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Canada's Assessment of the North American BSE Cases Diagnosed From 2003-2005 (Part II)

Introduction

After the first indigenous Canadian case of bovine spongiform encephalopathy (BSE) was confirmed in May 2003, an analysis of the information available at that time was issued in a report entitled, "Narrative Background to Canada's Assessment of and Response to the BSE Occurrence in Alberta." That report, now referred to as Part I, was issued in July 2003. With the additional cases of BSE in North America detected since May 2003 there is an opportunity to build upon the analysis from Part I with this new information and provide an updated examination of the current BSE situation based on the understanding of the disease to date.

There were five BSE cases diagnosed in North America from May 2003 to June 2005. Three of these were found in Western Canada, the fourth was a Canadian-born animal resident in the State of Washington (U.S.), and the fifth was an American animal born and raised in the State of Texas. Until 2003, there were no BSE-related restrictions on the trade of live cattle or their products between Canada and the U.S. within the extensively integrated North American cattle industry. This assessment examines elements common to these five BSE cases as a contribution to current theories about the natural evolution of the disease in North America.

This report is divided into several sections. First, an overview of the science around BSE is provided, followed by the history of BSE in Canada and the steps that have been taken to prevent its spread while continuing to protect human health. Next, there is an explanation of the current theories related to the development of BSE in North America and a summary of the epidemiological investigations of the four North American BSE cases diagnosed between May 2003 and January 2005. The investigation of the fifth case, confirmed in a Texas-born animal in June 2005, was completed by the State of Texas and the Unites States Department of Agriculture (USDA) and the related epidemiological report was issued on August 30, 2005.

Finally, there is a summary of the conclusions that can be drawn from the potential linkages among these five BSE cases. It is also explained how these epidemiological deductions and the surveillance data analysis completed to date support the prediction that the level of BSE in North America is extremely low and declining.

The Science of BSE

BSE is a fatal disease that affects the nervous system of infected cattle. It was originally identified in the United Kingdom (U.K.) in 1986 and is characterized by the sponge-like qualities that occur within the brains of affected cattle. It belongs to a group of diseases called transmissible spongiform encephalopathies (TSEs), which also includes a rare human disease called Creutzfeldt-Jacob Disease (CJD). A particular type of CJD, called variant CJD (vCJD), is accepted as being caused by the same agent that causes BSE in

cattle. Animals affected with BSE may show a number of different symptoms including nervous or aggressive behaviour, abnormal posture, lack of co-ordination or difficulty in rising from a lying position, decreased milk production and weight loss despite an increased appetite. These symptoms may last for a period up to six months before the animal dies. In the early stages of the disease, the behavioural changes and signs may be extremely subtle and obvious only to those familiar with the animal.

Since its original diagnosis in the U.K., BSE has been found in 23 countries worldwide and this number is expected to increase in the coming years. In addition, three countries have reported only imported cases of BSE. As of October 2005, approximately 189,650 cases of BSE have been reported internationally, with over 184,250 of these in the U.K. The annual number of U.K. cases peaked in 1992 at 37,280 (an average of 102 cases per day) and had declined to 343 in calendar year 2004. This reduction has been attributed to the implementation of specific safeguards in the U.K. and is evidence that the disease can be eradicated over time if the required control measures are taken.

Susceptible cattle are exposed to BSE when they consume feed that includes specified risk material (SRM) from other infected animals. SRM are tissues that, in BSE-infected cattle, contain the agent that may transmit the disease. SRM include the brain, trigeminal ganglia (nerves attached to the brain), eyes, spinal cord, dorsal root ganglia (nerves attached to the spinal cord), tonsils and distal ileum (portion of the small intestine). Although SRM would not have been included in all cattle feed prior to the implementation of feed bans in affected countries, they could have been added to certain products such as protein supplements and dairy rations. Since these products were more costly than normal feed, they would generally have been given to purebreds and other high-value animals. The level and use of such products would also be influenced by the availability of other protein sources.

Cattle are likely to vary in their susceptibility to the agent that causes BSE. It appears that not all cattle exposed to contaminated feed will develop infectivity. In addition, research and field experience in the United Kingdom have shown that the majority of animals become infected early in life, usually within their first year. The average incubation period for the disease is four to five years, but this can vary depending on the amount of infectivity the animal was exposed to in its early stages of life. Oral ingestion studies conducted in Europe have demonstrated that a higher dose of infected material could reduce the incubation period. In contrast, an animal exposed to a very low level of infected material could reach more than eight years of age before the disease develops. For example, in a recent ongoing study, one of 15 animals that consumed 0.001g of infected material became infected with BSE at 69 months of age. In the same study, three out of five animals that consumed 1 gram of infected material developed the disease and the youngest of these was 59 months. This relationship between level of exposure and length of incubation is a very important element in interpreting the information associated with the detection of BSE in a cattle population.

There is currently no live animal test for BSE. The disease agent progressively accumulates in infected animals during the prolonged incubation period, reaching highest

levels in the brain. As a result, BSE tests are performed on the brains of suspected animals after their death. Studies associated with the development of currently applied test methods on animals with the same exposure factors have found that tests are able to diagnose BSE about three months before clinical signs of the disease begin to appear. Animals may begin to exhibit signs of BSE up to six months before their death. However, these signs may be too subtle for anyone other than the owner to detect, especially in the early stages.

In 1996, a link was made by public health officials in Great Britain between the consumption of BSE-infected SRM in beef products and the expression of the newly identified vCJD in humans. Up until this time, BSE was considered to only affect animals. As a result, SRM continued to be included in some processed foods for human consumption, such as hotdogs, sausages and deli-style products. Slaughter practices at the time would not have included special care procedures to avoid cross-contamination with SRM of other beef products, such as muscle tissues, that are not known to carry the BSE agent.

Knowledge of the disease in 1996 was very limited. Since that time, the understanding of BSE and the identification and implementation of effective safeguards to prevent it have increased. Also, information available to date indicates that humans are likely to be much less susceptible to the disease than cattle. As a result, original projections by public health officials in Great Britain of worldwide vCJD cases that were in the range of ten million have been significantly reduced. In 2003, the same public health authorities estimated that between 40 and 100 additional international cases of vCJD associated with food consumption may develop over the next 70 years.

Canada and BSE

The current hypothesis of the Canadian Food Inspection Agency (CFIA) is that BSE entered North America through cattle imported from the U.K. during the 1980s. Based on the average incubation periods of the first animals diagnosed with BSE in the U.K, it was later determined that these cattle had most likely become infected with the disease during or following 1982.

There were 182 U.K. cattle imported directly into Canada from 1982 to 1990. American records indicate that more than 300 were imported into the United States during the same interval. The last shipment of 14 to Canada, still in quarantine in 1990 when the import ban was announced, was not released. Therefore, 168 animals from the U.K. actually joined the Canadian cattle herd through direct importation during this period and 1989 was effectively the last year that they entered in this manner. Following their arrival in Canada and the United States, the U.K. imports became members of the respective national cattle herds, which qualified them for exchange between the two countries until they agreed to no longer certify these cattle for trans-border movement after the Alberta case of BSE was diagnosed in 1993.

As a result, one or more of the importations to Canada and the United States may have introduced the first generation of BSE to North America. Given the potentially long incubation period of BSE, which was not known at that time, some of these U.K. cattle could have been infected with BSE despite appearing healthy when entering the continent. Nevertheless, all U.K. animals directly imported to Canada after 1987 would have been certified by the British government as originating from farms that had not reported a case of BSE.

Since the 1980s it had been prohibited to import from the U.K. many of the products that had the potential to spread BSE in Canada. These restrictions had been put in place to protect Canada from other foreign diseases, such as foot-and-mouth disease. While not directed at BSE, these measures reduced the probability of BSE entry into Canada. In 1990, BSE was made a reportable disease in Canada and a ban was implemented on live cattle imports from the U.K. A monitoring system was also initiated for the remaining U.K. animals in Canada that had been imported since 1982. In 1991, beef products from all other European countries not free of BSE were officially banned. By virtue of their acknowledged parallel BSE status, cattle and their products moved freely between Canada and the United States during the same interval.

Canada introduced passive surveillance for the disease in 1991 when a program to test rabies-negative mature cattle for BSE was initiated. In 1992, Canada began actively monitoring the national cattle herd for animals with clinical signs consistent with BSE to determine if the disease had emerged. Under this program, Canada steadily increased its surveillance levels for the disease in accordance with the guidelines of the World Organisation for Animal Health (OIE). Given the size of its cattle population, Canada was required to test a minimum of 300 animals per year that demonstrated clinical signs consistent with BSE in order to meet the recommendations contained in the OIE surveillance guidelines. Since 1993, Canada has consistently met and exceeded its OIE surveillance requirements for all years except 1995 when 90% of the annual target was met.

In 1993, one of the monitored U.K. animals tested positive for BSE in Alberta and was diverted from the human food and animal feed systems. As a result, the Government of Canada decided to depopulate the remaining U.K. cattle in Canada. Of the 168 imported U.K. animals that had entered the national cattle herd, 68 were no longer living due to slaughter (59) and death by natural causes (9). It is now suspected by Canadian authorities that the carcasses or inedible parts of some of these 68 animals entered the rendering system and may have been included in Canadian cattle feed. Figure 1 illustrates the provinces where these 68 imported cattle were located at the time they died or were sent to slaughter.



Figure 1: Distribution of the 68 Imported U.K. Cattle No Longer Living in 1993

Of the 68 cattle, 58 were traced to U.K. farms that had never reported a case of BSE. Of the other 10 animals, nine had originated from U.K. farms where at least one case of BSE had been diagnosed in cattle born on the farm (Figure 1). These diagnoses were made by U.K. officials at some point after the animals had been exported to Canada. Two of the nine animals were identified as originating from the U.K. birth cohort of the 1993 case in Alberta. Typically, the birth cohort consists of those animals born in the same herd within the 12 months preceding and the 12 months following the birth date of an affected animal. These animals are considered by international standards to be of equivalent risk for contracting BSE because they may have been exposed to the same contaminated feed as the affected cow. Both birth cohort animals had been slaughtered before the 1993 case was diagnosed. The farm of origin of the tenth animal could not be identified within the BSE registry of the U.K. government. As a conservative measure, it was also considered to be of high risk.

The U.K. animals that were still alive in Canada in 1993 were placed under quarantine according to the *Health of Animals Act*, until they were either repatriated to the U.K. or euthanized and tested for BSE. Although all of the tested U.K. animals were found to be negative for BSE, for future scientific analysis, brain tissues from these animals were placed into reserve and the balance of the animals was incinerated. These brain tissues were re-tested for BSE with more modern testing procedures in 2003 and again received negative results. All Canadian herdmates of the 1993 case and her offspring were also euthanized, tested and incinerated. All animals were found to be negative for the disease.

In 1997, Canada implemented two additional safeguards related to BSE. The first was a decision to only accept cattle and cattle products from countries that Canada had assessed to be free of BSE through the application of a common assessment protocol developed jointly with the U.S. and Mexico. The second measure was a ruminant animal feed ban, which was implemented in August 1997 under the Health of Animals Regulations. The ban applied to the production of feed containing prohibited materials for all ruminant (cud-chewing) animals, such as cattle, sheep, goats, deer, elk and bison. The prohibited material comprises proteins derived from ruminant animals, because these materials can potentially contain SRM. Many of these proteins had traditionally been marketed in the form of meat and bone meal (MBM). Since salvaged pet food, plate waste and poultry litter can contain prohibited material, these were also included in the ban. Milk, blood, gelatin, rendered animal fats or their products were not prohibited because scientific evidence had not demonstrated that these products carried infective levels of the BSE agent, and this continues to be the case to date. The feed ban requirements exceeded international guidelines in the OIE's Terrestrial Animal Health Code for a country that had not experienced a domestic case of BSE, which was the case for Canada at the time.

Figure 2 illustrates how a feed ban can effectively control and eventually eradicate BSE. The solid line indicates a situation where a feed ban is never implemented and indicates that the level of BSE continues to rise. The dotted upper curve demonstrates that if a feed ban is implemented after the first domestic case of BSE has been found, it is still effective in controlling the disease, but the number of BSE cases will be higher and it will take longer to eradicate the disease. This was the situation in the U.K. In contrast, the dotted lower curve would represent the situation in North America where initial BSE exposure was limited to just one or a few animals that may have contaminated the animal feed system during the late 1980s or early 1990s, the subsequent rate of amplification and spread would have been extremely slow due to the prolonged incubation period of BSE, and where feed bans were implemented before the first domestic case of the disease was found. In this situation, levels are low and the disease is eradicated in a shorter period of time because the amount of BSE contamination in the feed system is lower. The heights of the curves are not indicative of the relative levels of infection among the nations portrayed and are for illustrative purposes only.



Figure 2: Feed Ban Effectiveness on BSE Levels¹

In 2001, the Canadian Cattle Identification Program (CCIP) was established through the close collaboration of the CFIA and the Canadian Cattle Identification Agency (CCIA). This program assists the CFIA in tracing and eliminating disease sources. The program was launched in two phases. Effective January 1, 2001, cattle leaving the herds in which they were born were required to wear an approved ear tag. Then, on July 1, 2001, the program was extended to include cattle leaving all premises.

Following the 1993 case, there were no further cases of BSE in Canada until May 2003 (Case 1) when the first case of BSE in a Canadian-born cow was diagnosed. This meant that the animal had to have been infected with the disease in Canada. Since that time, there have been two more Canadian cases of BSE (Case 2 and Case 3) and one case in a Canadian-born U.S. cow in December 2003.

A number of measures were already in place that would have reduced the possibility of BSE getting into the human food chain. First, the majority of cattle slaughtered for human consumption in Canada were, and continue to be, young animals that are less than two years of age. Based on internationally accepted scientific evidence, infective levels of the disease have not been demonstrated to develop in young cattle. Also, cattle exhibiting neurological symptoms suggestive of BSE during pre-mortem inspections at slaughterhouses would have been diverted from the food system.

¹ Based on diagram in presentation by Dr. William D. Hueston, University of Minnesota. *The Science of Bovine Spongiform Encephalopathy: What We Know Today* (2005)

As a final safeguard, in July 2003 it became a requirement under the *Health of Animals Regulations* and the *Food and Drug Regulations* to remove SRM from all cattle slaughtered for human consumption. Removing these tissues from the human food system is internationally recognized as the most effective way to protect human health from BSE.

Conducted in accordance with the guidelines of the World Organization for Animal Health (OIE) since 1992, Canada's targeted BSE surveillance program, focused on the highest risk population, and achieved its intended outcome by detecting BSE in the May 2003 case. Guided by the same principles, upon confirmation of BSE in this domestically-born animal, Canada increased its surveillance capacity in order to assess the effectiveness of the suite of mitigating measures that had been implemented. Surveillance testing focused on animals over 30 months of age that were dead, down, diseased or dying (referred to as the 4-Ds). The program increased its surveillance goals to a minimum of 8,000 samples in the 2004 calendar year and a minimum of 30,000 samples in subsequent years. This target sample number will be continuously reviewed and analyzed based on results obtained to determine if any changes are required.

To assist the CFIA in achieving the annual BSE surveillance numbers, in December 2004 the CFIA launched the National BSE Surveillance Reimbursement Program, whereby producers and veterinarians became eligible to receive payments for providing services to the CFIA that result in the submission of eligible samples. These federal payments can assist producers in covering a portion of the veterinary examination fees and carcass disposal costs associated with obtaining surveillance samples.

The combination of the reimbursement program, the availability of compensation for animals ordered destroyed, a concentrated awareness and education campaign and a high level of producer commitment resulted in the 2004 surveillance goal of 8,000 samples being exceeded with 23,550 samples tested. In 2005, the target of 30,000 samples was met and surpassed in the first six months of the year.

The most recent addition to Canada's BSE safeguards came into effect in June 2005 when it became illegal to load or transport downer cattle in Canada. Although this was implemented for humane reasons, it further reduces the possibility of an animal infected with BSE entering a slaughter facility in Canada.

The North American Cattle Cycle

The Canada-U.S. border divided the Canadian and American segments of the North American cattle herd prior to May 2003. However, as described earlier, this mostly administrative separation permitted a free flow of cattle imports from the U.K. between the two countries until 1993 as well as indigenous cattle and their products until 2003. During the interval from 1982-1989 when 168 animals from the U.K. entered the Canadian herd, the U.S had imported over 300 cattle from the same area. As a result, it was considered by officials in both countries and by the international community more broadly, that the North American neighbours were of equivalent risk for BSE. Therefore,

they worked together in the design of similar and integrated systems intended to control the potential threat of the disease.

Cattle, beef and related by-products were consistently exchanged between the two countries until Canada's first domestic case of BSE in May 2003. Before this time, over 50 percent of Canada's cattle and beef production was exported and the majority of this was sold to the U.S. from Western Canada. On average, Canada exported approximately 1 million head of live cattle to the U.S. annually.

Canada also imported a large number of U.S. cattle. In 2000, for example, over 550,000 U.S. cattle were imported for feeding or slaughter. Also, before the CCIP was implemented in 2001, U.S. cattle would have been seamlessly integrated into the Canadian cattle herd. In 2000 alone, there were 25,000 U.S. cattle that became part of the national herd.

The feed systems in Canada and the U.S. were also deeply interconnected. Approximately 50% of the MBM in Canadian feed was imported from the U.S. in the post-North American Free Trade Agreement environment. With few exceptions since 1988, the U.S. had been the only country exporting MBM into Canada.

Although several hypotheses exist, it has not been possible to definitively pinpoint the source of the contaminated MBM that made its way into Canada's feed system prior to the 1997 feed ban. In the absence of equivalent knowledge of what transpired with the majority of the U.K. imports of equivalent BSE-risk in the U.S., to date, the Canadian investigators have been restricted to building their hypotheses around only the U.K. imports that entered Canada. All that follows must be read within this context.

Domestic BSE in Canada

Contaminated MBM was identified by the Canadian investigators as the most probable infection source for the Case 1 animal only after a range of alternative BSE transmission routes was rejected. These included spontaneous prion mutation, maternal transmission and the crossover of other North American TSE diseases. In the end it was determined by Canadian experts that the source of the BSE was likely feed contaminated by as few as one asymptomatic animal imported from the U.K. into North America prior to the implementation of similar feed safeguards in both Canada and the U.S.

It is believed that MBM containing SRM from one or more infected U.K. animals contaminated the integrated North American feed system and was eaten by a small number of indigenous animals during the early 1990s. Considering the average incubation period of BSE, the four Canadian BSE-infected cattle diagnosed from May 2003 to January 2005 are likely second generation animals infected from first generation cases that were exposed to contaminated feed during the general interval from 1991 to 1992. The BSE-infected cow born in the United States and described in the USDA's epidemiological report of September 2005 could have been such a first- generation case, given its calculated birth in the general interval of 1992. It is believed that the SRM from

one or more of these first-generation North American animals re-contaminated the Canadian feed system during the general interval of late 1996 to early 1998.

Canada implemented its feed ban in August 1997. It is estimated that it would have taken four to six months for the existing feed to work its way through the commercial segment of the feed system. Under current industry practices, it is possible that some feed could have infrequently been stored on farms for an additional interval. Audits by the CFIA of the commercial feed segment suggest that most, if not all, infected SRM materials would have entered the system prior to August 1997. At the time of the feed ban introduction in 1997, Canada had not detected a domestic case of BSE. Also, in 1994, all of the U.K. imports that were not repatriated to the U.K. had been euthanized and tested negative for the disease. Consequently, a phased implementation was undertaken by the Government of Canada without a recall of feed that was previously produced. This was in accordance with internationally accepted procedures for a country that had not found a domestic case of BSE.

The four BSE cases diagnosed up to January 2005 were born between October 1996 and March 1998. Since this was the same period of time when the changes to the feed ban were being phased in, the retrospective evidence would indicate that there had been residual contamination in the feed system during this period. The ages of these BSE cases at the time of disease onset offer insight into the level of BSE contamination in Canada before and after the ban. It took between 5.8 and 8.2 years (70-98 months) for the disease to develop in these animals. Research in the U.K. suggests that the level of contamination periods are representative of the exposed population of cattle, it could be further concluded that the level of infectivity was extremely low before the ban. In addition, the age of the animals detected suggests that the feed ban achieved its intended objective to limit the spread of the disease. If the level of BSE contamination had continued to recycle despite this intervention, then the number of animals detected would be expected to be significantly higher and of progressively younger ages.

These determinations, combined with intensive surveillance efforts, suggest that the potential number of BSE cases left in the Canadian cattle herd is extremely low. Most of the limited number of animals that could have been infected prior to the feed ban had already left the North American Cattle Cycle. The vast majority of these animals would have been slaughtered between 18 and 22 months of age under North American production practices. As infective levels of the disease have not been demonstrated to develop in young cattle based on the collective international experience, it is unlikely that these animals re-introduced BSE contamination into the Canadian feed system.

This is consistent with the recent findings of the BSurvE analytical model when it was applied to Canadian surveillance statistics. This model was created in 2004 for the European Union to objectively assess BSE prevalence in the national herds of its member countries. The BSurvE model compiles statistics from a nation's cattle population, production and marketing patterns, as well as surveillance results from animals of various ages to estimate the remaining number of BSE-infected adult cattle within the national

herd. Although the formal peer review process of the model requested by the OIE continues, this model is recognized by the OIE to be the most reasonable BSE-infection prevalence assessment tool developed to date.

When the BSurvE model was recently applied to Canada's statistics and adjusted to account for the effectiveness of the 1997 feed ban (based on experiences with the 1988 feed ban in the U.K.), the resulting prediction was that it could be expected that three infected animals remain within the national herd. The model also predicted that these infected cattle would have been born before or during the implementation of the 1997 feed ban.

BSE "Clustering" Theories

In this section, the potential linkages among the five North American cases diagnosed from May 2003 to June 2005 are analyzed to determine why these occurred when and where they did. The analyses incorporate two interconnected BSE exposure theories – temporal BSE clustering and geographic BSE clustering.

Temporal BSE Clustering

A temporal BSE cluster is a group of cattle born and exposed to contaminated feed over a limited and defined time period. U.K. research and experience point to the first 12 months of a cow's life as the crucial window of its susceptibility to BSE infection. The four Canadian-born BSE cases diagnosed from May 2003 to January 2005 were calved between October 1996 and March 1998 and are considered to represent the second generation of indigenous BSE in Canada. Epidemiologists view this grouping of events during a narrow window in time as a temporal BSE cluster that sheds light on the North American experience. It coincides with the era in the North American Cattle Cycle in which the amount of BSE-contaminated MBM in the feed system would have peaked and then plummeted immediately following the introduction of coordinated feed bans in Canada and the U.S. in 1997. These four infected cows emerged from among the calves born during this period when the exposure to BSE, although extremely small, would have peaked for North America. As stated previously, the vast majority of these animals would have left the North American Cattle Cycle between 18 and 22 months of age, which is before infective levels of the disease are known to develop.

In the same way that these second-generation North American animals became infected from 1996-1998 to form a temporal BSE cluster of animals born in that time period, they would have been preceded by another temporal BSE cluster around 1991-1992 when first-generation North American animals likely became infected with the disease from consumption of MBM contaminated by the infected SRM of one or more U.K. imports. Interpretation of the USDA's epidemiology report for the American-born BSE case diagnosed in June 2005 suggests it was born around 1992 and could have been a first-generation animal.

Geographical Feed Zones

Canadian renderers, feed mills and farmers are subject to geographic and economic forces that tend to group their interactivities in feed production, distribution and consumption into geographically-based feed zones. Renderers process dead stock and animal by-products. Given the low-unit value and high-unit weight of this material, transportation costs are kept to a minimum by sourcing material locally. Feed mills manufacture products that may contain this rendered material (MBM) and operate under similar economic influences. As a result, feed mill markets also remain primarily local. Therefore, a cycle is established of local deadstock and by-products being sent to a local renderer that distributes its rendered product to a local feed mill that, in turn, sells its products to local retailers and farms. Under these circumstances, if infected SRM entered the feed production system in a particular area, the resulting BSE would probably continue to circulate within the cattle herds of that geographic feed zone and a geographic BSE cluster could develop.

Geographical BSE Clustering

A geographic BSE cluster refers to a group of cattle diagnosed with BSE that in their early stages of life resided within a defined geographic feed zone. An animal that is diagnosed with BSE could belong to both a temporal BSE cluster and a geographic BSE cluster. Geographic BSE clusters could be isolated from one another's feed production systems while being ultimately connected to the same temporal BSE cluster.

Given the interlinked structure of the North American Cattle Cycle pre-2003, if SRM from an animal infected with BSE entered the feed production system in either Canada or the U.S. before the respective 1997 feed bans were implemented, it could have introduced BSE into one or more geographic feed zones. The extent of this dispersal would have depended on how widely the contaminated MBM from that animal had been distributed. The geographic feed zones would have tended to limit the further distribution of BSE from the primary geographic BSE cluster(s) due to the economic and geographic factors described in the following two paragraphs.

From time to time, economic conditions might alter traditional feed production patterns and infected cattle, rendered products or feed might move between geographic feed zones. For example, Canada had imported significant amounts of rendered MBM from the U.S. (approximately 50% annually since 1988). If any of this rendered feed material had been contaminated with the BSE agent it could have created a potential new cluster of BSE cases in a different geographic area. The same possibility would apply to similar materials moved from geographic feed zones within Canada such as that which harboured the temporal and geographic cluster of four Canadian-born animals described earlier.

However, the risk of a second geographic BSE cluster developing from the introduction of contaminated feed would depend on a number of factors within the recipient feed zone. These include: (1) the rate at which subsequently infected cattle were disposed of through the rendering system and re-entered the feed production system; (2) the number

of cattle in that area that were slaughtered at a young age before infective levels of the disease developed; (3) the level of BSE contamination in the feed; (4) the quantity of feed introduced; (5) the production processes that the feed was exposed to at destination; (6) and the degree to which this feed was disseminated to cattle of susceptible age for contracting BSE infection. The proper combination of these factors would support propagation of the disease in the recipient area, leading to the potential creation of a new geographic BSE cluster.

Finding BSE within a Geographic BSE Cluster

The identification of BSE that has been introduced into a geographic feed zone depends on two things. Of primary importance is the need to survey within specific high-risk classes of cattle that have been recognized by the OIE as offering the greatest potential for exhibiting the disease. The OIE and other BSE experts acknowledge that samples from some classes of animals (i.e., older animals showing neurological signs) offer up to 10,000 times greater likelihood of disclosing the disease than others (i.e., cattle sent for routine slaughter). In Canada, high-risk cattle have been identified as animals over 30 months that are diseased, down, dying or dead (the 4-Ds), which is consistent with the international standards of the OIE.

International evidence to date has shown that BSE begins to be detected once infection levels approach one in 10,000 within the sub-population of high-risk cattle within the national herd. It is estimated that there are 10,000 high-risk cattle for every one million cattle in the national herd. Thus, one BSE case within 10,000 high-risk cattle equals one case in a million within the national herd. As discussed previously, Canada, like many OIE member countries, has introduced measures to encourage increased surveillance levels in high-risk cattle.

The second important element in finding the disease and attributing it to a geographic BSE cluster is a cattle identification program. In Canada, the design of the CCIP incorporates the ability to record the geographic area(s) where animals have spent their lives. This includes the first 12 months of life for all animals, which is the interval when they are considered to be most susceptible to BSE infection. Therefore, the CCIP will allow geographic BSE clusters to be tracked should additional cases of the disease be discovered.

North America's first four cases (diagnosed from May 2003 to January 2005) were born and spent their first 12 months of life in a geographic area within Central Alberta and Western Saskatchewan (Figure 3). Investigation continues into whether these four cases reflect one or possibly two geographic BSE clusters as described above. It is noteworthy that this geographic area also includes the location of the Canadian herd where the infected U.K. import was diagnosed with BSE in 1993.

The fifth North American BSE case was described in the USDA's epidemiological report of September 2005 as having been born and raised in the State of Texas. It is possible

that this animal represents another geographic BSE cluster that is linked to a temporal BSE cluster that formed between 1991 and 1992. This geographic BSE cluster could have developed on its own from BSE-infected U.K. animals that were rendered into the geographic feed zone in that area, or it could represent a transfer of contaminated feed from another zone.



Overview of the Canadian-born BSE Cases (May 2003 to January 2005)

Provided below are the summary findings of the epidemiological investigation of the four Canadian-born BSE cases diagnosed from May 2003 through January 2005 that are considered to be part of the same temporal BSE cluster and may represent one or two geographic BSE clusters in Western Canada. A more detailed summary of each case is available in appendices A through D. For reference purposes, the renderers, feed mills and retailers referenced in this section are positioned on the map below (Figure 4).

Figure 4: Geographic locations of renderers, feed mills and retailers

Canada Case 1 – Confirmed May 20, 2003

Over the course of 21 days the CFIA conducted an intensive investigation into this occurrence of BSE. Investigative efforts into this case came to a close in the fall of 2003 when it was possible to confirm through DNA analysis which of the two principle farms under investigation was the actual farm of origin.

Approximately 2,700 cattle were culled during the investigation – a number deemed above and beyond the standard established by the OIE. More than 2,000 of these animals that were 24 months of age or older were tested for BSE, with negative results in all cases.

The infected animal (index cow) did not enter the human food chain. It did enter the feed system through Renderer A in northern Alberta. It was determined that the feed products manufactured with the potentially contaminated feed were further distributed from Renderer A through the feed distribution channel to over 1,800 farms. A sampling of these farms (204), the source rendering facility (1), feed mills (8) and feed retailers (87) was investigated to assess adherence to the feed ban. Of the 204 sampled farms, 91% were found to be in full compliance with the regulations, 6% had minor infractions that may have resulted in ruminants having incidental exposure to contaminated MBM and 3% had infractions that led to ruminants having routine or systematic exposure to contaminated MBM. As a result of this feed trace-out investigation, 63 animals were culled when the investigation could not rule-out the possibility that these cattle were exposed to contaminated feed. All 63 animals tested negative for BSE.

To identify the most probable source of the disease, inspectors investigated feeding practices at both of the potential farms of origin and all other farms where the index cow may have resided. Upon the DNA confirmation of the farm of origin, the investigators were able to identify that the infected cow was fed a single feed containing MBM from Renderer A. This renderer also processed the infected cow in 2003 giving further weight to the theory of infection recycling within a geographical BSE cluster.

Canadian-born U.S. Case - Confirmed December 25, 2003

Over the course of 15 days, the CFIA conducted a thorough investigation into this occurrence of BSE, working collaboratively with U.S. officials. As in the other instances, most movements represented historic events that preceded the introduction of the CCIP.

In accordance with international standards, inspectors traced 114 animals of an equivalent risk of being infected with BSE to final disposition. Twelve of these animals were located alive, subsequently euthanized and tested negative for BSE. Four cattle were not traceable to final disposition. Four were determined to be in a herd of 150 cattle which continue to be monitored by the CFIA. The remaining cattle were determined to have been slaughtered or had died of other causes.

To identify the most probable source of the disease, inspectors investigated the manufacturing and feeding practices pertaining to 18 commercial feeds used on the farm of origin and the related property. The investigation revealed that the infected cow had been fed a ration containing MBM in its first year of life. The MBM contained in this ration was from Renderer A. Although improbable, it is possible that the animal was also exposed to a protein block containing MBM from Renderer B in southern Alberta.

Canada Case 2 – Confirmed January 2, 2005

Over the course of 19 days, the CFIA conducted a thorough investigation into this occurrence of BSE. Within 24 hours of receiving notification from the province of Alberta of a suspect case of BSE, the CFIA had identified the birth herd. In accordance with international standards, inspectors traced to final disposition 135 animals of equivalent risk of being infected with BSE. Nine of these animals were located alive, subsequently euthanized and tested negative for BSE. Four cattle were not traceable to final disposition. The remaining cattle, one of which had already tested negative under the national BSE surveillance program, were determined to have been slaughtered or had died of other causes.

To identify the most probable source of the disease, inspectors investigated the manufacturing and feeding practices pertaining to nine commercial feeds used on the farm of origin. The investigation revealed that the infected cow had been fed three rations containing MBM in its first year of life. Although improbable, it is possible that the animal was exposed to a fourth ration containing MBM. All four rations were manufactured with MBM from Renderer A before the feed ban.

Canada Case 3 – Confirmed January 11, 2005

Over the course of 32 days, the CFIA conducted a thorough investigation into this occurrence of BSE. In accordance with international standards, inspectors traced to final disposition over 349 animals of equivalent BSE risk. Of these animals, 41 were located alive, subsequently euthanized and tested negative for BSE. Three cattle were not traceable to final disposition. The remaining animals were determined to have been slaughtered or to have died of other causes.

To identify the most probable source of the disease, inspectors investigated the manufacturing and feeding practices pertaining to 14 commercial feeds used on the farm of origin. This presented considerably more challenges than the three other cases. The exact source of MBM exposure could not be determined from available records. Instead, findings suggest only the possibility of incidental exposure through one of four feeds manufactured by Feed Mill I in southern Alberta or Feed Mill J in Saskatchewan. Feed Mill I generally sourced MBM from Renderer B. On occasion, Renderer B also received MBM from Renderer C. Feed Mill J sourced MBM exclusively from Renderer D.

The Geographic BSE Cluster in Western Canada

Reference was made earlier in this document to the possibility that BSE entered the feed system and recycled within the cattle population. Consideration was given to the possibility that the disease might remain within localized geographic feed zones as a result of underlying economic pressures. The relationship between the quantity of contaminated feed consumed and length of time the disease takes to develop in an animal were also explained. In this section, these criteria are now reviewed in specific reference to Western Canada in order to place its BSE experience in perspective within the North American context.

Geographic vs. Temporal BSE Clusters

Alberta contains 40% of the Canadian cattle herd. Therefore, it is not surprising that the majority of the 168 U.K. cattle imported from 1982-1989 resided in that province. A total of 68 of these animals had left the North American Cattle Cycle by way of slaughter (59) or death (9) before the balance of the U.K. animals were removed from the Canadian population in 1994 (Figure 1). Nine of these 68 animals had come from U.K. herds in which one or more BSE cases were subsequently discovered. A tenth cow was considered to be high-risk only because the U.K. birth herd for this animal could not be determined within the U.K.'s BSE tracking system. Some of these animals or their by-products may have made their way into the feed production system.

Although animals of similar risk were distributed throughout North America at that time, the known Canadian imports of greatest concern to this particular geographic BSE cluster include two cattle from the U.K. birth cohort of the cow that was diagnosed with BSE in 1993. These two animals had resided in Alberta along with their infected U.K. herdmate

and had left the North American Cattle Cycle before 1993. Either of these animals may have introduced the BSE infection into this geographic feed zone that, in turn, created a geographic BSE cluster.

As discussed earlier in this document, on the basis of the incubation periods represented by the imported and domestic BSE cases encountered up to January 2005, it would appear that two cycles of contamination existed in the North American cattle herd. The first would have circulated during the period from 1991 to 1992, possibly as a result of one or more U.K. imports that were infected with the disease upon entry into the Canadian feed system. This cycle would have caused the first generation of BSE infection in Canadian cattle.

Contaminated feed from one or more animals from Canada's first generation of BSE could have then entered the feed system during the period from 1996-1998, which coincided with the implementation of the feed ban. The cattle that were in their early stages of life during these two BSE cycles would have been most susceptible to contracting the infection. As a result, temporal BSE clusters can be expected to be associated with these two time periods. The temporal BSE cluster associated with the 1991-1992 cycle will probably never be diagnosed in Canada, notwithstanding the possibility that the BSE-infected cow described in the USDA's epidemiological report of September 2005 as born around 1992 in Texas could represent the first generation of indigenous infection in that country. The number of infected animals would have been exceedingly small and most, if not all, would have already died of other causes. It is the temporal BSE cluster from the 1996-1998 cycle (itself small in number) that continues to dominate as the primary focus of epidemiological investigations regarding the natural history of the disease in North America.

The diagnoses in Alberta and Texas from 2003 to 2005, viewed in the context of the flow of cattle and MBM between Western Canada and the Western U.S., support the theory that one or more of these BSE cycles occurred in the western part of the continent. The diagnosis in Washington State is indicative of other infected animals that could have entered the feed production system in the Western U.S. The levels of contamination that emerged within localized geographic areas of North America would have been determined by the initial BSE levels in the imported U.K. cattle, the disposal methods used for these cattle and their by-products, and the feeding and slaughter practices employed in localized cattle populations. Evidence suggests that at the time of the two theoretical BSE cycles in the North American cattle herd there were more commonalities in disposal, husbandry and slaughter practices between Western Canada and the Western U.S. than between Western Canada and Eastern Canada.

The levels of BSE that could have developed within localized geographic feed zones – cattle management practices and other factors being equal – would vary from one zone to another on the basis of economic forces. The disease could be expected to remain within the geographic feed zones that were exposed to contaminated MBM from an infected carcass. Given that MBM distribution generally remains localized, it could be expected

that the disease would have recycled primarily within each respective geographic feed zone unless infected cattle and contaminated MBM were moved to other areas.

BSE detection within Western Canada

A number of factors must be considered when analyzing why BSE in Canada has been detected within a narrow geographic region. Although this could be interpreted as an indication that there is a higher level of BSE in that area than in the rest of Canada or North America, this may not be an accurate conclusion.

International evidence to date has shown that BSE begins to be detected once infection levels approach one in 10,000 within the sub-population of high-risk cattle within the national herd. Therefore, it can be concluded that the level of BSE infection in Canada reached the minimal threshold for detection (one infected animal within 10,000 high-risk cattle or one in a million within the national herd) at the same time that national surveillance for the disease was significantly increased to over 3,700 samples in 2003.

The closure of the American border to live cattle also created a demographic shift within the age structure of the Canadian cattle population. The national herd is now older, particularly the beef cattle, and this creates a surveillance advantage in the search for a disease that has specifically expressed itself in older animals within North America. Since approximately 70% of Canada's beef-raising sector resides in Alberta, the BSE surveillance in that area is even more effective.

Several provinces provide support to Canada's BSE Surveillance Reimbursement Program. This includes increased lab capacity, education and awareness campaigns, sampling assistance and financial supplements to the federal payments. Currently, Alberta's financial top-up of the federal payment is the highest. The OIE recognizes that providing incentives to producers is crucial to a successful national BSE surveillance program that finds BSE cases at the earliest stage possible. In fact, these programs are the primary reasons for Case 2 and Case 3 being reported on the farm – before either animal entered the animal food system or human food chain. On-farm sampling also makes it easier for investigators to acquire a more immediate clinical history of the animal and provides for high-quality surveillance samples.

Given these factors and the diagnosis in Texas in a Texas-born twelve-year-old cow, the geographic BSE cluster in Western Canada should first be interpreted as evidence of previous low-level contamination in the North American Cattle Cycle. Results to date support the theory that low BSE levels exist in at least one and possibly two geographic feed zones in Canada. The case in Texas is supportive of the possibility that the U.S. also experienced a contaminated feed cycle prior to its feed ban. In Canada, the information available to date continues to be analyzed in the form of Phase III of the BSE Epidemiological Investigation, which will be documented in Part III of this report. Canada has always accepted the possibility that other undetected geographic BSE clusters could exist in North America. Because of this possibility, Canadian policies and safeguards to protect human health were implemented on the premise that the discovered

geographic cluster may not be the only one on the continent. Regardless, the feed bans implemented in both Canada and the U.S. in 1997 would have dramatically reduced or eliminated opportunities for further spread of the disease.

Interpreting the Meaning of Individual BSE Cases

World experience in the spread of BSE directs the investigator to feed sources as the primary, if not the singular, mode of transmission. The details of the four BSE investigations between May 2003 and January 2005 in the Western Canada geographic BSE cluster have revealed epidemiological relationships that found common elements among three of the four instances. The significance of these commonalities depends upon the microscopic or macroscopic interpretation applied to them.

The case-by-case investigation directly links a common feed source to the first two Canadian cases and the one found in the U.S. in December 2003. In each instance, the infected animal was fed one or more feed formulations produced before the feed ban was implemented in August 1997. Three of the feed mills that supplied protein products to the birth herds (index farms) for Case 1, Case 2 and the 2003 U.S. Case were found to have received consecutive loads of MBM from Renderer A on February 28, 1997. Given each feed mills' MBM usage patterns, it would have been reasonably possible that MBM from these shipments may have been used to manufacture feed for each of the index farms. There have not been any confirmed linkages from Renderer A to Canada's Case 3. Figure 5 illustrates which renderers supplied MBM to the feed mills and retailers that supplied feed to the affected animals.

Figure 5: Relationship between the Four North American Cases Diagnosed from May 2003 to January 2005 and the Western Canada Feed System

Investigators considered the possibility that the distributed SRM from only one infected animal from the first cycle of infection in 1991-1992 could have infected the subsequent four cases. The native-born BSE-infected animal described in the USDA's epidemiological report of September 2005 was calved during this timeframe, supporting the theory that there was a level of contamination in North America during that interval.

Potential linkages among Case 1, Case 2 and the 2003 U.S. Case are consistent with the concept of geographic BSE clustering. The linkage to Case 3 is tenuous because of the infrequent transfer of MBM from Renderer A to its counterpart, Renderer B, in southern Alberta. Renderer B contributed to feed products consumed by the birth herd of Case 3 and this could be interpreted as an inter-cluster transmission. On the other hand, Canada's Case 3 could also be interpreted as evidence of a second geographic BSE cluster that originated from somewhere else within the North American Cattle Cycle and was also linked to the same temporal BSE cluster.

Conclusion

Economic and geographic forces significantly influence the demographic distribution of the Canadian cattle sector. This has resulted in an industry where cattle and feed circulate in defined geographic feed zones. If a BSE-infected animal entered the feed system of such an area, cattle within its boundaries would likely be exposed to most of the resulting contaminated feed. Years later, a geographic cluster of BSE cases could emerge from the exposed cattle if a number of susceptibility factors existed in that area to support development of the disease.

Based on these feed circulation patterns, it was possible for BSE to become established in one area and potentially cross over into different geographic feed zones as animals and their by-products moved to new areas through the normal activities of the North American Cattle Cycle. During the period of interest to this report, the movement of animals and products in North America tended to be primarily North-South rather than East-West. For this reason, until May 2003 a North American Cattle Cycle had been established wherein animals and by-products flowed freely in both directions across the Canada-U.S. border. Investigation of the first four North American BSE cases indicates that these animals could represent one or possibly two geographic BSE clusters in Western Canada. The detection of a fifth case, indigenous to the U.S., may signal another geographic BSE cluster in Texas.

The ages of the five BSE cases diagnosed from May 2003 to June 2005 could also support the existence of two temporal BSE clusters in North America. These temporal BSE clusters may have resulted from the initial BSE infection that entered North America through the importation of cattle from the U.K. during the period from 1982 to 1989. One or more of these imported animals, without necessarily demonstrating signs of the disease, may have entered the North American feed system between 1991 and 1992 and caused the first generation of BSE in Canadian cattle. The Texas animal that was born around 1992 could signal the first generation of the disease in the United States.

In Canada, this low level of infection could have circulated undetected and recontaminated the feed system during the period from 1996 to August 1997, potentially lingering in the system until 1998. This could have then caused the second generation of BSE in Canada, which became evident in May 2003 when the first animal from this era was diagnosed with the disease. The ages (70-98 months) of the Canadian-born cases diagnosed from May 2003 to January 2005, support the temporal clustering theory in that these animals would have been in their early stages of life during 1996 to 1998.

Investigation of the first four North American cases and the common threads connecting the associated rendered products, feed and infected cattle support a theory that both geographic and temporal BSE cluster theories may be consistent with the historic North American situation. The geographic BSE cluster theory could explain the first three cases by virtue of their linkages to Renderer A in Northern Alberta. While the fourth case can be linked to the same temporal BSE cluster as the first three cases, it cannot be as easily connected to the same geographic BSE cluster.

With respect to the fourth case, products were purchased from Renderer B in southern Alberta, which occasionally received surplus shipments of MBM from Renderer A. By reaffirming that potentially contaminated feed can move between geographic BSE clusters, this fourth case may represent an extension of the primary geographic BSE cluster. Alternatively, this case could also suggest the possibility of a second stand-alone geographic BSE cluster in Western Canada that was caused by a separate North American source linked to the same temporal BSE cluster. In addition, the age of the fourth case (81 months) supports the theory that should additional cases of BSE surface in other geographic BSE clusters in North America, these will most likely be connected to the two temporal BSE clusters that emerged in the 1990s.

The future detection of a small number of cases within the recognized cluster(s) or further clusters that may be defined in the future, such as the Texas-born U.S. case, cannot be discounted. The recent application of the BSurvE model for the year 2005 predicted that it could be expected that three BSE-infected animals might remain in Canada's national herd and that these animals would have been born before or during the implementation of the 1997 feed ban. This prediction and the findings of the five BSE investigations into the animals diagnosed from 2003 to 2005 support the current hypotheses for how the disease likely evolved in North America and provide continued encouragement that the level of BSE is extremely low and declining.

Appendix A: Summaries of the Epidemiological Investigations

1) Canada Case 1

On May 20, 2003, BSE was confirmed in an Angus cow that was born in northern Saskatchewan in March 1997. The animal was approximately six years old at the time of death. Through the investigation, 15 premises were quarantined, 25 herds were investigated and over 2,700 cattle were culled. Of these, 2,000 animals were over 24 months of age and could be tested for BSE. All test results were negative.

The animal did not enter the human food chain. It entered the feed system through a rendering facility in northern Alberta (Renderer A). In compliance with regulations in place at the time, the rendered material, MBM, was incorporated into other animal feeds: pig, poultry, dog and feeds for other non-ruminants. The Canadian Food Inspection Agency (CFIA) issued an information notice identifying the potentially contaminated dry dog food and reminded livestock producers not to mix dog food with ruminant feeds. The facility (1), feed mills (8) and feed retailers (87) who potentially handled the infected cow's MBM were investigated to confirm adherence to the feed ban. The MBM that may have contained remains of the positive cow was traced to 1,800 farm sites. A sampling of 204 of these farms was inspected for compliance with the feed ban. Of these 204 farms, 91% were found to be in full compliance with the regulations, 6% had minor infractions that may or may not have resulted in ruminants having incidental exposure to index MBM and 3% had infractions that would lead to ruminants having routine or systematic exposure to index MBM. As a result of this feed trace-out investigation, 63 animals were culled as their exposure to poultry feed could not be ruled out. All 63 animals tested negative for BSE.

Birth Cohort

In June 2003, the CFIA presented its investigation findings to an international panel of experts. By this time, approximately 2,700 animals had been culled as a result of the occurrence and investigators had narrowed the farm of origin to one of two possibilities. Animal tracing at this point in time had largely been focused on efforts to locate the farm of origin. The international panel of BSE experts reviewed the CFIA's actions related to the investigation and concluded that the precautionary approach adopted in the CFIA's animal culling activity had surpassed the expectations of the international community and recommended that further culling be curtailed.

In the fall of 2003, the CFIA confirmed the location of the infected animal's farm of origin via protracted population and animal DNA testing. Consistent with advice from the international panel, once the farm of origin was located, no further investigation was required to locate and test additional animals because the conservative culling initiated in May had already addressed the birth cohort.

Recent Offspring

The animal gave birth twice in the two years prior to her death. Evidence indicated that the calf born in 2001 had been slaughtered and the heifer calf born in 2002 was located alive and euthanized on May 23, 2003.

Feed Exposure

CFIA investigated potential sources of infectivity at both possible farms of origin. Once DNA confirmed the farm of origin in the fall of 2003, investigators were able to identify the infected cow's single source of exposure to MBM: 18% Calf Starter.

18% Calf Starter

This ration was fed to the index cow from birth until she was turned onto pasture in the spring of 1997. The calf starter was manufactured with MBM by a local feed mill (Feed Mill A) before the implementation of the August 1997 feed ban. This mill received its MBM from the same rendering facility in northern Alberta (Renderer A) that later processed the Case 1 animal.

2) Canadian-born U.S. Case

On December 25, 2003, BSE was confirmed in a Holstein cow in Washington State. It was determined that the animal was born on April 9, 1997, and was 6.5 years old at the time of death. The cow was traced to its dairy farm of origin in central Alberta approximately 30 miles southwest of Edmonton. Like the first Canadian case, the animal exhibited signs that placed it in one of the surveillance classes recommended by the OIE. The animal had been identified and recorded in a shipment of 81 cattle exported to a dairy cattle finishing location in south-central Washington State on September 4, 2001. On October 16, 2001, 70 of these animals, including the infected cow, were purchased and relocated to a dairy farm 50 miles south of the finishing station. The owner of the dairy farm in Washington State had approximately 4,000 head of cattle at two separate locations. The index animal had resided in one of these locations that held around 1,700 head.

Birth Cohort

The birth cohort period for the index animal extended from April 1996 to April 1998, preceding the introduction of the Canadian Cattle Identification Program. Of the 57 birth cohort animals, 27 were confirmed dead, 25 were exported to the U.S. (as part of the 81 cattle exported to the dairy cattle finishing location in Washington), two were untraceable and three were still alive in Alberta. These three remaining cattle were euthanized and tested negative for BSE.

Another property under common ownership that related epidemiologically in terms of husbandry practices to the birth herd also had 57 birth cohorts. Of these, nine were still on the farm (euthanized and tested negative) and 48 had been dispersed among a group of 86 animals sold to numerous buyers. Of these 86 animals, 80 were confirmed

slaughtered, two were untraceable and four were traced to a herd of 150 head. The risk exposure of these remaining four animals is considered to be low and, therefore, they were not euthanized. The CFIA continues to monitor these cattle. In total, 12 animals were euthanized in Canada and all tested negative for BSE.

The U.S. also identified 255 animals that could have been from the index birth herd in Alberta. These 255 animals were on 10 premises in three states in the Pacific Northwest (Washington, Oregon and Idaho). All 255 animals were located, euthanized and tested negative for BSE.

Recent Offspring

The affected animal produced two offspring within the two years prior to the detection of BSE. These two animals were also located in the U.S., euthanized and tested negative for BSE. They were included in the total of 255 animals depopulated in the U.S.

Feed Exposure

As with all BSE investigations, the feed component focussed on what the animal consumed in its early stages of life. There were three commercial sources of protein available to dairy cattle on the birth-herd premises. These included a 26% calf starter, a 20% protein supplement block and a 15% dairy ration.

26% Calf Starter

The manufacturer of this product, Feed Mill B, did not include MBM in its calf starter formulation, but did handle MBM and products containing MBM produced by Renderer A. Feed Mill B's last purchase of MBM from this renderer was December 29, 1996. The producer believed that the calf starter, even if accidentally contaminated at the manufacturer's site, would have been consumed prior to the birth of the index cow in April 1997.

20% Protein Supplement Block

The source of MBM for the product cannot be definitively confirmed because records from Feed Mill C for 1997 purchases were not available; however, CFIA and industry knowledge of the product and feed mill during this time period indicates that the MBM was from a rendering facility in southern Alberta (Renderer B). A retail outlet, Feed Retailer A, was able to confirm that the producer had purchased product on March 4, 1997. The block would have been placed in the dry cow pen at that time and would have likely been consumed prior to the entry of the infected animal to the pen in mid-May 1997.

15% Dairy Ration

Once the 26% calf starter was used up, the 15% dairy ration was the only commercial source of protein for lactating cattle and dairy calves on the farm of origin. Renderer A had supplied MBM to Feed Mill D in Edmonton that manufactures 32% Supplement Pellets. These pellets would have been manufactured using MBM until July 11, 1997.

These pellets, in turn, were shipped to Feed Mill B for incorporation in the 15% Dairy Ration.

This dairy ration was purchased by the producer of the farm of origin every 7 to 14 days. The index case would have been exposed to this product in late April 1997.

At the related location, when checking or moving beef cattle between pastures, two to three pails of 15% Dairy Ration were used to bait the herd. The producer indicated that the beef cattle, including calves, consumed this ration; however, this exposure was low and irregular.

U.S. Feed System

The carcass of the affected animal had been sent for entry into the U.S. animal feed system. As a result, the Food and Drug Administration (FDA) traced 2,000 tonnes of rendered MBM and other by-products that could have come from the affected animal. U.S. officials have indicated that this material was located and contained before it entered the U.S. feed chain.

3) Canada Case 2

On January 2, 2005, BSE was confirmed in an eight-year-old Holstein cow. The animal was born on October 5, 1996, on a dairy farm located in Alberta approximately 85 miles northwest of Edmonton. At the time it was diagnosed the animal was residing at another farm located 44 miles northwest of Edmonton. No part of the cow entered the human food chain or animal feed system. After testing was completed, the remainder of the carcass was incinerated.

Birth cohort

Records from the farm of origin identified 135 calves born between October 5, 1995 and October 5, 1997: 38 dairy breeding animals; 49 dairy bull calves for slaughter; and 48 beef calves. Originally an additional six animals were treated as birth cohorts since their exact birth dates were not known. These six animals were subsequently determined not to be birth cohorts and were excluded from the investigation.

During the investigation, nine birth cohort members were located alive. These cattle were quarantined, euthanized and tested for BSE using an approved BSE rapid test. All nine birth cohorts tested negative for BSE and their carcasses were disposed of by incineration.

Investigators traced 122 cattle to slaughter and/or death. Five of these animals had died on the farm of origin. One was previously euthanized under the BSE surveillance program and tested negative. Five cattle were slaughtered in the U.S. An additional four cattle may have also been slaughtered in the U.S. Four cattle were untraceable. Three were dairy breeding cows: one born in 1996 and two born in 1997. The fourth was a beef cow born in 1996.

Recent Offspring

Although the index cow had a history of calving-related problems, she had given birth to three calves in the two years prior to her diagnosis. A heifer born in February 2002 was sold to a feedlot and slaughtered in March 2004. A bull calf born in the fall of 2003 was slaughtered on December 15, 2004, for the owner's personal use. This meat had not been consumed and was destroyed by incineration as a precautionary measure. The final calf was stillborn in November 2004.

Feed Exposure

Nine commercial feeds found on the farm were investigated as possible routes of MBM exposure. The index cow was never exposed to three of these feeds. According to farm records, she may have had access to six other feeds early in her life: three feeds containing MBM between April and late September, 1997; two feeds not formulated with MBM; and, while improbable, a heifer ration from Feed Mill B.

The infected cow was fed three commercial feeds manufactured by one of two feed mills, Feed Mill E and Feed Mill F. These two feed mills belong to a chain of feed mills. Both manufactured a portion of their ruminant feed products with MBM from Renderer A in northern Alberta prior to the implementation of the feed ban in 1997. Based on sales receipts and formulation records it was determined that these three feeds did contain MBM when they were fed to the index cow. As such, these feeds were identified as being the most probable source of BSE infectivity.

16% Dairy Ration

This ration was manufactured by Feed Mill E north of Edmonton and was purchased by the farm of origin at regular intervals in 12 tonne units from December 1996 through to April 1997. MBM was included in this formulation via the inclusion of a Dairy Supplement that contained 130 kilograms MBM per tonne. This feed mill purchased MBM from Renderer A. The final product contained 39 kg MBM per tonne of ration.

14% Dairy Ration

This ration was manufactured by Feed Mill E and purchased by the farm of origin at regular intervals in 12 tonne units from May 1997 through to September 1997. After July 1997, this ration was reformulated: meal made from poultry (poultry meal) was used as a substitute for MBM. Prior to the reformulation, MBM was included in this product via the inclusion of a Dairy Supplement that contained 125 kilograms MBM per tonne. The final product contained 37.5 kg MBM per tonne of ration.

Calf Heifer Ration

This ration was manufactured by Feed Mill F. A large quantity (12.51 tonnes) was purchased by the farm of origin in March 1997. This feed was not exhausted until the

end of September 1997. MBM content was derived from the inclusion of a Heifer Supplement that contained 100 kilograms MBM per tonne. Feed Mill F received its MBM from Renderer A. The final product contained 25 kg MBM per tonne of ration.

Heifer Ration

Although there is no evidence to confirm that the index animal was fed this product, it was fed to other animals on the farm before the animal was born and the possibility of some residual product remaining on the farm could not be ruled out. This heifer ration was manufactured by Feed Mill B. In manufacturing the heifer ration, a pelletized supplement containing MBM was sourced from one of two Edmonton area mills, Feed Mill D or Feed Mill G. The point of manufacturing of the supplement cannot be determined from the available records. Regardless of where the supplement was manufactured, it would have contained MBM from Renderer A because it was the only supplier to these feed mills.

Minerals

The minerals used during the summer at the farm of origin were purchased at a local retailer, Feed Retailer B. Although it cannot be confirmed because feed mill records are no longer available, it is suspected that these minerals were manufactured by a mill in Edmonton, Alberta (Feed Mill H). This mill also used MBM from Renderer A in the manufacture of feeds other than minerals on its premises.

4) Canada Case 3

BSE was confirmed in an Alberta cow on January 11, 2005. This animal was of the Charolais breed, born on March 21, 1998 and was 81 months old (6.75 yrs) at the time of death. The birth premise and lifetime residence of the animal was located about 70 miles north of Calgary, Alberta.

No part of the cow entered the human food or animal feed chains. After the testing was completed the carcass was incinerated.

Birth Cohort

Records from the farm of origin identified 349 calves born between January 1, 1997 and December 31, 1999: 113 in 1997; 112 in 1998, and 124 in 1999. The wider timeframe for birth cohorts for this case was due to the seasonal calving on the farm of origin. This means that all of these calves were of equivalent risk for BSE as the infected cow using the OIE definition of birth cohort. Consequently, the disposition of all 349 calves was investigated.

In addition to the birth cohort, other cattle left the farm from 1999 through 2005. Inventory records from the farm and auction market invoices did not provide sufficient information to distinguish these animals from the birth cohort. As such, these animals were also traced to final disposition. Of the animals being traced, 41 were euthanized and tested negative for BSE. 32 animals had died on the farm of origin. With the exception of 3 that were untraceable, the remaining animals were presumed to have died or been slaughtered. One of the untraceable cattle was a breeding bull that was born in 1998. The last known owner of this animal is deceased and there are no records pertaining to the bull's final disposition. Industry practice would suggest that a bull of this age has died or been slaughtered. The remaining two untraceable cattle were cows that left the farm of origin between 1999 and 2005. Available records could confirm neither their ultimate disposition nor their relationship to the infected cow.

Recent offspring

The cow had given birth twice in the two years prior to her death. One calf born in 2003 was slaughtered in Canada in the fall of 2003. The other, born in 2004, was located alive in a feedlot, euthanized and incinerated.

Feed Exposure

In a feed investigation, 14 commercial formulations found on the farm of origin were examined as possible routes of MBM exposure. The index cow was exposed to 9 of them.

Two feed formulations were not purchased until after she was one year of age; seven others were either directly or indirectly fed to her during her first year of life. Eight of the 9 have never been formulated with MBM. The other feed has not included MBM in its formulation since the inception of the feed ban (August 4, 1997).

Of the nine potential contamination sources, four feeds were manufactured by feed mills belonging to a chain. These mills were located in southern Alberta (Feed Mill I) or Saskatchewan (Feed Mill J). These were identified as the most probable route of exposure to MBM. Both mills manufactured non-ruminant feeds containing MBM. Although both had implemented handling, cleaning and documentation procedures for prohibited material in August 1997, the possibility of cross-contamination was investigated.

Approximately 99% of the MBM received by Feed Mill I originated from Renderer B. The remainder was received from a federal red meat abattoir in southern Alberta that slaughters young cattle (Renderer C). On occasion, Renderer B received shipments of over-production from Renderer A in northern Alberta. The Saskatchewan mill received all of the MBM it processed from Renderer D in Saskatchewan.

Feeds of interest

Medicated Calf Ration

A medicated calf ration was available from the infected cow's birth (March 21, 1998) until the herd went to pasture that spring (end of May 1998). This high protein ration

was formulated with MBM until the introduction of the feed ban. Sales receipts, reports and practices indicated that it was manufactured by Feed Mill I after the ban and specifically for the farm of origin.

Creep Feed

The creep feed was a cheap protein formulation that was available briefly in September 1998. One tote bag was purchased but subsequently discarded after one animal bloated and died. This feed had never contained MBM in its formulation: protein was often supplied in the form of grain screenings. The use of MBM in a ration of this nature would have been cost-prohibitive. Sales receipts, reports and practices indicated that this ration was manufactured by Feed Mill I after the ban and specifically for the farm of origin.

Mineral Supplements

A Cattle Range Mineral and a High Magnesium Mineral were available on summer pasture during 1998. These formulations were not designed to provide protein and were manufactured using grain millings or screenings. In addition, use of MBM in a mineral would have been cost-prohibitive. Although details cannot be confirmed because feed mill records are no longer available, it is suspected that the minerals were manufactured in Saskatchewan by Feed Mill J.

Based on the feed practices on the farm, it is less probable the index cow consumed the five remaining formulations during the first year of her life. Three were from Feed Mill K, which did not manufacture animal feed with MBM before 2002. The additional two (a mineral supplement and a cat food) were manufactured in mills (Feed Mill L and Feed Mill M) that did not handle MBM.

Although the evidence collected would indicate that the feed sources were manufactured after the feed ban, actual manufacturing records were no longer available. Therefore, the possibility that the feed was manufactured before the feed ban cannot be excluded.