 16 percent dairy rations (containing MBM from Renderer A) to the birth cohort herd until August 1997 and October 1997 respectively. They also supplied a 14 percent heifer ration that did not contain MBM.

3.4 Case #4

3.4.1 History and signalment

An 81-month-old Charolais cow with posterior paresis was confirmed positive for BSE on January 11, 2005 by immunohistochemistry at the Canadian Science Center for Human and Animal Health in Winnipeg. No part of the cow entered the human or animal food chains; once confirmed positive, the carcass was incinerated.

The CFIA investigation indicated that the cow, born on March 21, 1998, remained on the premises of birth in Alberta, roughly 70 miles north of Calgary, throughout its life. The calves born to the cow within the previous two years (2003 and 2004) are no longer alive. The 2003 calf died as a young animal after a diarrheal illness and the 2004 calf was slaughtered.

3.4.2 Location, tracing, and animal demographics

The birth cohort has been identified and totals 349 Charolais cattle. Of these 349, a total of 41 were initially placed under quarantine, euthanized and tested (all results are negative for BSE); 32 animals had died on the farm of origin; 273 cattle have been confirmed as slaughtered or died in Canada; and three cattle were considered untraceable due to inadequate records. No animals were traced to the United States.

3.4.3 Feed investigation

The feed investigation, to identify potential sources of exposure, is now completed. It is hypothesized by CFIA that the Charolais cow consumed contaminated feed, medium calf ration, or two types of mineral supplement as a young animal. The epidemiological investigation indicates that all sources of feed were manufactured after implementation of the feed ban. However, some suspect MBM may have been included in the feed, calf ration, or mineral supplements during the 'practical implementation period,' estimated by CFIA to be up to six months subsequent to the actual implementation of the ban (see Section 4.2).

Another exposure route initially considered was consumption of pet food. Barn cats were fed in the area that also housed the calf hutches; therefore, consumption of suspect cat food, by the calves, could have occurred. However, based on the CFIA findings, the pet food aspect was eventually ruled out as a potential route of exposure.

3.5 Summary of epidemiological investigations and potential 'point source' of exposure

The CFIA feed investigations compared the four cases to determine if cattle movement or a common feed source linked all cases. The CFIA states that the investigations have not yielded conclusive evidence to make such a claim. However, the birth herds of the first three cases did share a distribution date of MBM from Renderer A to a limited number of local feed manufacturers in the Edmonton area. Three of the feed mills that supplied product to the producers of cases 1, 2, and 3 were found to have received an MBM delivery from Renderer A on February 28, 1997. The CFIA has documented that two mills actually received sequential loads of MBM from this renderer. Although CFIA has not definitively stated that a point source of contaminated feed caused the first three cases, this association is very difficult to dismiss.

For Case #1, the implicated product consisted of 18 percent Calf Starter (actually contained 3.2 percent MBM) produced from a pelleted protein product that contained 8 percent MBM and an

Internal Dairy Pellet that contained 6 percent MBM. Both products were produced using MBM received from Renderer A between January 30 and February 28, 1997. The products were sold to a feed store in March of 1997 and purchased by the birth herd farm on May 22; the final product fed on the farm contained on average 0.48 percent bovine MBM.

For Case #2, the implicated product is a 32 percent Equalizer Pellet manufactured in Edmonton. The pellet manufacturer received MBM from Renderer A; on February 28, 1997, they actually received MBM that followed a load to an unrelated feed mill about 135 miles east of Edmonton. The pellets were then shipped to a local feed manufacturer, during the time period of January 31 to March 10, 1997, for incorporation into a 15 percent Dairy Ration, Texturized. The Dairy Ration was purchased by the producer of the index herd premises on at least April 9, 16, and 23; the index case had potential to be exposed to this ration post-weaning in late April 1997.

For Case #3, the implicated product is heifer ration from a feed manufacturer roughly 75 miles northwest of Edmonton. This manufacturer received 8.3 tons of MBM from Renderer A on February 28, 1997, and subsequently manufactured heifer ration that was purchased by the producer in early March 1997.

In addition to the three aforementioned feed manufacturers, Renderer A also supplied MBM to two other manufacturers in Edmonton and Wetaskiwin on February 28, 1997. The MBM produced by Renderer A that is associated with these first three cases was produced prior to the implementation of Canada's ruminant-to-ruminant feed ban in August 1997.

Per the investigation summaries provided by CFIA, the feed investigation involving the fourth case, confirmed on January 11, 2005, does not seem to be associated with the MBM source of the previous three cases. There is no evidence of a definitive link to Renderer A.

Regardless of the source of contamination, it does appear that all four cases of BSE in North American cattle resulted from the consumption of feed contaminated with infected bovine tissues during the early part of the animal's life (when they are most susceptible) and either prior to implementation of the Canadian feed ban or soon after its implementation.

4 General Summary of Canada's response to BSE

4.1 Importation

There were 182 cattle imported into Canada from the UK between 1982 and 1990, at which point Canada banned all further cattle imports from the UK. At that time, the importation ban was the primary control measure initiated by CFIA to prevent the introduction of BSE into Canada. Following the detection of BSE in a UK-born Canadian cow in 1993, all remaining UK imports were traced. Those that were found alive were slaughtered and incinerated or returned to the country of origin. Of those that were not found alive, it was determined that 68 had potentially gone into the rendering stream after being slaughtered (59) or dying on farm (nine).

Additionally, 405 cattle were imported from mainland European countries between 1979 and 1985 that were not known to contain BSE at the time but in which it was subsequently detected. According to the OIE Code, CFIA considered these imports to be of negligible risk.

Meat and bone meal of ruminant origin for livestock feed has not been imported from the UK or any other country subsequently affected by BSE since 1978. All MBM for livestock feed has come from Australia, New Zealand, or the United States since that time; the vast majority has been from the United States.

In 1991 the importation of beef products from European countries not free of BSE was banned, and in 1994 a ban was imposed on the importation of live cattle from countries where BSE had been diagnosed in native cattle.

In late 1996, an evaluation process was implemented that required exporting countries to be recognized as BSE-free by Canada (using OIE standards) in order to send live cattle to Canada. In late 1998, this policy was amended to include live sheep and goats. Additionally, bovine embryos were allowed to be imported from BSE-infected countries (other than the UK) with restrictions; bovine specified risk materials, livestock feeds containing mammalian protein, pet food, and mechanically-separated meat were not allowed from BSE-infected countries; bovine-origin meat, cell lines, and veterinary biologics were allowed with conditions; and sheep and goat embryos were banned from countries not recognized as free from BSE.

In 2000 the import ban was extended to include all animal protein products, including blood meal and feather meal, from any species from any country that Canada does not recognize as free of BSE.

4.2 Animal feed exclusions

Canada implemented a ruminant-to-ruminant feed ban on August 4, 1997. The feed ban prohibits the use of animal proteins of ruminant origin (excluding milk, blood, gelatin, and fat) in feed for ruminants. All products containing “prohibited” ruminant material are required to be labelled with the statement: “do not feed to cattle, sheep, deer, or other ruminants.” Currently, enforcement of the feed ban is the primary control measure utilized by CFIA to eliminate BSE within the cattle population.

Renderers and feed manufacturers are required to take steps to avoid cross contamination by providing clear labelling, storage, and dedicated equipment for processing prohibited materials, or thoroughly cleaning non-dedicated equipment. If both ruminants and non-ruminants are fed on the same farm it is required that accurate records and invoices are retained for two years.

The Canadian feed ban was timed to coincide with implementation of the United States’ feed ban, and contains similar provisions with the exception that the United States permits feeding of poultry litter and plate waste whereas Canada does not.

It was anticipated by CFIA feed officials that there would be a phase-in period following implementation of the rule. It was estimated that it would take approximately 30 days for feed mills and retailers to use up and distribute “old” product (i.e., unlabeled feed intended for ruminants and produced using ruminant MBM), 60 days to add the caution statement to labels, invoices and production records, and 60 days for farms to use up their stores of “old” product. However, there have been recent articles in the popular press and findings through feed tracing

associated with the most recent Canadian BSE case that have suggested that feed produced prior to implementation of the feed ban may have been available at feed stores and on-farm several months longer than anticipated (CFIA personal communication January 2005). Therefore it is considered that the 'practical implementation period' may have been up to 6 months after the date of the ban.

Following implementation of the ban in 1997, almost all rendering plants and feed mills were inspected between August 4, 1997 and March 31, 1998 to determine compliance with the new ban. The only exceptions to inspection were those facilities that processed only fish meal and a few other minor exemptions. None of the inspections found evidence of prohibited material still being incorporated into ruminant feed formulations.

CFIA has enforced the feed ban by conducting regular inspections at four points in the animal food and production chain. These include annual inspections at rendering plants (the feed ban requires rendering plants to have a permit from CFIA in order to operate and must be found in full compliance with regulatory requirements in order to have their permit renewed), inspections of commercial feed mills every three years initially with attempts to inspect these more frequently, inspections of 100 retail feed stores per year (there are approximately 1,300 total of these), and inspections of farms wherever feeds are made and/or ruminants are fed.

The CFIA compiles and reviews inspection findings on a regular basis. In cases where 100 percent compliance is not demonstrated during a specific inspection cycle at the time of reporting (usually on a fiscal year basis), the CFIA conducts follow-up inspection activities into the next inspection cycle in order to verify that any outstanding non-compliance has been resolved. The CFIA policy requires significant non-compliance issues to be followed-up immediately.

From August of 1997 to the end of 1998, the focus of compliance inspections was to promote education and awareness about the feed ban, begin verifying implementation of new manufacturing practices and controls, and develop a more robust inspection program. Full compliance with the feed ban requirements has been necessary in order for rendering facility operators to obtain new permits each year.

By the end of 1998, all commercial feed mills in Canada had been inspected at least once specifically with respect to feed ban compliance to ensure they were implementing the necessary procedures to comply with the new regulations. In calendar year 1999, 65 feed mill facilities were inspected and all achieved compliance during that review period.

On December 10, 2004, Canada proposed additional animal feed restrictions which would require removal of all bovine-specified risk materials from the animal feed chain in order to diminish the effects of potential cross-contamination of ruminant animal feeds that could occur as feed is produced and distributed, as well as any inappropriate on-farm use. Other measures included the prohibition of condemned and dead stock cattle and other ruminants used to make animal food (including pet food), and in fertilizers, including additional measures providing for identification and segregation of the prohibited materials. These proposed regulations were posted on the *Canada Gazette I* website for public review and comment.

4.3 Surveillance

Testing for BSE began in January 1991 in Canada, with the initiation of a program to test rabies-negative mature cattle. A national surveillance program followed in 1992, targeting mature cattle with central nervous system signs from abattoirs, and provincial and university veterinary pathology labs. In 1997, the program was enhanced to increase the number of samples collected at federally-inspected abattoirs. In 2001, minimum targets were assigned within selected federal abattoirs based on provincial cattle populations. In 2002, cattle were also collected from within the 4-D (dead, downer, distressed, and diseased) population.

Since 1993, Canada has met or exceeded the minimum level of annual sampling required by OIE in order to detect one positive case per one million animals for all years except 1995.

In January 2004 Canada announced a five-year surveillance plan that would enhance its BSE testing to at least 8,000 cattle during the first year and 30,000 cattle each year for years two to five. Canada appears able to easily reach such goals since 23,451 specimens had been collected during 2004 alone; 52 percent were from Alberta. It is believed that at least 40 percent of these samples (possibly up to 50 percent), annually, will arise from animals reported by producers and private veterinarians.

The outcome of Canada's epidemiological investigation greatly benefited from the ability to effectively identify and trace animals to and from their birth herds due to the identification system. In addition, a large portion of the animals that were traced were purebred and dairy animals which had registry, dairy, or farm production records that provided identification information.

5 BSE Epidemiology of Alberta, Canada

5.1 Background epidemiology of the Alberta area

Alberta is the largest cattle producing area of Canada with primarily cow/calf operations in the north central area around Edmonton and a heavier concentration of fed cattle in the southern Calgary area. The cow/calf herds generally reside on open range land and, with the exception of purebred herds, receive minimal supplements except for range blocks. On the other hand, calves in purebred herds are more likely to receive protein-containing supplements in creep feeds and starter rations.

The primary source of MBM in the Edmonton area in the pre-feed ban part of the 1990s was the main rendering plant in the area, Renderer A. In 1997, this facility was utilizing low-temperature vacuum processing which does not appear to decrease the infectivity of the BSE agent. Numerous feed mills and distributors in the local area purchased and processed feed that could have contained MBM from Renderer A.

5.2 Risk profile of a BSE case

The Canadian investigation of the recent four BSE cases defined several risk factors for an animal likely to have BSE.

1) Importation from the United Kingdom.

The 182 animals imported to Canada prior to the import controls of the early 1990s were traced in 1993. Many of this cohort had died or been slaughtered and the remainder were destroyed upon tracing. The BSE status of the origin herds was determined through UK records and risk was assigned to the animals based on origin as well as age and demographic factors. The final assessment indicated that 52 animals (the largest group among the UK imports), including three of the highest risk cattle, were shipped to Alberta. One of the highest risk Alberta trace cattle tested positive for BSE in 1993 while the other two had already died and potentially entered the feed supply. The UK birth herd of the 1993 Alberta case was found to have had two additional BSE positive animals. The localization of the UK animals was considered to be a risk factor for the local area around the rendering plants where they were processed.

2) Purebred and dairy animals.

Livestock feeding practices in western Canada, before the feed ban, were far more likely to provide MBM containing supplements to purebred and dairy calves in the form of creep feed and other supplements. Range calves on the other hand were generally grade animals and not provided the more expensive feed products. This risk factor was further verified by the four current cases which were identified as being purebred or dairy animals.

3) Age and geographic area.

The CFIA predicted that their first case was representative of an epidemic already in decline based on the time line of UK cases after implementation of their feed ban. The CFIA further predicted that additional cases would most likely occur in approximately the same location and age group which proved to be the scenario that is unfolding.

4) Expression of clinical signs.

The Canadian surveillance targeted higher risk animals based on factors such as central nervous system signs, “downers,” dead on farm, and so forth in a similar manner to the United States.

5.3 Active and intensive surveillance in Alberta

The provincial government provided additional funding to increase the payment for BSE samples to \$225 each. This was combined with widespread public outreach, educational campaigns, and a depressed cattle market that resulted in an enthusiastic response from veterinarians and livestock producers. Alberta’s requisite number of samples based on the Canadian surveillance plan of 2004 was 2,780 samples but the Province exceeded that with 12,230 tests for the calendar year 2004.

5.4 Cluster concept

During the epidemiological investigations of feed sources, CFIA made two interesting observations. First was that renderers, feed mills, and farmers were grouped by geographic and economic forces into clusters. The clusters are influenced by the costs involved in transport of products and raw materials over large distances. In Canada as well as the United States, the expense of moving dead animals over long distances is impractical and results in carcasses being processed at the nearest rendering plant. In Canada, on average, one renderer supplies MBM to approximately 20 feed mills who then service about 4,000 producers in a geographic area. These localized areas were termed “catchment areas” and centered on the renderer who not only provided MBM but also received raw material (carcasses) from the same area. This localized cycle of “carcass→renderer→MBM→feed→carcass” provides an epidemiological argument that a single source of exposure should result in nearly all cases having birth herds in the local catchment area.

After a substantial amount of field tracing, the CFIA mapped the birth herds of the recent four cases to reflect an Edmonton cluster that seemed to center on the local renderer, Renderer A. They hypothesized that the cluster effect impeded the geographic distribution of BSE and limited its distribution (the fourth case, confirmed on January 11, 2005, was slightly outside this catchment area).

6 Theories regarding the origin and development of BSE in Canada

A 1994 internal risk assessment completed by CFIA determined that the likelihood of BSE arising under Canadian conditions was extremely low, given the differences in key risk factors between Canada and the UK. The occurrence of BSE in Canada would therefore be dependent upon the importation of infected animals and contaminated livestock products and the subsequent amplification of infectivity through the livestock feeds system prior to the specified risk material and ruminant feed ban.

A separate risk assessment initiated by the Government of Canada in 2002¹ discussed BSE risk factors identified in the OIE code, including the potential for the introduction and recycling of BSE agent through the consumption of MBM of ruminant origin and the importation of cattle.

The 2002 assessment determined that:

1. Meat and bone meal for livestock feed has not been imported from the United Kingdom or any other countries subsequently affected by BSE since 1978.
2. A ban on the feeding of ruminant-derived MBM to ruminants has been in place since 1997. The level of compliance with the ban has been high as verified by routine inspections of both renderers and feed mills.
3. A small number of potentially-infected cattle imported from the United Kingdom in the 1980s may have entered the animal feed system prior to 1993.

This third possibility, combined with the appearance of the small cluster of cases of BSE in northern Alberta, has led Canadian investigators to propose a scenario that explains the origin of

¹ Risk Assessment on Bovine Spongiform Encephalopathy in Cattle in Canada; Animal, Plant and Food Risk Network (APFRAN), December 2002.

BSE in Canada and to also propose a model for the expression of these ‘third generation’ cases in Alberta.

The Canadian proposal of a scenario for BSE occurrence in North America is based on surveillance, origin assessments, and other factors as discussed below.

6.1 Geographic distribution of cattle in Canada

The cattle population in Canada is concentrated in the province of Alberta (see Figure 1, page 3).

6.2 Origin Assessments

- Of the 68 UK imported cattle that were potentially rendered (details on page 13), the majority (58 or 85.3 percent) came from farms in the UK that have never recorded a case of BSE, and 10 were sourced from farms that had had at least one case of BSE diagnosed in cattle born on the farm. Of those 10, two originated from an infected birth cohort; these cattle were herdmates of the imported cow that was diagnosed with BSE in Canada in 1993. Both of these animals were slaughtered prior to the diagnosis of the imported case.
- The farm of origin was not identified for one animal and therefore its status is unknown, but is assumed for the purposes of this report to have been infected with BSE.
- The status of the farms of origin for the 70 cattle imported from the UK and Ireland prior to 1982 (1979 to 1981) was not determined because the animals were not considered a BSE risk at the time.

6.3 Rendering

It has been reported that in Alberta, prior to 2003, virtually all ruminant-derived MBM had been processed in a “low temperature” or vacuum rendering system. Such a system would potentially enhance the risk of BSE amplification as it does not inactivate the infectious agent.

6.4 Feed ban implementation and implications of feeding practices

- A mammalian-to-ruminant feed ban (with the exception of pure porcine and equine meal; and milk, blood, gelatin, and rendered animal fat from all species) was introduced in 1997. Prior to this ban, rendering and feeding practices would have allowed BSE to cycle through cattle.
- The feed ban would have resulted in a dramatic reduction in exposure, significantly reducing further spread and amplification of the BSE agent. Given the impact of the feed ban, its effective implementation, likely age of infection, and the incubation period of BSE, the number of BSE cases would be expected to peak approximately six years later, which would be in 2003.
- The potential number of BSE cases remaining in the cattle population in 2003 would be extremely small as only a few animals are likely to have become infected prior to the feed ban and the majority of these would have already been culled, slaughtered or died.

6.5 Clustering hypothesis

In addition to catchment areas, CFIA presented a concept that described broader areas of increased BSE risk. This concept was based on numerous Canadian databases that contained records of animal movement in the 1980s and 1990s and indicated that movement of potentially

BSE-contaminated feed and animals was primarily north and south rather than east and west. The data indicated the feed and animal movement in eastern Canada (border of Ontario and points east) had little intersection to the western area; however, the western area could include parts of the United States Pacific Northwest.

6.6 Generations of exposure

The history of BSE in Canada has been postulated by the CFIA to be the result of two indigenous generations of exposure. The first introduction of BSE would have been cattle imported from the early part of the UK epidemic (approximately 1986 to 1988). These animals would have reached a likely age to express the disease (three to six years) in the early 1990s during a period of lower surveillance testing. They would have then entered the rendering process and subsequently be re-fed back to ruminants. This second generation would have then been old enough to express the disease at about the time of the feed ban in 1997. The current third generation cases would have been infected by MBM from the second generation of infectivity in 1997 and would be expected to express the disease in 2002 to 2005.

6.7 Epidemiological implications to the United States

The concept of broader feed and animal movement areas presented by CFIA could be considered to implicate the Pacific Northwest of the United States as being of elevated risk due to Canadian BSE exposure. CFIA expanded on the previously described catchment concept to include a larger geographic movement area based on the flow of materials and animals from the catchment areas. The majority of MBM produced by the local renderer was consumed within the catchment area but a small portion of select products as well as live animals moved within a larger area which included the northwestern part of the United States. Because very little product moved from Western to Eastern Canada, the eastern part of Canada was considered, by CFIA, to be a separate BSE movement area.

In addition, the Canadian feed-trace investigations identified two specific shipments of MBM from Renderer A, processed at the end of February 1997, that went to a distributor in the United States. These shipments, which were 80,631 kg on February 6, and 72,404 kg on February 27, 1997, coincided with the suspect MBM that the first three BSE-positive cases had in common. Analysts at APHIS, VS, and the Centers for Epidemiology and Animal Health (CEAH) have used the Import Tracking System database to locate the two shipments and to confirm the identity of the purchaser of the product. Further tracing of this material revealed that the distributor directly exported protein commodities to Asia or supplied product for local incorporation into poultry meal. The CEAH has also retrieved a list of other imported product (flour meal, pellet meat, meat offal inedible, and greave) from Renderer A through Sumas, Washington during April to August 1996.

Based on available data supplied by CFIA, which is somewhat limited, during the time period 1996 to May 2003, at least 10,924 breeding cattle were exported from four cities in Alberta (Battleford, Edmonton, Red Deer, and Wetaskiwin) to the United States. However, the age, breed, or the destination of the animals is unknown. These same Alberta locations also exported 3,813 nonfeeders for slaughter during the same time period.

7 Conclusions related to the objectives of the mission

7.1 Point source of the infection

The geographic and temporal proximity of the Canadian BSE cases are suggestive of a common exposure although definitive proof of a single source of infection may likely never be found. The first three cases of BSE (confirmed on May 20, 2003; December 25, 2003; and January 2, 2005, respectively) all have in common a source of MBM from Renderer A that was distributed to local feed mills on February 28, 1997. Such MBM would have been produced prior to the implementation of the Canadian feed ban in 1997 when inclusion of ruminant protein into MBM was legal. This MBM source similarity is extremely difficult to dismiss or ignore. However, other feed mills and manufacturers may also have contributed various unreported products to the birth herds of the confirmed cases. The fourth case originated in close proximity to this geographic area and was exposed at approximately the same time (date of birth March 1998) but the feed links are more tenuous. However, links to Renderer A have not been definitively ruled out.

Geographical clustering is very evident in the Canadian outbreak. Although approximately 12,000 BSE samples were tested from Alberta and nearly 24,000 tested in all of Canada during 2004, there have been no confirmed cases of BSE found outside of a relatively small area (~450 km in diameter or 279.6 miles) of north central Alberta. This area also includes the location of the UK BSE case that was identified in 1993.

Temporal clustering also suggests a localized exposure. In all four North American cases the cattle were born during a fairly narrow time period: October 5, 1996 to March 21, 1998. If BSE were randomly distributed, it would be an unusual coincidence that all of the animals were all born within a year or two and were approximately six-to-eight years of age when diagnosed.

Based on the current epidemiological investigation information provided by CFIA, the USDA team cannot definitively state that a point source of contaminated feed resulted in the four cases since many factors contribute to both the apparent and true association. However, based on the relatively small geographical location, the temporal association, and apparent clustering of all four North American BSE cases, this information strongly suggests a localized exposure.

7.2 Investigation into other cattle of concern

As part of the Canadian investigations of these four cattle of Canadian origin, 851 animals were initially identified as known or possible birth cohorts (animals born within one year before or after each case). These cattle were the animals that would be expected to have been exposed at a young age to the source of infection for the index cases (247 for case #1, 114 for case #2, 141 for case #3, and 349 for case #4). Additionally, eight animals were identified as progeny born within two years of the death of the case (a minor but potential route of infection of BSE). Of these 859 total animals, six were eliminated as part of the birth cohort; eight progeny were either dead or euthanized; 11 animals were considered untraceable; four animals are still alive and under observation by CFIA; 801 are confirmed dead or slaughtered; and 29 were believed to have entered the United States. Of the cattle that entered the United States, 18 (62.1 percent) were definitively identified and either depopulated or confirmed slaughtered.

Based on the temporal and geographic distribution of the birth herds of the recent BSE cases of Canadian origin, plus risk factors identified by Canada, the highest risk category of animals within the United States due to this occurrence would include, but not be limited to, purebred cattle born between 1996 and 1998 (currently between six and nine years of age, approximately) from the Provinces of either Alberta or Saskatchewan.

Although the exact number of animals meeting the risk factors described above is unavailable, initial estimates from the APHIS-VS Import Tracking System (ITS) suggest that roughly 40,000 breeding cattle came into the United States from the Alberta region between 1994 and 1998 and approximately 18,000 of those during 1997 to 1998. These imports could generally represent the high risk animals that the Canadians have profiled. Normal aging and attrition would be expected to have removed the majority of these cattle from the population. Based on an age distribution model for United States cattle, less than three percent would be expected to remain in the United States herd at this time $[(0.03)(40,000) = 1,200$ alive from 1994 to 1998 and $(0.03)(18,000) = 540$ alive from 1997 to 1998].

The initial destination in the United States of the breeding cattle can be determined from the ITS; however, many of the animals were shipped to dealers that re-shipped them to other addresses. If an assumption can be made that most cattle remained near the initial destination, the data could support CFIA's hypothesis that Canada's western movement area includes the northwestern region of the United States, particularly Washington, Idaho, and Montana.

7.3 Feed evaluation

The expense of moving MBM, a bulky, low-cost product, tends to localize its distribution. In addition, financial factors may determine movement of product. Based on the value of the Canadian dollar versus the United States dollar, the exportation of feed from Canada to the United States would be minimal when the value of feed and MBM was higher in Canada than in the United States. During the time period 1994 to 2001, the value of a ton of MBM in Canada ranged from \$267.7 to \$431.25 CDN while the cost for the same amount of product in the United States ranged from \$140 to \$270 per ton. Therefore, due to the large cost differential, MBM would have been more likely imported into Canada from the United States than exported from Canada.

Renderer A, the renderer associated with three of the four cases, distributed MBM product primarily to feed mills and farms within its local distribution area. However, two feed mills located outside of this local distribution area also received MBM from Renderer A during the same time period that the index cases were believed to have been exposed (i.e., 1996 to 1997). One mill was located in British Columbia near the United States border and the other was located in the United States Pacific Northwest.

A search of the Plant Protection & Quarantine (PPQ) Automated Targeting System for the years 1996 and 1997 indicated that seven shipments of MBM from Renderer A entered the United States. Five separate shipments of MBM, totalling 742,096 kg, were delivered to one distributor between April and August 1996. This same system also documented the importation of two additional shipments of MBM, totalling 153,035 kg, to the same distributor in February and March 1997.

Although the 1996 shipments have not been traced further, tracing of the material shipped in early 1997, the time period most closely related to potential feed exposures for three of the four BSE cases, revealed that the distributor directly exported protein commodities to Asia or supplied product for local incorporation into poultry meal. In 1999, the company expanded to include a pet food manufacturing company as a source of product. This distributor has not produced any product intended for cattle consumption.

Additional follow up with this distributor in early 2005, indicated that in 1997 almost all (99 percent) MBM product went to the export market, especially if it came through a Washington State port by rail. Only 1 percent of product was used to provide poultry producers in the Pacific Northwest States. Therefore, it is extremely unlikely that any MBM imported from Renderer A to this United States distributor in early 1997 was incorporated into feed intended for cattle in the United States.