2012 Review of the Enhanced Feed Ban

***Disclaimer*: This document is a review of the Canada's Enhanced Feed Ban. The intent of this document is to undertake and complete a full review of the enhancements to the feed ban regulations, including an assessment of the merits of continuing to exclude the full list of specified risk materials (SRMs) from feed. The facts and figures contained herein were derived from various sources and may include some inaccuracies and/or deficiencies. The authors make no representations of any kind concerning the accuracy or suitability of the information contained herein for other purposes.**

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LIST OF ABBREVIATIONS

AAFC	Agriculture and Agri-Food Canada
AEB	Audit and Evaluation Branch
BSE	Bovine Spongiform Encephalopathy
BVCRT	Beef Value Chain Roundtable
CFIA	Canadian Food Inspection Agency
CMC	Canadian Meat Council
DRG	Dorsal Root Ganglia
DPR	Departmental Performance Reports
EAC	Evaluation Advisory Committee
EFB	Enhanced Feed Ban
EU	European Union
FDA	Food and Drug Administration
HC	Health Canada
OIE	World Organisation for Animal Health
OTM	Over Thirty Months of Age
PHAC	Public Health Agency of Canada
PM	Prohibited Material
RIAS	Regulatory Impact Analysis Statement
RPP	Report on Plans and Priorities
SIP	Slaughter Improvement Program
SRM	Specified Risk Material
SWIP	Slaughter Waste Innovation Program
TB	Treasury Board
TBS	Treasury Board Secretariat
TSE	Transmissible Spongiform Encephalopathy
UK	United Kingdom
U.S.	United States
USDA	United States Department of Agriculture
UTM	Under Thirty Months of Age
vCJD	Variant Creutzfeldt-Jakob Disease
WTO	World Trade Organization

For a list of definitions related to terms such as “standards set by the World Organisation for Animal Health” or “classical versus atypical BSE,” please refer to *Annex 1: List of Definitions*.

EXECUTIVE SUMMARY

Context of the Enhanced Feed Ban 2012 Review

Following the implementation of the 2007 Enhanced Feed Ban (EFB), an initial review was undertaken by the EFB Preliminary Implementation Review Working Group, to investigate opportunities to reduce costs in the packing sector. The working group included government and industry stakeholders. In December 2007, this working group recommended to carry out and complete a full review of the enhancements to the feed ban regulations five years post-implementation in 2012, including an assessment of the merits of continuing to exclude the full list of specified risk materials (SRMs) from feed. To accomplish this task, the Canadian Food Inspection Agency (CFIA) proposed a two-step approach, which included undertaking the EFB 2012 Review in the short term and developing Canada's Bovine Spongiform Encephalopathy (BSE) Roadmap in the long term.

The EFB 2012 Review has been developed to fulfill this commitment using the best-available data and scientific knowledge. Stakeholders' views were also considered as essential to the review. To seek these views, a short-term basis committee, the Ad Hoc Advisory Committee on the EFB 2012 Review, was created in January 2013. Membership of that committee included representatives from government departments, as well as other organizations. The Committee met four times from February 2013 to June 2013. In addition, during the fall of 2013, a broader consultation with stakeholders was undertaken through the Beef Value Chain Round Table and the Canadian Council of Chief Veterinary Officers.

Program Overview

The CFIA began enforcing an initial set of feed ban regulations in 1997. However, the focus of this review is the enhanced feed ban regulatory framework that took effect in 2007, following the detection of BSE cases in Canada. The EFB addressed the prevention of opportunities for cross-contamination or cross-feeding of ruminants with prohibited proteins. To provide further animal health protection, SRM was also banned from all animal feeds, pet foods, and fertilizers. The main objective of the EFB was to accelerate Canada's progress in BSE management by preventing more than 99% of potential infectivity from entering the feed system and by enhancing risk management of transmission of BSE in the cattle herd. These efforts and many other BSE-related initiatives contributed to Canada obtaining the World Organisation for Animal Health (OIE) classification of a "controlled BSE risk" country.

Assessments

Analysis of the number of Canadian BSE cases in the context of birth year shows that the situation has generally improved since 2004, as no case born after that year has been detected. However, the disease is known for its long incubation period; therefore, information accumulated for cattle born after 2004 has not yet been finalized. The earliest year for Canada to qualify as an OIE "negligible risk" country for BSE is determined, in part, by the youngest cohort in which BSE was found. For Canada, this is 2016.

However, this outcome must be considered as the best case scenario. If Canada were to scale back from a full to a partial SRM ban at this time, it would be when insufficient evidence has been accumulated through ongoing surveillance to convincingly demonstrate that the SRM ban has achieved its intended objective.

The CFIA has increased inspection capacity and frequency throughout the feed supply and use chain since the implementation of the feed ban and the EFB. The Agency has also implemented and administered a system of control permits and inspection activities at dead stock collectors, landfills, and other processing and disposal sites regarding the collection, transport, treatment, and disposition of cattle SRM tissues. Different strategies are used to assess compliance and action is taken on any identified non-compliance.

SRM use in Canada remains in the early stages of market development. Currently, over 90% of total SRM is being confined in Canadian landfills, with no conversion into valuable product. This results in increased costs to cattle producers and a decrease in international competitiveness. Since the EFB, many initiatives that aim at reducing SRM confinement have been explored. Canada's current effort to support the SRM disposal initiatives is beginning to show tangible benefits to the beef industry. While these projects have clearly demonstrated the capacity to divert the majority of SRM from landfills, two of the locations are in Eastern Canada where only 33% of the national SRM is generated. To note, these technologies require a minimum volume of organic material to operate at an optimum level of profitability. This situation is identified as a potential project risk, as the net savings would be significantly reduced due to low volume of SRM for processing.

Given the nature of Canada's feed ban, which does not lend itself to permit definitive testing with currently available methodologies, surveillance becomes the only tool available to confirm that Canada has an effective feed ban. For this reason, maintaining an adequate surveillance program is crucial and is why the federal government and other stakeholders have invested heavily in surveillance within the last two decades. However, relying on surveillance to confirm that Canada has an effective feed ban leads to a time lag, which is a direct result of the length of time from when an animal is exposed and becomes infected with BSE, to when it can be detected using currently available tests. On average, this takes about five to six years. As a result, monitoring the cattle population for BSE, at a level of sufficient intensity to gather the evidence required, is a long-term commitment. To address a recent downward trend in the number of cattle tested, the federal government and various stakeholders have put in place an integrated and collaborative surveillance approach through various collaborative forums.

Over the next couple of years and considering current trading partners, Canada could be one of the few in the top 10 beef exporting countries that remain in the OIE "controlled risk" category for BSE.

The incremental costs of the EFB (post-2006), borne by the industry, are an important aspect of the EFB that should be considered in the review. Information from the Canadian Meat Council (CMC) clarified certain costs borne by the industry; however,

determining whether these costs relate directly and only to the EFB requirements and/or to other aspects of the feed ban or SRM removal for food requires further analysis. Therefore, it is suggested to include a complete analysis of the incremental costs of the EFB (post-2006) as part of the recommendations in this review.

It is premature to assess the achievement of longer-term outcomes related to the EFB (i.e. its effectiveness), due to the long incubation period; that is, the time from an animal becoming infected until it first shows symptoms of the disease.

Alternative SRM Uses

This review has identified possible considerations for alternative SRM uses that require further investigation. A few of these originate from the 2007 EFB Working Group and are at various stages of implementation, and include the skull pilot project, modified backbone saw project, dorsal root ganglia (DRG) project (harvesting more meat from the vertebral column), and blood exports to the U.S. Other considerations, such as SRM compost for both land application and in road construction, have not been fully explored.

Outcome and Recommendations

Recommendation #1: Use the criteria that were developed during the review to analyze any potential alternative SRM uses and/or potential changes to the BSE programming, such as the ones discussed in the following recommendations. Criteria:

- Minimize existing risk pathways and avoid the creation of new risk pathways, including spill over into other susceptible species.
- Enhance Canada's OIE BSE status.
- Enhance domestic and international confidence, including market access into the U.S. and beyond.
- Be economically sustainable.
- Maximize harmonization with U.S. SRM regulations.
- Reduce regulatory burden.
- Be environmentally sustainable.
- Ensure that funding is available through the current Government of Canada budget for the BSE Program. If new funding from the Government of Canada is required, identify a new source of funding.

Recommendation #2: Analyze further the possibility of harmonizing the SRM list with that of the U.S., (i.e. a shorter SRM list) through the BSE Roadmap process within the coming year.

Recommendation #3: Conduct various analyses on the impacts of the EFB within the coming year by possibly updating the BSE risks and economic and trade analyses. To provide the required input into any updated analyses, working groups, comprising government and industry representatives, could be created to manage this project. There is a need to include the greater context of risk tolerance and risk management for BSE in the results of these reviews, which could perhaps be done in the context of the BSE Roadmap exercise. Funding sources would need to be discussed.

Recommendation #4: Further investigate how certain elements related to the EFB could be moved from various regulations to policy instruments to streamline the process for updating these elements without incurring extended waiting periods. This investigation could also be realized in the context of the BSE Roadmap expected to be completed in 2014.

In terms of the next EFB review, the committee recommends another review of the EFB post-2016, after the first opportunity for an adjustment to Canada's BSE OIE risk status.

1. CONTEXT OF THE EFB 2012 REVIEW

Following the implementation of the 2007 Enhanced Feed Ban (EFB), an initial review was undertaken by the EFB Preliminary Implementation Review Working Group, to investigate opportunities to reduce costs in the packing sector. The working group included representatives of the federal and provincial governments, as well as industry stakeholders. In December 2007, this working group made several recommendations, many of which have been implemented by the CFIA since then. One of these recommendations was to undertake and complete a full review of the enhancements to the feed ban regulations five years post-implementation in 2012, including an assessment of the merits of continuing to exclude the full list of SRMs from feed.

The Agency proposed a two-step approach in fall 2012, which included the development of the EFB 2012 Review in the short term and Canada's BSE Roadmap in the long term. The EFB 2012 review is the first step in the overall review of Canada's BSE program. The purpose of the BSE Roadmap will be to communicate to the general public and domestic and international stakeholders the Canadian long-term approach to BSE disease control. The roadmap will require a full review of all BSE programs in Canada (from both government and industry) and will consider all policy and regulatory options. Decisions regarding future BSE programming will need to be supported by strong scientific evidence, international standards, and stakeholder views.

1.1. Objectives of the EFB 2012 Review

Five years post-implementation of the EFB, the Agency is conducting a review of the enhancements to the feed regulations, including an assessment of the merits of continuing to exclude the full list of SRM from feed (2007–2012). This review also includes an assessment of financial costs, related activities/achievements, and a high-level description of the processes to evaluate potential options for the future.

The review does not include the restriction on SRM use in human food or in fertilizers. The CFIA's Fertilizer Safety Office carried out a review of SRM use in fertilizers and has developed a position in its issue paper on the "Risks and Considerations on the Use of SRM in Fertilizers" (summarized in Annex 3: "Summary of the Issue Paper on the Use of SRM in Fertilizers"). Existing SRM removal policies, as well as regulations put in place in 2003 prohibiting their use in human food, are not included in this review. Health Canada's current requirement is to remove all SRM from the food chain. The Minister of Health is responsible for setting food safety standards, which are reflected in regulations that are enforced by the CFIA. The EFB 2012 Review is organized as follows: Context of the EFB 2012 Review; Introduction; Current Situation and Update; Compliance with the EFB; Achievements: Sources, Processing and Disposal of SRMs; Monitoring BSE Prevalence in the Canadian Herd; International Trends and Trade; Incremental Costs of the EFB (post-2006); Internal CFIA Evaluation of the EFB; Alternative Uses of SRM;

Summary of Assessments; and Outcome and Recommendations. The review also includes several annexes.

1.2. Process to develop the EFB Review

The EFB 2012 Review has been developed with the best-available data and scientific knowledge. Stakeholders' views were also considered as essential to the review. To seek these views, a short-term basis committee, the Ad Hoc Advisory Committee on the Enhanced Feed Ban 2012 Review, was created in January 2013. This committee provided strategic direction and expert input on the development of the EFB 2012 Review document, as well as recommendations to the CFIA about potential program efficiencies and changes to the related programs, policies, regulations, etc. These recommendations will also inform the path forward for BSE management, including possible harmonization with the U.S. SRM regulations and/or goals for Canada with respect to its OIE BSE-risk status.

Membership to the Ad Hoc Advisory Committee included representatives from other federal government departments (Department of Foreign Affairs and International Trade; Market Access Secretariat – Agriculture and Agri-Food Canada; Health Canada), provincial governments, and industry. The Ad Hoc Advisory Committee on the Enhanced Feed Ban 2012 Review met four times from February 2013 to June 2013.

In addition to the members of the committee, the CFIA has consulted with broader industry stakeholders and other government departments. This broader consultation took place in the fall of 2013. The review was finalized without significant changes from the draft used for consultation.

2. INTRODUCTION

2.1. Program Overview

As stated in the CFIA's 2011–2012 Departmental Performance Report (DPR)[1], the Agency began enforcing an initial set of feed ban regulations in 1997. To limit BSE spread among cattle, the Government of Canada banned most mammalian proteins, including SRM, from ruminants feed, in 1997. (There are certain exceptions, including pure porcine and equine meal, which can be legally incorporated into ruminant feed.)

At that time, these new regulatory requirements were integrated into existing inspection programs for feed and feed ingredient manufactured, distributed, and used by inedible rendering plants, commercial feed mills, and on farms.

[1] CFIA's 2011-2012 Departmental Performance Report http://www.inspection.gc.ca/about-the-cfia/accountability/reports-to-parliament/2011-2012-dpr/eng/1348777953917/1348778053447 (accessed on December 31, 2013).

The Government amended the federal *Food and Drug Regulations* and the *Health of Animals Regulations* to define and ban SRM from human food in July 2003. This was the single most important step that could be taken immediately following BSE detection to protect public health. In those amendments, the list of tissues, defined as SRM, that are required to be removed from the human food supply are as follows: skull, brain, trigeminal ganglia, eyes, tonsils, spinal cord, and dorsal root ganglia of cattle over thirty months of age (OTM), and the distal ileum (portion of the small intestine) of cattle of all ages. As of the beginning of 2006, the Government of Canada had implemented several new or enhanced measures with respect to human food safety, animal traceability, and BSE surveillance in the cattle population.

The CFIA received additional funding in 2005–06 and subsequent fiscal years to support implementation and enforcement of an EFB regulatory framework that took effect in 2007, which is the focus of this review. More specifically, the Agency received an additional $241 million from 2004–05 to 2013–14 and $26.6 million per year ongoing, as stated in CFIA's 2013–14 Estimates Report on Plans and Priorities (RPP)[2].

The EFB in 2007 addressed the following: the prevention of opportunities for cross-contamination or cross-feeding of ruminants with prohibited proteins. To provide further animal health protection, SRMs, as of July 12, 2007, were also banned from all animal feeds, pet foods, and fertilizers.

These efforts and many other BSE-related initiatives contributed to Canada obtaining the OIE classification of "controlled BSE risk" country. For more information on this classification, please consult Annexes 1 and 2. Annex 2, entitled "2006 RIAS Background," includes background information from the *2006 Regulatory Impact Analysis Statement (RIAS) on the Omnibus Regulation that Strengthened Canada's Safeguards against Bovine Spongiform Encephalopathy (BSE)***.**

As a result of these initiatives, the following federal regulations now address the SRM removal from feed and constitute the legislative framework for the feed ban and EFB:

- ***Health of Animals Act (HAA)* and *Health of Animals Regulations (HAR)*:** Regulate various activities, including oversight related to SRM removal from food and feed and use of prohibited material along with, for example, the feeding of certain animals. More specifically, the list of SRMs is detailed in section 6.1 of the HAR. Sections 6.2 to 6.22 specify how the SRMs should be handled during and after slaughter. Sections 6.3 and 6.4 list additional restrictions related to the export, transport, destruction, etc., of SRMs.

  Subsection 6.5(1) stipulates that: "…no person shall feed to any animal material in any form – whether or not incorporated into another thing — that is derived from specified risk material…" Part XIV of the HAR is about the food for ruminants,

[2] CFIA's 2013–14 Estimates Report on Plans and Priorities http://www.inspection.gc.ca/about-the-cfia/accountability/reports-to-parliament/2013-14-rpp/eng/1360599842184/1360600011529 (accessed on December 31, 2013)

livestock and poultry, rendering plants, fertilizers and fertilizer supplements. This includes section 162, which describes what is prohibited material: "… means anything that is, or that contains any, protein that originated from a mammal, other than (*a*) a porcine or equine; (*b*) milk or products of milk; (*c*) gelatin derived exclusively from hides or skins or products of gelatin derived exclusively from hides or skins; (*d*) blood or products of blood; or (*e*) rendered fats, derived from ruminants, that contain no more than 0.15% insoluble impurities or their products. (2) Prohibited material that has been treated in a manner approved by the Minister to inactivate the agents that cause transmissible spongiform encephalopathies is no longer prohibited material." Section 164 states that "No person shall feed prohibited material to a ruminant." Sections 165 to 171 list other restrictions related to rendering plants, fertilizers and fertilizers supplements.

- ***Feeds Acts* and *Feeds Regulations***: govern activities related to feeds such as registration, labelling, etc. In terms of SRMs, the *Feeds Regulations* specify in section 19 the various restrictions about what feed shall not contain. Paragraph 26(1)(*i*) also states restrictions about labelling: "if the feed is or contains prohibited material, as defined in subsection 162(1) of the *Health of Animals Regulations*[3], the following statement written legibly, indelibly and conspicuously: "Feeding this product to cattle, sheep, deer or other ruminants is illegal and is subject to fines or other punishment under the *Health of Animals Act*[4]…"

Other aspects of SRM removal is covered under other acts and regulations. SRM removal from food is regulated by the *Food and Drugs Act*, *Food and Drugs Regulations*, and the *Meat Inspection Act* and *Regulations*. The *Fertilizers Act* and the *Fertilizers Regulations* regulate SRMs in the content of fertilizers.

2.2. EFB Objectives

The main objective of the EFB is to accelerate Canada's progress in BSE management by preventing more than 99% of potential infectivity from entering the feed system, as well as to enhance risk management of BSE transmission in the cattle herd. In other words, the EFB regulations are intended to ensure that SRM, which has been excluded from the human food supply since July 2003, is also excluded from animal feed, pet food, and fertilizers. The regulations are designed to minimize the opportunities and consequences of cross-contamination that may arise during feed production, transport, storage, and end use, as well as potential misuses in animal feed, pet food, and fertilizer by segregating SRM and redirecting it to disposal, destruction, or for an alternative use that would not, or that would unlikely, result in BSE spread in Canada.

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[3] Justice Laws Website, Health of Animals Regulations (C.R.C., c. 296), http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.%2C_c._296/ (accessed on December 31, 2013).

[4] Justice Laws Website, Health of Animals Act (S.C. 1990, c. 21), http://laws-lois.justice.gc.ca/eng/acts/H-3.3/ (accessed on December 31, 2013).

To this end, the EFB aims to

- strengthen animal feed restrictions through amendments to the relevant regulations;
- ensure compliance with control measures around prohibited material and SRM removal; and
- increase the level of verification and confidence that SRM is segregated from feed, fertilizer, and pet food, and that prohibited materials are not fed to ruminants.

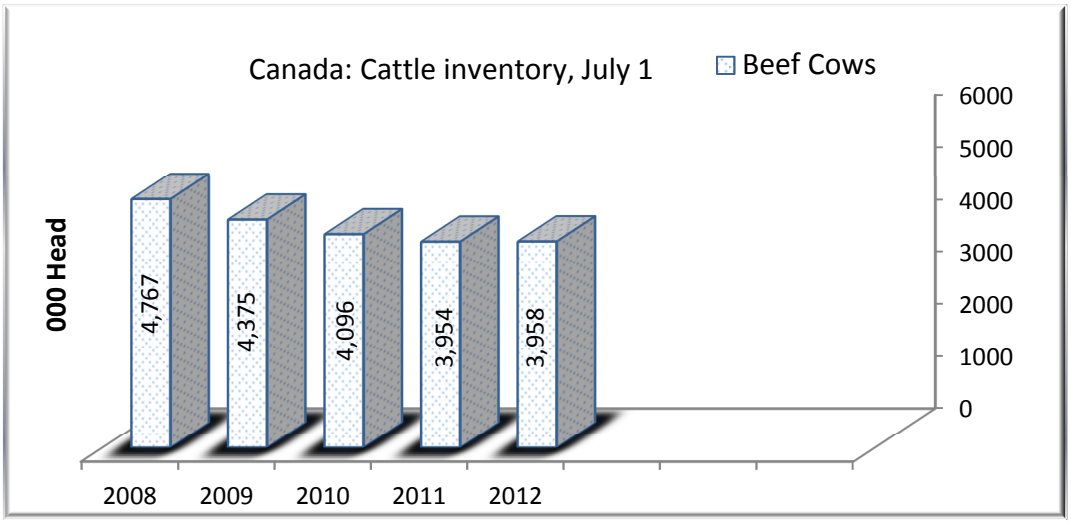
3. Current Situation and Update

Since 2006, the situation related to BSE and EFB has evolved.

3.1. Update on Cattle Inventories in 2012

From an industry perspective, recent data on cattle number suggest some stabilization. For instance, the total cattle inventories on July 1, 2012 are virtually unchanged from the 2011 level, confirming that the sector has now stabilized after many years of decline. In terms of cattle inventories, the data included in Figure 1, released by Statistics Canada on July 1, 2012, show an increase in the number of beef cows for the first time in seven years. Though small, this expansion, coupled with a continued increase of 3.5% in the number of heifers retained for beef cow replacement, suggests the cattle sector may soon move toward a new rebuilding stage. Cattle prices have remained at high levels throughout 2012, well above the average levels of previous years.

FIGURE 1. **Canada's Cattle Inventory (Beef Cows) as of July 1, 2012**



Source: Statistics Canada

3.2. Update on Number of BSE Cases

From 2003–12, there was a total of 19 cases of BSE found in Canadian cattle, with the latest case detected in February 2011 in a dairy cow born in 2004 (Table 1). Of those, 12 were born 3 or more years after the 1997 feed ban. Such animals are referred to as BABs (born-after-the-ban). Post-2007, there were seven cases of BSE found in Canadian cattle.

Of Canada's BSE cases, 17 (10 dairy, 3 beef-cross, 4 beef) were the "classical" type of BSE (C-BSE), the form responsible for the vast majority of cases in most BSE-affected countries. The other two cases, beef cattle detected in 2006 and 2007, were "atypical" cases. These animals were significantly older, and the abnormal prion's biochemical characteristics differed slightly from that of the classic form. Note that, in July 2007, the UK Spongiform Encephalopathy Advisory Committee (SEAC) suggested that atypical BSE may be a distinct strain of prion disease. Unlike typical (classical) BSE, cases of atypical BSE, according to SEAC, may arise spontaneously, although transmission through feed or the environment cannot be ruled out. Recently reported French surveillance data support this theory that, unlike typical BSE, atypical BSE appears to represent sporadic disease.

TABLE 1. **Number of BSE cases confirmed in Canada, 2003–12 (all cases were found in animals born before the 2007 EFB)**

Year	Number of Cases*
2003	2
2004	0
2005	2
2006	5
2007	3
2008	4
2009	1
2010	1
2011	1
2012	0

Source: CFIA Website[5]

*The date of birth of the affected animal, and not the year of detection, is the critical factor. No cases were born after 2004.

[5] CFIA, BSE Enhanced Surveillance Program http://www.inspection.gc.ca/animals/terrestrialnimals/diseases/reportable/bse/enhanced-surveillance/eng/1323992647051/1323992718670 (accessed on December, 31, 2013)

3.3. Possible Ascension to OIE Negligible Risk –Category I

Although the OIE considers a number of factors when determining whether a country qualifies as negligible risk for BSE, the required time frame is essentially determined by the most recently affected birth cohort. As a result, the earliest that a country can qualify, all other factors being satisfied, is 11 or more years after this cohort.
In Canada's case, considering that BSE cases were found in cattle born as recently as 2004, the earliest Canada could be considered for negligible risk would be 2016.

Accordingly, Canada has implemented several longstanding BSE mitigating measures that are internationally recognized to protect the health and safety of Canadians and animal health, including the requirement that SRMs be excluded from both the food and feed chains and diverted to disposal or destruction. Further, Canada has maintained a surveillance program since 1990, which demonstrates the effectiveness of BSE-mitigating measures.

3.4. Assessing BSE Risk in Animals in Canada

3.4.1. Comparing a Full Versus Partial SRM ban

In 2004, as part of the response to an International Panel's report following the detection of BSE in an indigenous cow in Canada in May 2003[6], a model was developed to assist in determining the impact of excluding SRM from the animal feed chain on the subsequent evolution of BSE. The model, however, did not attempt to predict the absolute incidence of BSE in Canada. Although the results indicated that a partial SRM ban – excluding dead stock, downers, brains, and spinal cords from the feed chain – would likely be almost as effective as excluding all SRM or all meat-and-bone meal (MBM) from the animal feed chain, other factors, such as the emergence of new information or developing circumstances, must be considered in reaching a final decision. These factors underscore the complexity of the policy environment surrounding BSE.

3.4.2. Challenges Facing Canada – EFB Implementation

Although Canada's feed ban, prior to the 2007 enhancements, was likely to lead to the eventual eradication of at least the classic form of BSE (C-BSE), the rate of progress was anticipated to be slower than with the enhancements, based on experiences gained in the UK and elsewhere. Following the introduction of the feed ban in Canada in 1997, it was almost certain that the feed containing ruminant MBM would have remained in the cattle feed system for some time before being exhausted, similar to what occurred in the UK. In addition, similar risk factors associated with cross-contamination in rendering plants, feed mills, and during the transportation of ruminant feed, together with accidental or

6 Kihm U, Heuston W, Heim D, MacDiarmid S. 2003. Report on actions taken by Canada in response to the confirmation of an indigenous case of BSE (available upon request).

deliberate cross-feeding on farms on which multiple species are raised, were likely to exist.

At the time of EFB implementation in 2007, Canada was facing enormous challenges in convincing key trading partners, including Korea and Japan, that BSE was being effectively controlled. The ongoing detection of even a small number of BSE cases that were born a few years after the 1997 feed ban, referred to as BABs, was seen as evidence by some that Canada's feed ban was ineffective.

This was underscored by the OIE itself when assessing Canada's BSE status in 2007 under the new categorization system. It characterized Canada's feed ban as being "*partial*[ly] *implemented,*" based on a consideration of the "*absence of a prohibition on the use of specified risk material for animal feed,*" "*the limited capacity of the rendering practices within Canada to reduce the infectivity*" together with "*the absence of sampling and testing in the framework of the control and audit of the feed ban.*" The OIE concluded that Canada's feed ban was "*allow[ing] the risk of recycling and amplification of the BSE agent within the country.*"

Fortunately, Canada could indicate that a full SRM ban would be implemented from July 2007, countering the OIE's concerns that "*as long as potentially infective material continues to be rendered and enters the animal feed chain there remains the potential for cross-contamination.*" Against the backdrop of the BABs and the concerns surrounding the limited impact of rendering, as practised in Canada, on BSE infectivity, together with the lack of a feed-testing program, the impending SRM ban and the surveillance results, depicted through a birth cohort analysis,[7] were the key factors when the OIE categorized Canada as a controlled-BSE risk in May 2007.

The type of rendering process, or the actual parameters employed, are not regulated under Canada's feed ban. As noted in Canada's original submission to the OIE in January 2007, the impact on BSE infectivity, both currently and historically, are likely to range from no reduction in infectivity for those facilities rendering under vacuum conditions to up to a 95% (~1.4 log) reduction where continuous atmospheric systems with added fat are employed. As reported to the OIE, six facilities were handling both prohibited and non-prohibited material in 2005. They accounted for about one-third (34%) of all the raw material processed in that year. Given the amounts of raw material they each processed, approximately 60% would have been rendered under vacuum conditions, where it is unlikely that any reduction in infectivity would be achieved. Although we now know that the assumption that rendering would likely reduce infectivity from 90%–99% in the original modelling work undertaken in 2004, based on information available at the time,

[7] Since the vast majority of BSE cases are likely to have been infected in their first year of life, their year of birth or birth cohort is widely accepted as a surrogate indicator of when they were exposed to the BSE-agent. As a result, a birth cohort analysis is used as a measure of the likely level of exposure to BSE infectivity in the cattle population. It is a powerful tool that enables trends in exposure to be monitored over time enabling the effectiveness of a feed ban to be assessed. It is much more informative than a simple tally of the number of cattle tested or OIE points acquired.

was overly optimistic, the results comparing the relative impact of the various options explored remain valid.

In granting Canada controlled BSE-risk status, the OIE "recommended that Canada carefully consider sampling and testing within the framework of control and audit of the … feed ban." The CFIA subsequently weighed the merits of testing, but given the nature of Canada's feed ban – with its exceptions that allow MBM from pigs and horses, as well as blood from ruminants to be incorporated into ruminant feed – all tests (historical and currently available) were unable to sufficiently discriminate between prohibited and non-prohibited materials. As a result, it would be impractical to implement a meaningful testing protocol, as there would be too many inconclusive results.

3.4.3. How BSE Surveillance Informs Estimates of Effectiveness of Feed Ban

The ongoing results of Canada's BSE surveillance program confirm that the occurrence of a limited number of BSE cases born several years after the 1997 feed ban, referred to as BABs,[8] do not indicate that the feed ban is failing, nor do they indicate a likely resurgence in the epidemic. Rather, they provide evidence of a limited level of recycling of infectivity that is most likely associated with cross-contamination of cattle feed with ruminant MBM during feed manufacture, storage, transport, or feeding on-farm. This has also been the experience of many other BSE-affected countries and has led to the implementation of increasingly stringent feed bans, ranging from a complete ban on processed animal protein (PAP) in feed for any animals farmed for the production of food, similar to Europe and Japan, to a more measured risk-based response that has been adopted in Canada, whereby SRMs are excluded from all non-ruminant animal feeds (both terrestrial and aquatic).

With enhancements to Canada's feed ban, from July 2007, to exclude SRM from the entire terrestrial and aquatic animal feed chains, it would be reasonable to conclude that the potential consequences of cross-contamination that inevitably arise during feed production, transport, storage and end use, as well as potential misuses should have been virtually eliminated. As a result, even those limited opportunities for recycling of infectivity, leading to a small number of BABs that have occurred in the past, should no longer pose a risk. At this stage, given the protracted incubation period of BSE, it is too early to convincingly demonstrate that this is the case. It takes five to eight years of accumulated surveillance results for any one birth cohort to gather sufficient evidence that a control measure is achieving its intended objective. So it is only from 2013 that sufficient evidence is beginning to be accumulated for the 2008 birth cohort, which is the first cohort born after the EFB.

[8] As of June 2013, 12 of Canada's 19 BSE cases were born several years after the 1997 feed ban and are in the following birth cohorts: 2000 (3), 2001 (3), 2002 (3), 2003 (1), and 2004 (2).

3.4.4. Implications Associated with Atypical BSE

With the discovery of atypical BSE strains from 2003 in several European countries, Canada, the United States, Japan, and most recently Brazil, it is more than likely that BSE can never be truly eradicated. Atypical strains are likely to represent a spontaneous form of BSE, akin to sporadic Cruetzfeldt-Jakob (sCJD) in the human population, perhaps arising at a similar rate of approximately 1–2 per million. Evidence is mounting that atypical strains are likely to have been the precursor of C-BSE, which has been responsible for the vast majority of cases reported in BSE-affected countries. The United States, Sweden, and most recently Brazil are notable exceptions, as these countries have reported atypical strains only (i.e. 3, 1, and 1 respectively). Ultimately, the discovery of atypical BSE underscores the importance of maintaining some form of a feed ban as the "new normal."

3.4.5. Navigating a Path Forward

It could be argued that the prevalence of BSE in Canada today is so low that it is difficult to justify continuing to exclude the full list of SRM from the animal feed chain, particularly considering the competitive disadvantage that the beef sector faces, relative to the United States where a partial SRM ban is in place. Concerns are expressed that Canada has invested heavily in excluding the full list without realizing sufficient benefits, particularly through expanded market access beyond the U.S. With this in mind, achieving negligible BSE-risk status is not seen as a priority. Balanced against this, others believe that it is premature to consider scaling back, particularly when the attendant consequences of a BSE case arising in an animal born after 2007 or of a case of variant Creutzfeldt-Jacob disease arising in a Canadian who has never travelled abroad could be devastating. From a technical perspective, risk has two elements, the likelihood of something happening and the likely magnitude of its associated consequences. In reality, there is a third element, a social/cultural component that influences how people perceive risk through, for example, their beliefs, attitudes, judgments, and feelings.

To conclude, assessing BSE risk in animals in Canada depends on many factors. The CFIA is a world leader in terms of risk assessment, which contributes to science-based regulations. Thus, any future changes to regulations need to be based on science.

3.5. Collaboration with Stakeholders

Canada's BSE Program, which includes the EFB, requires the collaboration of stakeholders from the private and public sectors. Ongoing communication among stakeholders is maintained through different mechanisms. One example is the Beef Value Chain Roundtable (BVCRT)**,** which was launched in January 2003 to foster collaborative industry–government action to secure an enduring competitive advantage for Canada in international markets. The BVCRT emerged as Canada's central organization for a coordinated, government–industry response to BSE. Since then, the BVCRT has focused

its attention on improving the sector's competitive position. The CFIA has participated many times at the BVCRT to present and discuss topics related to BSE and EFB.

3.6. Assessment

Since the first BSE cases were found in Canada, there have been significant efforts from stakeholders to control this disease. The federal government has amended a number of regulations, established new programs, and invested in various initiatives related to BSE. The industry and other stakeholders have also contributed significantly to these efforts.

The analysis of the number of BSE cases in the context of their birth year shows that the situation has generally improved since 2004, as no case born after that year has been detected. However, the disease is known for its long incubation period; therefore, information accumulated for cattle born years after 2004 has yet not been finalized, especially data from cohorts born after the introduction of the EFB in 2007. The earliest year for Canada to qualify as an OIE “negligible risk” country for BSE is determined, in part, by the youngest cohort in which BSE was found. For Canada, this is 2016. Nevertheless, this outcome should be considered as the best case scenario. Several factors could potentially affect this outcome, including possible identification of a BSE case in cattle born after 2004.

If Canada were to scale back from a full to a partial SRM ban at this time, it would be at a time when insufficient evidence has been accumulated through ongoing surveillance to convincingly demonstrate that the SRM ban has achieved its intended objective.

4. Compliance with the EFB

As stated in the CFIA’s 2011–12 DPR, the impact of implementing the enhancements to the feed ban principally involved:

- increasing inspection capacity and frequency throughout the feed supply and use chain (i.e. at inedible rendering plants, commercial feed mills, feed retail outlets, and farms). implementing and administering a system of control permits and compliance inspection activities at dead stock collectors, landfills, and other processing and disposal sites regarding the collection, transport, treatment, and disposition of cattle SRM tissues. As part of the enhanced regulations, SRM must be segregated, identified, and appropriately managed until final disposal. The CFIA’s workload increased to include inspection oversight of SRM equipment and facilities, tracking movement at several points in the chain, to final disposal or alternative use which was not historically subject to CFIA inspection.

During 2011–12, the CFIA maintained its marketplace monitoring program to verify compliance of fertilizers and supplements containing prohibited material (PM) with the requirements of the EFB.

This included the review of fertilizer and supplement labels for proper precautionary statements, record keeping and recall procedure verification to mitigate potential feeding to animals, and to ensure manufacturers, distributors, importers, and sellers could conduct an effective product recall if necessary. To address the potential use of SRM in fertilizers and supplements, the CFIA continued to issue permits, under the *Health of Animals Regulations*. Permit issuance was based on adherence to processing requirements (e.g. composting), as well as on conditions for final disposal (i.e. use on non-food non-feed and non-grazing land), to effectively mitigate any potential risks to human, animal health, and the environment.

During the 2011 calendar year, the CFIA continued to verify compliance with the enhanced 2007 regulatory framework at facilities along the animal food and production chain (i.e. at rendering plants, commercial feed manufacturers, feed retail outlets, on-farm feed manufacturers and ruminant feeders as well as at meat slaughter and processing establishments, cattle dead stock collectors, transporters and receivers of SRM, commercial composting and fertilizer manufacturing facilities).

4.1. Feed Industry – Context

The feed industry in Canada is more fragmented than in other countries, such as the U.S., given that there has been less consolidation. More specifically, in Canada, there are smaller mills across the country that service a broader spectrum of farmers. The feed industry in Canada is made up of primarily multi-species mills, whereas in the U.S., many mills are single species and/or integrated operations. This difference in context may have an impact on inspection work. For instance, inspectors may require more time for certain inspections. In this context, the CFIA uses a variety of strategies to assess compliance. For instance, the inspection rates are based on risk level.

4.2. Permits Regarding Cattle SRM Tissues

A total of 1226 permits were issued or renewed at cut-and-wrap establishments, dead stock collection sites**,** landfills, and other processing and disposal sites regarding the collection, transport, treatment, and disposition of cattle SRM tissues in the 2012 calendar year. In addition, inspection tasks were completed on a quarterly basis at cut-and-wrap plants that had a CFIA SRM permit. These tasks included the following: inspection of the documentation submitted with the permit application, site inspection, inspection of the operating procedures, inspection of equipment and cleaning.

The following provides some additional data that related to some of these permits, issued or renewed for specific activities in the 2012 calendar year:

- 789 permits were issued or renewed for the transport of cattle SRM tissues
- 147 permits were issued or renewed for the harvest of cattle SRM tissues
- 92 permits were issued or renewed for the salvage of cattle SRM tissues

- 27 permits were issued or renewed for landfill activities related to cattle SRM tissues
- 14 permits were issued or renewed for the dead stock collection of cattle SRM tissues

4.2.1. Compliance Data

The following sections include data related to the feed ban-related inspection in the 2011 calendar year.

4.2.2. Commercial Feed Mills

In 2011, 4843 tasks were assessed at 452 facilities under the *Health of Animals Act* and *Regulations.* More specifically, for commercial feed mills, the CFIA was present at 93% of all facilities at least once during the 2011 calendar year. The current inspection model includes routine inspection activities for all commercial feed mills across Canada. The following risk categories are identified for commercial feed mills:

- high risk – TSE: facilities that manufactured feeds, containing prohibited material (PM), and that manufacture ruminant feeds;
- high risk – medications: facilities that manufacture feeds containing medicating ingredients that have a withdrawal period at any use level OR that manufacture medicated feeds for multiple species or classes of animals;
- low risk – TSE: facilities that do not have both risk factors for TSE; and
- low risk – medications: facilities that do not have either risk factor for medicating ingredients (e.g. multi-species/class mill, using no medicating ingredients or single species/class mill, using only non-withdrawal drugs).

The inspection frequencies depend on the risk categories. For instance, the facilities considered as high-risk TSE and high-risk medications are inspected three times per year. For facilities in the high-risk TSE and low-risk medications and low-risk TSE and high-risk medications' categories, the inspection frequency is twice per year. Finally, the facilities included in the low-risk TSE and low-risk medications category are inspected once yearly. Examples of the tasks that were assessed are as follows:

- labels for feeds manufactured in the facility – PM;
- ingredient compliance – domestic and imported rendered products;
- feeds for further manufacturing containing PM;
- distribution records – ruminants, equines, porcines, chickens, turkeys, ducks, geese, ratites, or game birds;
- cross-contamination of manufacturing equipment with PM; and
- recall Procedures – *Health of Animals Regulations*.

As a result of these inspection activities, facilities may be found non-compliant with the requirements under the *Feeds Act* and *Regulations* and the *Health of Animals Act* and

Regulations. Table 2 provides an example of the results of these inspection activities, with the non-compliance data for commercial mills.

TABLE 2. **Non-Compliance Data for Commercial Mills in the 2011 Calendar Year**

	Number of Mills	**% of Mills** (total number of mills: 470*
Open Major Non-Compliance** (*Feeds Regulations*)	45	9.57%
Open Major Non-Compliance (*Health of Animals Regulations*)	12	2.55%
Total Open Major Non-Compliance (all Regulations) (Note: totals are slightly lower, because a few non-compliance cases included both regulations.)	52	11.06%

Source: CFIA 2011-12 DPR

Note: the non-compliance data has been taken at a certain point in time. This data is time-sensitive as it considers whether or not a corrective action request (CAR) (i.e. non-compliance) has been closed or not.

*Fall under CFIA's Inspection Program for both sets of Regulations.
**Open means the non-compliance was not resolved at the time of reporting; and "major" means the non-compliance is not administrative in nature. Major non-compliance includes situations in which: there is evidence of non-compliance; required records or written procedures are not available; or there are labelling violations related to the use of medication or prohibited material in feed.

4.2.3. Rendering Facilities

In 2011, 792 tasks were assessed at 47 facilities. The task delivery and compliance rate is 100%, which is a requirement of the permitting process. These are examples of the tasks that were assessed:

- labels for feeds manufactured in the facility – PM;
- production records – *Health of Animals Regulations;*
- raw material and finished product delivery vehicles' procedures – *Feeds Regulations* and *Health of Animals Regulations;*
- recall procedures – *Health of Animals Regulations;*
- dedication of SRM processing line procedures – *Health of Animals Regulations;*
- raw SRM transportation storage and receiving procedures – *Health of Animals Regulations;*
- fats rendered from SRM records – *Feeds Regulations* and *Health of Animals Regulations*; and

- storage transport and disposal of treated SRM procedures – *Health of Animals Regulations*.

4.2.4. Retail

In 2011, 2676 tasks were assessed at 534 facilities, which represented approximately 40% of the total number of facilities. The population of retail facilities is estimated at 1300. The inspection rate is based on a facility risk level. Facilities handling at least some feeds in bulk are to be inspected yearly. Facilities handling only packaged feeds are to be inspected once every three years. The following includes examples of the tasks that were assessed:

- labels for feeds manufactured in the facility – PM;
- feeds and feed ingredients for further manufacturing containing PM;
- distribution records – ruminants, equines, porcines, chickens, turkeys, ducks, geese, ratites, or game birds;
- cross-contamination of receiving, storage, handling, packaging, and disposal equipment with PM;
- conveyances distributing feed for the feed retail facility – PM; and
- recall Procedures – *Health of Animals Regulations*.

4.2.5. Farms

In 2011, 789 tasks were assessed at 185 facilities. The level of delivery is difficult to assess for farms, given that the population of farms was estimated at more than 200,000. Therefore, a risk approach is taken for compliance verification.
The selection of farms for inspection is based on survey work to assess risk level of farm. These are examples of tasks that were assessed:

- labels for feeds manufactured in the facility – PM;
- feeds for further manufacturing containing PM;
- retention of feed invoices;
- cross-contamination of manufacturing equipment with PM;
- conveyances transporting bulk feed and feed ingredients to the farm and/or distributing feed manufactured in the on-farm facility – PM;
- recall procedures – *Health of Animals Regulations*; and
- controls to prevent PM from being fed to ruminants.

4.3. Process for addressing Non-Compliance

The role of an inspector is to assess the compliance of regulated parties and products that are subject to requirements under the *Feeds Act* and *Feeds Regulations* and the *Health of Animals Act* and *Regulations.* The required action when a facility or product is found non-compliant depends on the regulated party's actions to correct the problem and the extent and the severity of the problem.

Inspectors must take immediate enforcement action when necessary to protect public or animal health. The inspector issues the regulated party a corrective action request (CAR). Usually, there is a CAR issued for each non-compliance case. This CAR identifies the non-compliance and requires the regulated party to implement corrective measures by

- providing an action plan; and
- effectively implementing the corrective measures, described in the action plan, by a specified date.

After completing a follow-up inspection, if the inspector identifies that the non-compliance has not been corrected, as required, and the CAR cannot be closed, the inspector initiates a management review of the file. At that stage further regulatory actions are considered.

4.4. Assessment

The CFIA has increased inspection capacity and frequency throughout the feed supply and use chain since the implementation of the feed ban and the EFB. The Agency has also implemented and administered a system of control permits and inspection activities at dead stock collectors, landfills, and other processing and disposal sites regarding the collection, transport, treatment, and disposition of cattle SRM tissues.

The feed industry in Canada is more fragmented than in other countries such as the U.S. This difference in context may have an impact on inspection work. For instance, inspectors may require more time for certain inspections. In this context, the CFIA uses different strategies to assess compliance. For instance, the inspection rate is based on risk level in some cases.

The Agency takes action on any non-compliance. The required action depends on the regulated party's actions to correct the problem and the extent and the severity of the problem.

The industry has demonstrated a good understanding of the consequences of BSE and has shown high compliance with the Canadian regulations.

5. ACHIEVEMENTS: SOURCES, PROCESSING, AND DISPOSAL OF SRMS

5.1. Advancements in Science and Technology

BSE infectivity agents (prions) exhibit a remarkable ability to resist deactivation and degradation. Prior to 2007, in preparation for the “entry into force of the enhanced feed

ban regulations," the CFIA's Science Branch performed risk assessments on a number of SRM disposal options.

The objective was to determine

- the residual level of BSE risk of transmission to domestic ruminants, posed by each of the SRM disposal options.
- whether the end product would require further disposal or could be released without restriction.

Two categories of SRM disposal, confinement and destruction, and their related methods were assessed:

- Three methods of SRM containment, including engineered landfills, natural landfills, and burial on non-contiguous premises, were established as presenting a negligible risk of BSE transmission to domestic ruminants.
- Three other methods related to destruction, namely incineration, thermal hydrolysis and alkaline hydrolysis, were also assessed, and it was determined that when operating under specific baseline parameters, these methods have the ability to inactivate the BSE agent. As a result, CFIA approved these three technologies as SRM destruction methods. The end product would not be subject to any further SRM regulatory controls.

Since July 2007, the vast majority of raw SRM is rendered at a CFIA-authorized facility, once all avenues for further segregation and salvaging are exhausted. The rendering industry extracts the tallow[9] as non-SRM, reduces the volume by two-thirds, and sends the remaining SRM, typically called "cracklings," to a CFIA-approved confinement site.

5.2. SRM Sources and Uses

5.2.1 Sources

SRM is predominantly sourced from slaughterhouses and on-farm bovine dead stock. Western Canada, with the highest SRM production capacity, generates 66%[10] of the national volume.

The beef-packing industry has undergone significant rationalization within the last five years, which has meant reducing the number of abattoirs by increasing the slaughtering

[9]The tallow must contain less than 0.15% of insoluble impurities.

[10]The percentage is taken from 2010 CFIA's SRM permit system.

capacity without affecting the overall slaughtering service. The closure of two major beef slaughtering facilities in Saskatchewan (Moose Jaw) and Quebec (Drummondville) created a situation wherein large volumes of SRM were no longer generated in these two provinces. Consequently, producers were forced to ship their cattle to Alberta and Ontario, respectively, where the slaughtering capacity has significantly increased. Nationally, this geographical redistribution of the SRM sources has resulted in the concentration of large SRM volumes into very restricted geographical areas and the reduction of raw SRM transportation.

5.2.2 Uses

SRM exploitation in Canada remains in the early stages of market development. Since the EFB came into effect, many initiatives that aim at reducing SRM confinement were explored. In 2010, and in conjunction with the Abattoir Competitiveness Program, the Government of Canada provided $25 million to help cattle slaughterhouses maintain critical slaughter capacity for OTM cattle, while the industry has undertaken efforts to become more innovative and competitive when dealing with SRM. A distinction is made between OTM and UTM cattle, because a larger set of tissues is defined as SRM within OTM cattle.

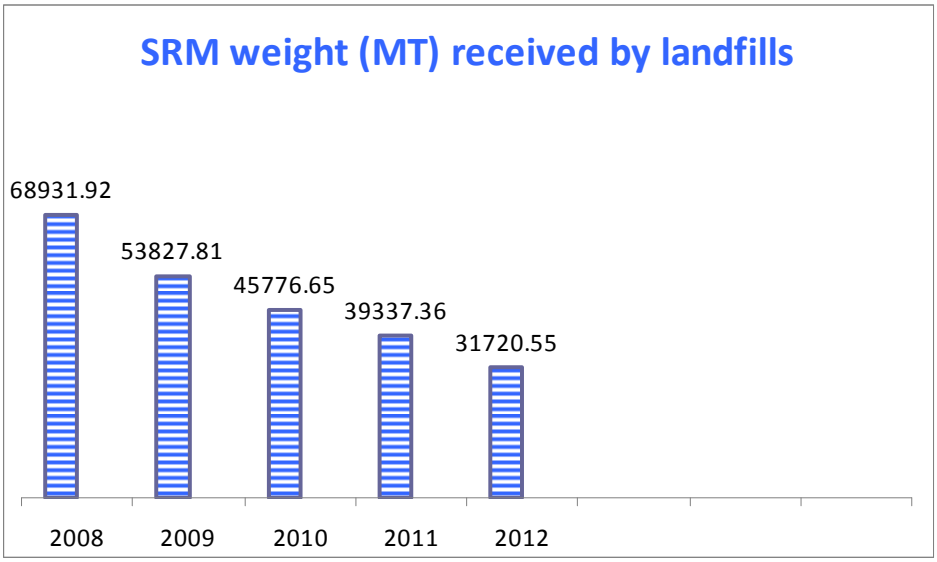
The categorization of at-risk tissues by age is primarily based on the level of infectivity. The latter is established upon observations of naturally occurring disease or primary experimental infection by the oral route.[11]

As a result, most of the salvaging and harvesting facilities reviewed their segregation protocols and then submitted their new SRM handling approaches to the CFIA for consideration. In 2011, CFIA staff recorded a significant increase in standard operating procedure updates by industry (which must be approved by the Agency for SRM permit renewal or amendment purposes), as well as in approval of new segregation methods.

Figure 2 shows the steady decrease of rendered SRM received by landfills. Up until 2010, there was no commercial scale for SRM destruction facilities in Canada, although few pilot plants and demonstration projects were in operation to test the viability of certain energy conversions of SRM (e.g. Biosphere Technologies Inc. in Lacombe, Alberta.)

[11] In cattle experimentally exposed by the oral route, BSE infectivity has been detected by mouse assay in the distal ileum through much of the disease course, from six months post exposure. Hence, the international scientific community recommended considering the distal ileum as SRM in cattle of all ages. The distribution of BSE infectivity in tissues, other than distal ileum tissues, has been mainly established from late in the incubation period. Therefore, it was recommended to consider additional tissues as SRM only in OTM cattle.

FIGURE 2 **National SRM Weight, recorded by the CFIA-Approved Rendering Plants and the receiving CFIA-Approved Landfill Sites**



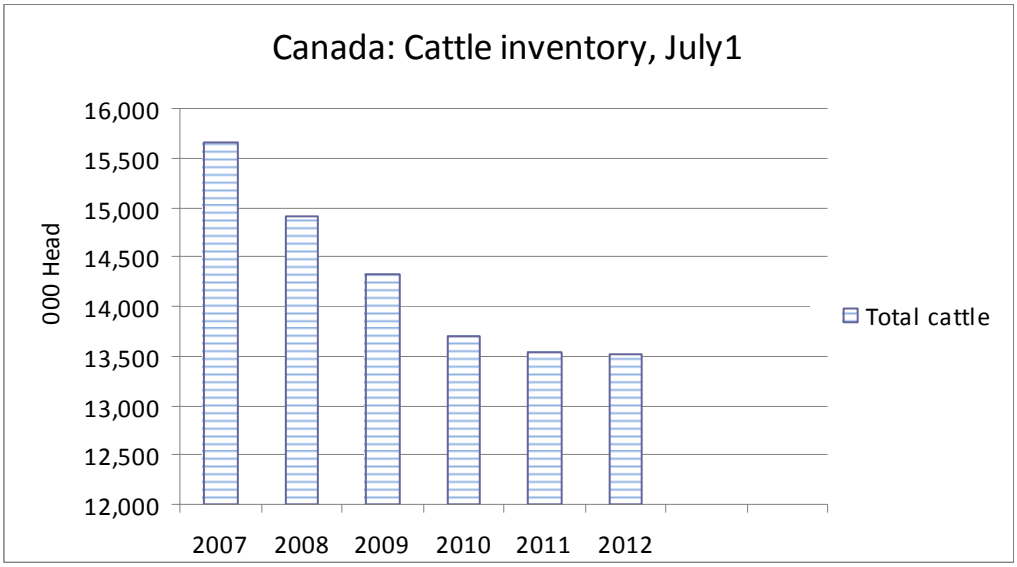
Source: CFIA SRM permit database

SRM Volume versus Cattle Herd Population. The annual SRM volume generated by the cattle industry is proportional to the cattle herd population, and correlates with the size of animals exiting this population annually via the slaughtering and death process.

Figure 2 demonstrates that the cattle cycle has been experiencing lower production numbers, with a marked and ongoing downward trend in the general cattle population.

The proportion of cattle exported to the U.S. reached its peak in 2008, with an average of 10% of the number of OTM and UTM cattle being exported to this country (Figure 3). At the end of 2010, exports reached 1,055,215 head, contributing to the decrease in the volumes of SRM generated domestically.

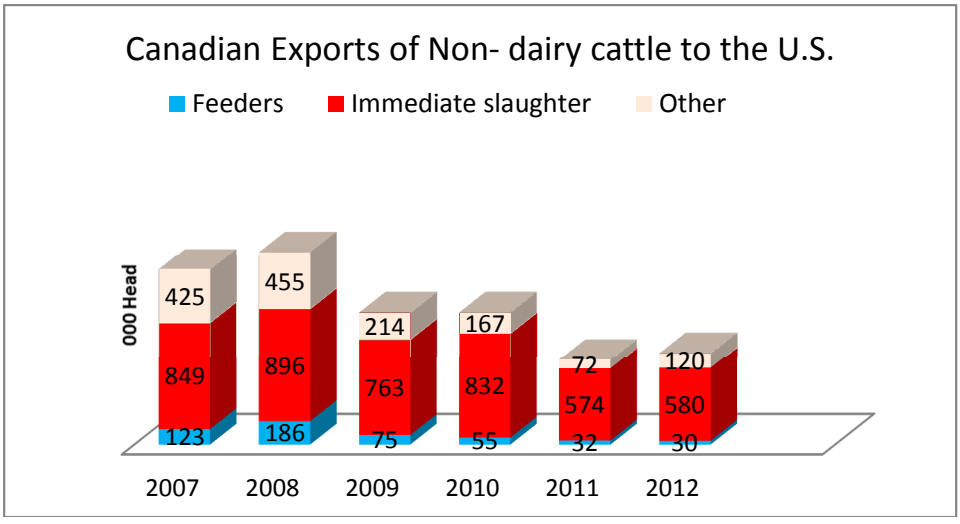
FIGURE 3. **Canada's Cattle Inventory (Total Cattle) as of July 1, 2012 (for each year in July)**



Source: Statistics Canada

The current year was differed in that, during the first half of 2012, exports of feeder cattle increased significantly by almost 46%, compared with the same period in 2011. This trend was curbed over the summer, when the prospect of a shortage of grains and high feed prices settled in the U.S., lowering the demand for feeder cattle, which remained in feedlots in Canada. It is forecasted that cattle exports will remain around 700,000 head, comparable with the levels recorded in the previous two years. Canadian cattle imports are estimated to be around 50,000 head per year. Figure 4 summarizes these export figures.

FIGURE 4. **Canadian Exports of Non-dairy Cattle to the U.S.**



Source: Statistics Canada

5.3. SRM Processing Technologies and Value-Added Potentials

In September 2010, the Government of Canada launched the Slaughter Waste Innovation Program (SWIP) – a three-year $40 million program, funded under the Economic Action Plan – to encourage the real potential of the cattle industry and to capitalize on the knowledge, experience, and technology advancement that were achieved while dealing with the first three years of the EFB. The SWIP provided industry with the ability to move toward implementing longer-term solutions to potentially improve the competitiveness of the sector.

Three major SRM destruction projects that were funded under the SWIP are being implemented across Canada:

- Project 1: gasification system
- Project 2: biomass boiler
- Project 3: fluidized bed boiler

The anticipated SRM destruction capacity of these projects is estimated at 88.000 metric tonnes (MT) of SRM.

The technology for the three projects is based on incineration. The CFIA has approved incineration as a method of destroying any form of SRM, provided it operates at a temperature ≥ 850°C for the period of time that is required to reduce all organic material inputs to ash. The required residency time varies, depending on the size and nature of the organic material inputs used in each particular scenario.
In addition to its ability to inactivate prion, the gasification process supplies a rendering plant with energy in the form of heat. This renewable energy substantially reduces the current consumption of natural gas by the rendering operation. The resulting ash material has value as a fertilizer for land application or as fly ash for cement making.

Similarly, the biomass boiler and fluidized bed boiler projects generate energy, but in the form of steam.

While these promising projects have clearly demonstrated the capacity to divert the majority of SRM from landfills, two are located in Eastern Canada where only 33% of the national SRM is generated. In other words, the newly built facilities in the East will have to compete for a volume of SRM "cracklings" that does not exceed MT 20,000. The costs related to SRM handling in the East have already begun decreasing by nearly 50%. Clearly, these technologies require a minimum volume of organic material to operate at an optimum level of profitability.

This situation may change soon, with the recent announcement that a $32 million biorefinery, located in the city of Lacombe in the heart of Alberta's diversified livestock region, will proceed and, in fact, be operational by 2014. The Lacombe biorefinery project will serve as the first full demonstration facility for the BioRefinex technology, which destroys infectious proteins in organic waste, including BSE, converting it into fertilizer. Though not a compost system, BioRefinex can handle organics that have a

moisture content and that are relatively clean of contaminants. The plant will use thermal hydrolysis to break down organic waste into safe and usable by-products.

5.4. Federal Investments

The challenges and costs that are associated with SRM and the EFB for the processing industry – in particular for those who handle OTM cattle – have been identified as barriers to competitiveness. Since introducing the EFB in 2007, the Government of Canada has provided several financial incentives for processors to assist with costs associated with SRM removal and disposal. This document details these federal programs, which are all managed by AAFC.

5.4.1 Slaughter Waste Innovation Program (SWIP)

The SWIP, ending March 31, 2013, provided industry with the ability to capitalize on the knowledge, experience, and technology advancement, achieved while addressing the first three years of the EFB, and to move toward implementing longer-term solutions to potentially improve the competitiveness of the sector.

The objective of SWIP was to support research, development, and commercialization or adoption of innovative technologies or processes related to the removal, disposal, or SRM use to reduce handling costs and/or to create potential revenue sources from SRM.

The program provided contributions of up to $10 million or 50% of eligible costs, whichever was less. The contributions were a combination of repayable, conditionally repayable, and 50% non-repayable loans. The contributions may be non-repayable for research and development, or a portion may be conditionally non-repayable, dependent on levels of company profitability and whether the project involves the destruction of prions. The percentage of non-repayability would be determined according to a project merit scoring process that would attribute the highest points to projects (and highest percentage of non-repayability) that

- involve complete destruction of prions;
- treat the highest volumes of SRM; and
- create or preserve SRM handling capacity for a region that would otherwise not be served through the reduction of SRM handling costs and/or creation of potential revenue sources from SRM, as an outcome.

SWIP supported the development and commercialization of various systems such as the biomass boiler at Sanimax in Quebec, the boiler system at Cargill in Alberta, and the gasification unit at Atwood Resources in Ontario, all of which utilize SRM to provide energy for the facilities, thus reducing SRM destined for landfill.

5.4.2 Slaughter Improvement Program

Introduced in 2009, the Slaughter Improvement Program (SIP) was a three-year $60 million program that was designed to strengthen the competitiveness of the red meat industry by providing interest-free, conditionally repayable contributions to support investments that improved and modernized slaughter operations and capacity, as well as those which improved environmental and animal welfare conditions. This program was designed to ensure that livestock producers have available viable and sustainable slaughter options. Specifically, $14.5 million was directed to the beef and veal processing sectors to purchase equipment, improve technologies, and increase storage and processing capacity. In total, 21 projects were approved for an allotment of $55 million.

5.4.3 Facilitating the Disposal of SRM Initiative

The federal government allocated $76.5 million in partnership with the provincial governments to help the industry adjust to the challenges of SRM. The objectives of this program were to assist in developing infrastructure for the segregation and disposal of SRM, to help the industry meet the new regulatory requirements in order to maintain domestic and international confidence in the BSE risk mitigation measures that Canada has undertaken, as well as to invest $2.5 million in research to seek long-term value-added uses for SRM. Over 300 SRM-related projects have been undertaken across Canada, with funding to support industry competitiveness and enhance infrastructure (e.g. composting sites and incinerators) to comply with feed ban regulations. In addition, there have been investments in research to seek long-term value-added uses for SRM.

5.4.4 Abattoir Competitiveness Program

The Abattoir Competitiveness Program (ACP) assisted federally and provincially registered cattle facilities to address short-term competitiveness issues by providing $25 million in funding. The targets for this program were facilities that process OTM cattle.

The ACP facilitated the improved management of SRM and contributed to maintaining a critical slaughter capacity in Canada for OTM cattle. This program also helped to defer costs associated with OTM animals and to better manage the cost differential with the U.S.

The first round of federal funding was directed toward short-term solutions in terms of SRM disposal such as helping landfills meet BSE containment requirements. However, the purpose of the second wave of funding was to promote new infrastructure undertakings.

5.5. SRM Disposal Infrastructure and the Ability to Recover Value

There is an economic link between the development of SRM disposal infrastructure and the volume of SRM generated in Canada. In recent years, due to several elements such as federal investments, some progress has been realized regarding the building of an infrastructure to begin generating value from SRM.

Raw SRM consists of three primary constituents: water, organic matter, and inorganic matter. Specifically, it is about water, fuel, and ash. Depending on the nature and source of SRM (abattoir or on-farm dead stock) and the level of segregation practices in the abattoirs or salvaging operations, SRM composition includes approximately 30% water, 55% fuel, and 15% ash.

Currently, hundreds of thousands of tonnes of SRM (over 90% of total SRM) are confined in landfills in Canada, with no conversion into a valuable product. This results in increased costs to cattle producers and a decrease in international competitiveness.

As previously mentioned, AAFC, under the SWIP, supported three major incineration/gasification projects.

A few of the expected benefits are that they would

- destroy the most resistant pathogens.
- generate renewable energy.
- reduce landfill waste by diverting nutrient-rich materials to the facility.
- extend landfill life by up to 50% through diversion.
- reduce pollutants and odours.
- decrease greenhouse gas emissions from landfill (methane).
- provide environmental containment.
- enable the processing of large volumes.
- increase material life cycle.

With respect to customers, the denominator for the three projects is the market of waste management solutions. SRM tipping fees will obey the supply and demand rule. The waste management market is the source from which input is obtained. Currently, the SRM processing capacity of the two newly built plants in Eastern Canada exceeds the amount of available SRM. This situation is identified as a potential project risk, as the net gas savings would be significantly reduced because of low volume of SRM for processing. Finally, if the feed ban rule in Canada were made similar to the standard in the U.S., the situation would become even more aggravated, due to a loss of raw material for processing.

5.6. Assessment

SRM use in Canada remains in the early stages of market development. Currently, hundreds of thousands of tonnes of SRM (over 90% of total SRM) are confined in Canadian landfills, with no conversion into a valuable product. This results in increased costs to cattle producers and a decrease in international competitiveness.

Since the EFB came into effect, many initiatives, aiming at the reduction of SRM confinement, were explored. Canada's current effort to support the SRM disposal initiatives through the SWIP is beginning to show tangible benefits to the beef industry.

For instance, the rendering industry in Eastern Canada has recently announced significant discounts (50%) on SRM disposal fees.

While these promising projects have clearly demonstrated the capacity to divert the majority of SRM from landfills, two are located in Eastern Canada where only 33% of the national SRM is generated. To operate at an optimum level of profitability, these technologies require a minimum volume of organic material. Currently, the SRM processing capacity of the two newly built plants in Eastern Canada exceeds the amount of available SRM. This situation is identified as a potential project risk, as the net gas savings would be significantly reduced because of low volume of SRM for processing. Further, if the Canadian feed ban rule is made similar to the U.S. standard, the situation would become even more aggravated due to a loss of raw material for processing.

6. MONITORING BSE PREVALENCE IN THE CANADIAN HERD

6.1. Importance of the Surveillance Program

Canada's feed ban prohibits the feeding of most mammalian protein to ruminants. There are certain exceptions, including pure porcine and equine meal that can be legally incorporated into ruminant feed. Currently available commercial tests cannot readily discriminate proteins from different species or non-SRM tissues from SRM tissues, thus making testing for the presence of prohibited proteins not an option.[12] As a result, microscopy alone is unsuitable, as the species of origin cannot be determined by examining bone spicules. Although a panel of tests may facilitate in differentiating between species, it is likely that there would be many inconclusive results. Current testing technology simply does not have the necessary specificity for useful application.

Considering that testing for the presence of SRM or prohibited material in feed is not an option and unlikely to be an option in the foreseeable future, given the nature of Canada's feed ban, testing cattle for BSE through the surveillance program is the key measure of success. Moreover, surveillance continues to be the only tool available to objectively demonstrate that the EFB is working and BSE continues to be under effective control.

Relying on surveillance to confirm that Canada has an effective feed ban leads to a lag time, which is a direct result of the length of time from when an animal is exposed and becomes infected with BSE, to when it can be detected using currently available tests. On average, this takes about five to six years. As a result, monitoring the cattle population at a sufficient level of intensity for BSE to gather the evidence required is a long-term commitment.

[12] In contrast, the feed ban in the EU is a total prohibition on the feeding of all animal proteins to farmed terrestrial and aquatic species. As a result, testing for the presence of any animal protein, regardless of the species of origin, is a feasible option.

6.2. The Surveillance Program

Canada has a long history of testing for BSE, dating as far back as 1992, when a national program based on the requirements of the OIE was first implemented. Prior to detecting BSE in a Canadian cow in 2003, over 10,500 animals had been tested. Following this detection, enhancements were made to the surveillance program. Whereas in the past, the emphasis had been on detecting BSE in the cattle population by primarily focusing on cattle exhibiting symptoms suggestive of BSE, the focus has now shifted to determining the likely level of BSE and assessing effectiveness of the feed ban. To ensure consistency with the international guidelines provided by the OIE, the scope of the program was broadened to increase the sample size and include other groups of cattle in which BSE was also likely to be found.

As a result, a targeted program was implemented from the beginning of 2004 that not only focused on clinical suspects, but also on OTM cattle that are dead, down, dying, or diseased (referred as the "4Ds"). In practice, this means that all OTMs that would not be likely to pass ante-mortem inspection and qualify for healthy slaughter are potential candidates for testing.

Although it is not an OIE requirement to ensure the sanitary safety of beef or to monitor the cattle population for BSE, many other BSE-affected countries test healthy slaughter cattle. As explained in the EU's 2005 TSE Roadmap, testing these cattle is not a public health protection measure. It has more to do with restoring consumer confidence.

6.3. Surveillance Levels

From 2004 to July 2012, just under 355,000 cattle had been tested for BSE. In 2004, a national target of at least 30,000 per year was established. While this target was significantly exceeded from 2005 to 2007, the overall numbers have been around 35,000 in the last few years. Recent trends, particularly in Alberta and Saskatchewan, have seen the national tally fall below 30,000 for the first time in 2012, with just over 27,000 cattle tested. Table 3 summarizes the number of cattle tested for BSE per year.

TABLE 3. **Number of Cattle tested for BSE per Year**

Year	Samples Collected	Negative	Positive
2012	27 371	27 371	0
2011	33 458	33 457	1
2010	35 655	35 654	1
2009	34 618	34 617	1
2008	48 808	48 804	4
2007	58 177	58 174	3
2006	55 420	55 415	5
2005	57 768	57 766	2
2004	23 550	23 550	0

Source: BSE Enhanced Surveillance Program[13]

During this period, the CFIA has worked with provinces and industry to target samples from high-risk populations, as recommended by the OIE in its Terrestrial Animal Health code. The probability of detecting BSE in targeted high-risk bovine populations has been documented to be about 20 times greater than the probability of detecting BSE in an apparently healthy animal.
Therefore, in addition to testing BSE suspect cases, the surveillance program's targets include the following:

- cattle found dead by undetermined causes
- cattle that are non-ambulatory and may be euthanized for humane reasons
- cattle that display an acute (distressed) or chronic (diseased) deviation from normal behaviour or appearance

6.4. Collaboration with Stakeholders on Surveillance

The CFIA has been working closely, particularly in recent years, with Alberta Agriculture and Rural Development (AARD). In fact, beginning in January 2012, AARD organized several meetings with the participation of provincial industry and government stakeholders from Alberta and Saskatchewan, together with the CFIA. Given that ongoing surveillance requires continuous support from an operational and diagnostic perspective and a significant time investment from disease control specialists, epidemiologists, and data and IT technicians, an integrated and collaborative surveillance approach is desirable. In addition, ongoing surveillance provides continuous results,

[13] Canadian Food Inspection Agency, BSE Enhanced Surveillance Program http://www.inspection.gc.ca/animals/terrestrialanimals/diseases/reportable/bse/enhanced-surveillance/eng/1323992647051/1323992718670 (accessed on December 31, 2013)

requiring constant analysis of available data and frequent design adjustments. A concerted approach that brings together the key people into committees to organize sampling activities, and to collate and analyze available data creates an efficient working environment. A structured approach allows for changing situations within BSE disease management, and the necessary surveillance design adjustments, to be addressed in an effective, timely, and transparent manner, while maintaining engagement of all stakeholders. Subsequent to the early success of these meetings, a national level program, CanSurvBSE, initiated by the CFIA, has been endorsed by stakeholders from various industry groups and provincial governments across Canada, as well as by Health Canada and the CFIA.

CanSurvBSE, fully implemented in 2013, provides a collaborative forum in which industry, and federal, provincial, and territorial participants inform, discuss, identify, and develop consensus on future options to ensure that the BSE surveillance program continues to be science-based and serves the interests of all stakeholders. Its objectives are to work together nationally as stakeholders to ensure that

- Canada continues to have a credible and efficient surveillance program that clearly demonstrates BSE remains under effective control; and
- a sufficient level of surveillance is maintained to support the marketing of Canadian cattle and beef products and by-products.

6.5. Assessment

Given the nature of Canada's feed ban, which does not lend itself to permit definitive testing with currently available methodologies, surveillance becomes the only tool available to confirm that Canada has an effective feed ban. Therefore, maintaining an adequate surveillance program is crucial for Canada in order to demonstrate that BSE continues to be under effective control. For this reason, the federal government and other stakeholders have been investing significant resources in surveillance for the last two decades.

For instance, the federal government spent $16.2 M in surveillance in 2011, which represented approximately half of the budget of the BSE program for fiscal year 2011–12.

However, relying on surveillance to confirm that Canada has an effective feed ban leads to a lag time, which is a direct result of the length of time from when an animal is exposed and becomes infected with BSE, to when it can be detected using currently available tests. On average, this takes about five to six years. As a result, monitoring the cattle population at a sufficient level of intensity for BSE that is necessary to gather the evidence required is a long-term commitment.

In terms of recent trends in the surveillance program, the national tally fell below 30,000 for the first time in 2012, with just over 27,000 cattle tested. This downward trend in the number of samples tested was noted particularly in Alberta and Saskatchewan. This could

be due to several factors, one of which is the cessation of financial assistance by specific provinces (i.e. Alberta and British Columbia).

Therefore, the federal government and various stakeholders have concluded that an integrated and collaborative surveillance approach is desirable for the surveillance program, given that ongoing surveillance requires continuous support from an operational and diagnostic perspective and a significant time investment from disease control specialists, epidemiologists, and data and IT technicians. To achieve this approach, various collaborative forums have been put in place.

7. INTERNATIONAL TRENDS AND TRADE

7.1. International Trends

Currently, Canada is in the OIE controlled BSE-risk category. Of the top 10 beef exporting countries, seven (Australia, Argentina, Brazil, India, New Zealand, Uruguay and the U.S.) are in the negligible BSE-risk category (note that the U.S. received negligible-risk status in May 2013). Mexico is in the controlled BSE risk category and the EU-27 includes countries that are in negligible and controlled BSE risk categories. Mexico has not had any BSE cases, whereas the U.S. has had three, all of which were "atypical BSE". In contrast, Canada has had 19 cases of BSE, 12 of which were born 3 or more years after the original feed ban was implemented in 1997. From this total, 2 cases were atypical. Table 4 summarizes this information.

The percentage of the world market share for the top 10 beef exporting nations is shown in Table 5.

Annex 4 provides detailed information on international trends and trade.

TABLE 4. **BSE Status for Beef Exporting Countries (with the number of reported BSE cases into brackets), including total of number of countries in each category**

Controlled		**Negligible**	
No cases	**BSE cases (n)**	**No cases**	**BSE cases**
Chinese Taipei Croatia Cyprus Hungary Korea (Rep of) Latvia Lithuania Malta Mexico Nicaragua	Canada (19) Czech Republic (30) France (875) **Germany (387)** **Greece (1)** Ireland (1,653) Italy (142) **Japan (36)** **Lichtenstein (2)** **Luxembourg (3)** **Netherlands (85)** Poland (73) Portugal (1,080) **Slovak Republic (25)** **Slovenia (8)** Spain (779) **Switzerland (467)** United Kingdom (184,619)	Argentina Australia Chile Columbia Iceland India New Zealand Norway Panama Paraguay Peru Singapore Uruguay	Austria (8) Belgium (133) Brazil (1) Denmark (15) Finland (1) Sweden (1) U.S. (3)*
10	**18**	**13**	**7**

Note: Up to 10 BSE-affected countries could qualify for negligible BSE-risk status in the next few years ahead of Canada. In red: BSE affected countries that are likely to qualify as negligible BSE-risk ahead of Canada.
*In May 2013, the OIE granted the U.S. negligible risk status for BSE.

TABLE 5. **Top 10 Beef Exporting Nations in 2010 (% of world market share in terms of metric tonne, excluding live cattle exports)**

Rank	**Country**	**World Market Share (%)**
1	Brazil	23
2	Australia	18
3	United States	14
4	India	10
5	Canada	7
6	New Zealand	7
7	Uruguay	5
8	Argentina	4
9	EU-27	2
10	Mexico	1

Source: USDA

7.2. Trade

Most of the markets that were lost in 2003 have subsequently reopened, though some of these have been opened only to a narrow range of beef products. The major market for Canadian cattle and beef is the U.S., and that market has recovered substantially for almost all commodities. In 2010, for example, more than 300,000 tonnes, representing 76% of Canada's total beef exports, with over one million cattle exported to the U.S.

In the meantime, Australia, a negligible BSE-risk country, has taken advantage of both Canada and the U.S. being locked out of the Japanese and Korean markets. Prior to 2003, these Asian markets were the third and fourth most important for Canada, accounting for 5% (Japan) and 3% (South Korea) of the total beef exports. Although there has been some market recovery, it has been slow and has not returned to pre-BSE levels. Australia not only has an advantage in terms of its BSE status but can also compete head on with North America's traditional grain-fed beef. Contrary to seemingly widely held beliefs, Australia exports significant volumes of grain-fed beef. In 2010, for example, it exported 365,212 tonnes of beef to Japan, 154,362 (42%) of which was grain fed. In the same year, Canada and U.S. exports were 16,021 and 91,616 tonnes, respectively. Further, Australia exported 123,150 tonnes of beef to Korea, 34,150 (28%) of which was grain fed. The U.S. exported 84,823 tonnes, while Canada continued to be locked out of the market, due to BSE.

In terms of the domestic market, the Canadian public has demonstrated its confidence in, and support of, the Canadian beef industry since the beginning of the BSE crisis. The domestic market was a mainstay of the industry following the loss of export markets. The domestic market for Canadian beef remained strong in the period after the BSE finding in 2003, and has generally remained robust, accounting for about 40% of the total beef production in Canada. The perception among consumers is that there is adequate regulatory oversight of the food chain in Canada, which results in their continued confidence in Canadian beef products.

7.3. Assessment

Over the next couple of years and considering current trading partners, Canada could be one of the few top 10 beef exporting nations that remain in the "controlled risk" category for BSE. According to the data included in table 4, seven of the top ten beef exporting nations are already in the OIE negligible-risk category. In addition, some European countries are expecting to reach the negligible-risk status in the next couple of years (e.g. Germany, Greece, Netherlands, Switzerland, and Slovenia).

Most of the markets that were lost in 2003 have subsequently reopened, though some of these have been opened only to a narrow range of beef products. The major market for Canadian cattle and beef is the U.S., and that market has recovered substantially for almost all commodities.

8. INCREMENTAL COSTS OF THE EFB (POST-2006)

In a presentation from the Canadian Meat Council (CMC) entitled "Feed Ban Cost: Forecast for 2011 and 2012 (December 2010)," there is information on the incremental costs of the EFB under the following themes: SRM Disposal Costs, Blood Control, Distal Ileum Removal and Segregation of SRM, Lost Revenue from the Animal Feed Supply, and Other Costs.

In summary, the presentation indicates that the estimated total 2009 average cost associated with the EFB was $31.70/head for OTM and $4.52/head for UTM.

Although actual costs for 2011 and 2012 were not part of this presentation, forecasts were included. More specifically, the total forecasted cost associated with the EFB on a per head basis for OTM was $27.50/head for 2011 and decreased to $22.50/head for 2012. The reductions in 2011 were forecasted to be due to the following factors: reductions in disposal volume attributed to continuous plant improvements (moisture removed from SRM trucks, yield improvement on the vertebral column), and other improvements.

For 2012, the forecasted reductions were based on these considerations: reductions in disposal volume attributed to the implementation of new technologies (removal of the brain from the skull, further improvements to yield around the vertebral column, resulting from the SWIP), and increased revenues from improved access to the U.S. market for blood.

The 2011 and 2012 forecasted cost, associated with the EFB on a per head basis for UTM, remained the same at $4.52/head.

8.1. Assessment

The incremental costs of the EFB (post-2006), borne by the industry, is an important aspect of the EFB that should be considered in the EFB Review. The information extracted from the CMC presentation clarified certain costs borne by the industry; however, further analysis is required to determine whether these costs relate directly and only to the EFB requirements and/or to other aspects of the feed ban or SRM removal for food.

This analysis could include an examination of the costs associated with the estimated total 2009 average cost associated with the EFB on a per head basis for OTM of $31.70/head, such as the increase in fixed costs due to the EFB and the increase in the number of employees and salary associated with the EFB.

In addition, it could clarify certain aspects of lost revenue; for instance, the calculation of lost revenue, the proportion of total lost revenue that is due to lost revenue related to

removing SRM from under the EFB, and how lost revenue is segregated from lost revenue due to other factors (e.g. reduction in sale).

This analysis would also benefit from a more wholesome look at SRM use. In other words, look at the complete cycle of SRM use – from the slaughter plants to disposal – to obtain a more complete picture of all aspects involved in SRM management. Further, take into account the additional revenues that certain SRM components with the most recent technological advancements can generate. For this reason, a complete analysis of the incremental costs of the EFB (post-2006) is included as part of the recommendations in this review.

9. INTERNAL CFIA EVALUATION OF THE EFB

9.1. Objective and Scope of the Evaluation

The CFIA's Audit and Evaluation Branch conducted an evaluation of the CFIA's EFB in 2011–12. The first evaluation of the EFB, it covered the program since its inception, from fiscal year 2004–05 to June 2011.

In the context of the Government of Canada, an evaluation is the systematic collection and analysis of evidence on the outcomes of programs to make judgments about their relevance, performance and alternative ways to deliver them to achieve the same results. In addition, an evaluation provides Canadians, Parliamentarians, Ministers, central agencies and deputy heads an evidence-based, neutral assessment of the value for money (i.e. relevance and performance) of federal government programs (source: Treasury Board Policy on Evaluation[14]).

However, an evaluation should not be confused with internal audit, which is a professional, independent, and objective appraisal function that uses a disciplined, evidence-based approach to assess and improve the effectiveness of risk management, control, and governance processes (source: Treasury Board Policy on Internal Audit[15]).

This evaluation encompassed all EFB activities for which the CFIA received funding, including activities undertaken by the CFIA alone, as well as in collaboration with EFB partners (federal and provincial government departments).

The primary objective of the evaluation of the CFIA's EFB was to assess the relevance and performance of the EFB and to provide recommendations to improve program effectiveness and efficiency, as necessary. As the EFB was implemented in July 2007, the assessment of the achievement of outcomes focused primarily on targeted short-term

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14 Treasury Board of Canada Secretariat, http://www.tbs-sct.gc.ca/pol/doc-eng.aspx?section=text&id=15024 (accessed on December 31, 2013)
Treasury Board of Canada Secretariat,
15 http://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=16484&section=text (accessed on December 31, 2013)

outcomes. Because of the long incubation period – that is, the time an animal becomes infected until it first shows symptoms of the disease – the evaluation of the long-term EFB outcome (i.e. the effectiveness of the EFB in controlling BSE) is possible only after 2015.

This evaluation is separate from the 2012 EFB Review. As such, the evaluation process sought to gather, analyze, and report feedback from the regulated parties and other stakeholders in order to inform the 2012 review.

For additional information, refer to Annex 5, which outlines the findings of the internal CFIA's evaluation of the EFB.

9.2. Findings of the CFIA Internal Evaluation

As concluded in the evaluation, the current EFB is an important component of the Government of Canada's response to BSE, given the ongoing need to reduce the risk of transmission of BSE in the Canadian cattle herd in order to protect animal and public health and to facilitate market access for Canadian beef and other related products.

In addition, the evaluation found that the circumstances and factors that prompted the introduction of the EFB have not changed significantly, which warrants its continuation in its current design and structure. To a large extent, the continuation of the current EFB is justified in that it is a requirement for Canada's BSE status, as determined by the OIE. For BSE, an effective feed ban is one of the conditions for maintaining Canada's controlled risk status, as classified by the OIE, as well as in qualifying for the negligible BSE risk status.

Given its alignment with long-term federal government priorities and goals, as well as current departmental responsibilities (including regulatory responsibilities), the EFB continues to remain relevant to the mandate of the CFIA.

To date, it is too soon to assess the achievement of longer-term outcomes (i.e. the effectiveness of the EFB), due to the long incubation period; that is, the time in which an animal becomes infected until it first shows symptoms of the disease.

The EFB has faced some considerable challenges since its implementation, and thus making it important that the CFIA address those challenges to continue building on its achievements to date. In particular, there is a need to improve communication around the EFB internally and externally to better demonstrate how the overarching objective of the EFB (animal and public health) is aligned with the needs, priorities, and mandates of key EFB stakeholders and partners. Such communication efforts also need to clearly highlight the close linkage between product safety and market access within the context of the CFIA's mandate.

10. ALTERNATIVE USES OF SRM

This review has identified alternative SRM uses to consider for further investigation.

10.1. Considerations from the 2009 EFB Working Group

Some of the considerations originate from the 2009 EFB Working Group and are at various stages of implementation:

10.1.1 Skull Removal Project

The objective of this project is to explore the possibility of treating parts of the skull as non-SRM, once high-risk tissues such as the brain, eyes, and trigeminal ganglia have been removed. Planned meetings took place between industry and the CFIA. Discussions revolved around the approach and feasibility of the project, key technical issues, and next steps, including a cost-benefit analysis of two different SRM removal techniques. An industry partner was identified to do the research, and develop the technique and equipment needed to treat parts of the skull as non-SRM. When/if the skull project is shown to be technologically feasible, industry will be asked to consider an appropriate time frame for implementation in relation to maintaining export markets.

10.1.2 Modified Backbone Saw Project

The objective of this project is to design a backbone saw with greater versatility for cutting different sizes and shapes of backbones, with the goal of minimizing the SRM parts, while abiding with the EFB regulations.

The technology, which is new to the beef sector in Canada, was validated and approved by the CFIA in 2012. It has the potential to reduce SRM volumes by facilitating further segregation of non-SRM from SRM at different points of the beef processing chain, including abattoirs, cut-and-wrap facilities, and salvaging sites.

These two projects – the Skull Removal Project and the Modified Backbone Saw Project – have the potential to reduce SRM volume by at least 32 pounds (or 14.5 kg) per OTM animal (12 pounds or 5.5 kg) for the skull and 20 pounds (or 9 kg) for bones around the vertebral column. The CFIA has approved the validation protocol of the projects as meeting the EFB requirements. Riopel Industries is developing the technology for these two projects. For the skull, the Riopel project involves the splitting of cattle skulls by mechanical means to allow for the removing the brain and associated SRMs, with the objective of reducing the volume of SRM. Similarly, the second component of this project involves reducing the amount of non-SRM tissue on the vertebral column. Prototypes were designed for both these projects, and testing has been completed.

The details of the prototype for removing SRM from skulls have been sent to some industry representatives. The research and development project, funded by SWIP, is in its final stage of completion.

10.1.3 DRG Project (harvesting more meat from the vertebral column)

The objective of the project is to examine the possibility of permitting more edible meat to be harvested from the vertebral column. Initial technical evaluation of processes to obtain more meat from the vertebral column and the ability to test for the SRM tissue was carried out at the CFIA laboratory. Results of this feasibility study were provided to industry and Health Canada (HC) for comment. A meeting was held with the CFIA, HC, and the CMC to discuss next steps. The expectation regarding the current one-inch best practice measurement was clarified, and the opportunity for the industry to further develop technologies and methodologies within the limitation of achieving the policy's outcome of removing the DRG was communicated. The intent of the policy was further clarified via memorandum, and the policy will be improved during the next update of the Meat Hygiene Manual of Procedures.

10.1.4 Blood Exports to the U.S.

A United States Department of Agriculture (USDA) delegation visited two plants in Canada in April of 2010 to observe beef blood collection. The USDA accepted all the CFIA's approved blood collection methods, which resulted in the decision to allow blood exports to the U.S. This is reflected in the new export certificate (available upon request).

To export blood to the U.S., establishments in Canada must meet various U.S. requirements, including those on blood collection. Since the export certificate has been validated, two Canadian establishments have been approved and have been exporting blood to this country.

10.2. Other Considerations

There are other considerations that have not yet been fully explored.

10.2.1 Land Application of SRM Compost

While the composting of SRM is an effective volume-reduction step, the resulting mature compost must still be considered SRM, because current science indicates that composting is not an effective prion destruction method. The disposal and use of compost on land is regulated by the provinces and territories; however, the introduction of SRM into raw material requires federal consideration. Production and application of SRM compost on land, contiguous to the location where the SRM is generated, is not regulated by the CFIA.

In many cases, composting facilities do not have the land base immediately available for land application. Although the composting process itself can be completed within a few months, the final compost material may be stockpiled for several years before a sufficient quantity has accumulated to make land application necessary and/or cost-effective. Ultimately, the final compost material requires disposal. The available disposal options include transporting under a CFIA-issued permit to a permitted composting facility, to a permitted SRM disposal site, or with a permit application to land.

The provincial or territorial authority will prescribe the regulatory requirements for the composting process, conditions, restrictions, and application within its jurisdiction. Where none exists, the relevant parts of the Guidelines for Compost Quality, published by the Canadian Council of Ministers of the Environment, will be followed.

Application to land is restricted to non-food, non-feed, non-grazing land (such as land reclamation, forestry, Christmas tree farms, site preparation for turf, and sod farms). Annex 6 provides additional information on provincial regulations.

A review of certain aspects of the ban on applying SRM compost on food, feed, and grazing land is warranted, given the results from recent scientific research.

10.2.2 SRM Use in Road Construction

This SRM disposal option is available under a CFIA-issued permit to confine SRM. As a prerequisite, the applicant shall comply with the specification for facility construction, which covers the requirements for roads, road ditches, and rip-rap erosion protection. An independent Canadian Standards Association (CSA)-certified testing agency should perform the testing of materials and compaction. The test program and frequency of tests should be approved by a road construction inspector.

11. SUMMARY OF ASSESSMENTS

Since the first BSE cases were found in Canada, there have been significant efforts by stakeholders to control this disease. The analysis of the number of BSE cases in the context of their birth year shows that the situation has generally improved since 2004, as no case born after that year has been detected. However, the disease is known for its long incubation period; therefore, information accumulated for cattle born years after 2004 has not yet been finalized. The earliest year for Canada to qualify as an OIE “negligible risk” country for BSE is determined, in part, by the youngest cohort in which BSE was found. For Canada, this is 2016. This outcome must be considered as the best-case scenario. If Canada were to scale back from a full to a partial SRM ban at this time, it would be at a time when there is insufficient evidence, accumulated through ongoing surveillance, to convincingly demonstrate that the SRM ban has achieved its intended objective.

The CFIA has increased inspection capacity and frequency throughout the feed supply and use chain since the implementation of the feed ban and the EFB. The Agency has also implemented and administered a system of control permits and inspection activities at dead stock collectors, landfills, and other processing and disposal sites regarding the collection, transport, treatment, and disposition of cattle SRM tissues. Different strategies are used to assess compliance and action is taken on any identified non-compliance.

SRM use in Canada remains in the early stages of market development. Currently, over 90% of total SRM is being confined in Canadian landfills, with no conversion into a valuable product. This results in increased costs to cattle producers and a decrease in international competitiveness. Since the EFB, many initiatives that aim to reduce SRM confinement were explored. Canada's current effort to support the SRM disposal initiatives is beginning to show tangible benefits to the beef industry. While these projects have clearly demonstrated the capacity to divert the majority of SRM from landfills, two are located in Eastern Canada, where 33% of the national SRM is generated. These technologies require a minimum volume of organic material to operate at an optimum level of profitability. This situation is identified as a potential project risk, as the net gas savings would be significantly reduced due to low SRM volume for processing.

Given the nature of Canada's feed ban, which does not allow for testing of the feed for feed ban oversight purposes, surveillance becomes the only tool available to confirm that Canada has an effective feed ban. Therefore, maintaining an adequate surveillance program is crucial. For this reason, the federal government and other stakeholders have been investing significant resources in surveillance for the past two decades. However, relying on surveillance to confirm that Canada has an effective feed ban leads to a lag time, which is a direct result of the length of time from when an animal is exposed and becomes infected with BSE, to when it can be detected using currently available tests. On average, this takes about five to six years. As a result, monitoring the cattle population at a sufficient level of intensity for BSE – enough to gather the evidence required – is a long term-commitment. To address a recent downward trend in the number of cattle tested, the federal government and various stakeholders have put in place an integrated and collaborative surveillance approach through various collaborative forums.

Over the next couple of years and considering current trading partners, Canada could be one of the few countries in the top 10 beef exporting countries that remain in the OIE "controlled risk" category for BSE.

The incremental costs of the EFB (post-2006), borne by the industry, is an important aspect of the EFB that should be considered in the review. The information extracted from the CMC presentation clarified certain costs borne by the industry; however, further analysis is required to determine whether these costs relate directly and only to the EFB requirements and/or to other aspects of the feed ban or SRM removal for food. Therefore, it is suggested to include a complete analysis of the incremental costs of the EFB (post-2006) as part of the recommendations in this review.

It is premature to assess the achievement of longer-term outcomes related to the EFB (i.e. its effectiveness), due to the long incubation period; that is, the time when an animal becomes infected until it first shows symptoms of the disease.

To conclude, by continuing the BSE program, Canada is on a path to becoming part of the "negligible risk" category for BSE in a few years (possibly 2016). Making any changes to the current program would likely result in disruptions and delays in achieving the OIE "negligible BSE risk" status. In addition to animal and public health considerations, OIE recognition of BSE risk mitigating measures also has implications for consumer confidence, market access, and trade, as well as program costs for government and industry. Canada would stay competitive with other beef exporting countries that have already obtained or will obtain "negligible risk" status. This would also position Canada to recover markets that have remained closed.

12. OUTCOME AND RECOMMENDATIONS

12.1. Development of Criteria for Future Analyses

As a first recommendation, the following criteria, which have been developed during the EFB 2012 Review, can be used to analyze the alternative SRM uses under consideration, as discussed in section 10:

- Minimize existing risk pathways and avoid the creation of new risk pathways, including spill over into other susceptible species.
- Enhance Canada's OIE BSE status.
- Enhance domestic and international confidence, including market access into the U.S. and beyond.
- Be economically sustainable.
- Maximize harmonization with U.S. SRM regulations.
- Reduce regulatory burden.
- Be environmentally sustainable.

An additional variable for consideration:

- Ensure that funding is available through the current Government of Canada budget for the BSE Program. If new funding from the Government of Canada is required, identify a new source of funding.

Similarly, use these criteria to analyze any potential changes to the BSE programming, such as the ones discussed in the following recommendations.

12.2. Investigate the Possibility of Harmonizing the SRM List with the U.S.

Clearly, some committee members believed that the status quo with respect to the list of SRMs should not be indefinite. Indeed, certain members of the Canadian beef supply chain partners have continued to raise concerns about the ongoing costs associated with the implementation of the July 2007 regulatory enhancements to Canada's feed ban. The situation is worsened because the U.S. cattle industry, Canada's most important competitor, does not face the stringent regulatory requirements that the cattle industry in Canada does. Therefore, it is recommended to further analyze the possibility of harmonizing the SRM list with that of the U.S., and to move to a shorter SRM list through the BSE Roadmap process within the coming year. This analysis should be based scientific evidence. It is also possible that certain conditions and circumstances – for instance, a change in Canada's OIE-risk status for BSE – would affect this analysis. Finally, it should consider the U.S. experience in achieving the negligible risk status and its implications.

12.3. Review/Update Risk and Economic/Trade Issues

The committee suggests conducting various analyses on the impacts of the EFB within the coming year, including possibly updating the BSE risks and economic and trade analyses.

Risk analysis could involve the following elements:

- the reduction in risk related to BSE infectivity that has been achieved by the implementation of the EFB from 2007 to present, in terms of the absolute level of risk reduction as well as the incremental risk reduction over the feed ban measures (had they been continued).
- the level of incremental risk reduction that could be achieved in the future by maintaining the EFB versus implementing:
    - the short list of SRMs, as defined in the U.S.;
    - a shorter list of SRMs, removing the requirement for segregation of SRMs from certain cattle populations that are considered less at risk for BSE (e.g. UTM); and
    - other options, including alternative disposal methods of SRMs.

Undertake a second analysis to review the costs and benefits from both an economic and international trade perspective on, for example,

- the EFB, as implemented from 2007 to present.
- the EFB, as currently implemented from the present to Canada achieving negligible BSE-risk status.
- the short list of SRMs, as defined in the U.S.
- a shorter list of SRMs, removing the requirement for segregation of SRMs from certain cattle populations that are considered less at risk for BSE (e.g. UTMs).

The EFB Economic and Trade Analysis would also include the analysis of the incremental costs of the EFB (post-2006).

To provide the required input into any updated analyses, working groups, which include government and industry representatives, could be created to manage this project. The greater context of risk tolerance and risk management for BSE must be included in the results of these reviews, which, perhaps, could be done in the context of the BSE Roadmap exercise. There would be a need to discuss funding sources.

12.4. Investigate the Possibility to conduct Analysis of Policy Instruments

As a fourth recommendation, it is proposed to further investigate how certain elements related to the EFB could be moved from various regulations (e.g. *Feed Regulations* and *Health of Animals Regulations*) to policy instruments in order to streamline the process for updating these elements without incurring extended waiting periods. This investigation could also be realized in the context of the BSE Roadmap within the coming year.

12.5. Future EFB Review

In terms of the next EFB review, the committee suggests conducting another review of the EFB post-2016, after the first opportunity for an adjustment to Canada's BSE OIE risk status.

ANNEX 1: LIST OF DEFINITIONS

1. Standards set by the World Organisation for Animal Health

The World Organisation for Animal Health (OIE) is the international body that establishes animal health and disease standards. Since 1998, the OIE has had the mandate from the World Trade Organization (WTO) to officially recognize disease-free areas of countries for trade purposes. The procedure for the official recognition of disease status by the OIE is voluntary and applies to four diseases, one of which is BSE. Consequently, the OIE has developed standards to prevent the introduction of infectious agents, pathogenic for animals and humans, into an importing country during trade of animals and animal products, while avoiding unjustified sanitary barriers. The OIE also provides guidelines for countries to use in developing their respective import policies, based on a country's disease risk status.

For BSE, the OIE adopted a three-tiered BSE categorization system to better reflect the state of the science in May 2006. OIE classifications are based on a risk assessment, a functioning meat and bone meal (MBM) ban to ruminants, the presence of indigenous cases, and the quality of the surveillance. The categorization procedure includes the following:

- Category 1: Countries with a **negligible BSE risk** and surveillance program, detecting a design prevalence of 1 per 50,000. The country must have had a functioning ruminant MBM ban for at least 8 years and no indigenous case of BSE born within the last 11 years.
- Category 2: Countries with a **controlled BSE risk** and surveillance program, detecting a design prevalence of 1 per 100,000. The country must have a functioning ruminant MBM ban.
- Category 3: Countries with an **undetermined BSE risk**.

Under OIE guidelines, a country that has reported BSE cases in indigenous animals may still qualify as "negligible BSE-risk." For this qualification, the criteria considered by the OIE include the following:

- completion of a risk assessment;
- every indigenous BSE case having been born more than 11 years ago;
- an effective ruminant to ruminant feed ban implemented more than 8 years previously;
- ongoing BSE surveillance program for more than 7 years (including an awareness program for veterinarians, farmers, and others who are in the agricultural industry to ensure that all cattle displaying signs that are consistent with BSE are reported to the Government Authority, and samples are tested in an approved laboratory);
- all BSE cases destroyed; and
- all equivalent risk animals are permanently identified, and their movements controlled and, when slaughtered or at death, are completely destroyed.

The OIE standards are not legally mandatory, but they are recognized or utilized as minimal standards by many countries. Consequently, OIE standards must be adhered to in order to achieve access into export markets. Some importing countries differ in how they interpret the standards, which can affect import requirements. The OIE website [16] provides additional information on the OIE processes for BSE.

2. Classical versus Atypical BSE

Until 2003, BSE was associated with a single strain of prion protein, which is now referred to as classical BSE (C-BSE). In 2003, following a dramatic increase in the number of cattle tested, scientists found evidence of two atypical BSE strains. These atypical strains, higher (H-type) or lower (L-type), were differentiated by their molecular weight relative to classical BSE. Animals diagnosed with atypical strains had been older and exhibited a different distribution of spongiform changes. While considerably more study is required, it has been shown that the L-type exhibited greater virulence in a humanized mouse model. However, the complete biological significance of atypical BSE strains is unknown.

The decline of the classical form of BSE cases in the world demonstrates that the risk mitigation measures are showing success. The atypical strains, however, require further research.

The OIE does not distinguish between classical and atypical forms of BSE in Chapter 11.5 of the *Terrestrial Animal Health Code*. The CFIA adopted the same approach.

16 OIE, Bovine spongiform encephalopathy (BSE), http://www.oie.int/en/animal-health-in-the-world/official-disease-status/bse/list-of-bse-risk-status/ (accessed on December 31, 2013)

ANNEX 2: 2006 RIAS BACKGROUND

1. Context in 2005–06

Before introducing any updated information and considerations about the EFB, we are revisiting certain sections from the 2006 Regulatory Impact Analysis Statement (RIAS) on the Omnibus Regulation that Strengthened Canada's Safeguards against Bovine Spongiform Encephalopathy (BSE) to remind the audience of the thinking at that time. Following this context, we present updated information and considerations about the EFB.

2. Knowledge of BSE

Source: 2006 RIAS[17]

As stated in the 2006 RIAS, BSE, commonly referred to as "mad cow disease," is part of a group of diseases known as transmissible spongiform encephalopathies (TSEs), such as scrapie in sheep, chronic wasting disease in deer and elk and variant Creutzfeldt-Jakob disease (vCJD) in humans. These diseases are progressive fatal neurodegenerative diseases, with no effective treatment or vaccine.

BSE is not considered a contagious disease; there is no evidence to date of horizontal transmission between cattle. Consumption of feed that contains infective tissue has been identified as the major route of transmission. Species known to have contracted a form of the disease from consumption of BSE-infected tissues include cattle, goats, humans, felines, captive zoo primates, and zoo ungulates. Although meat-and-bone meal (MBM) contaminated with BSE may have been fed to sheep, water buffalo, bison, cervids, and camelids before implementing the ruminant protein feed bans in many countries, there is, to date, no conclusive evidence of BSE in any of these species under typical livestock production practice.

Infectivity has been detected in parts of the brain, spinal cord, and spinal ganglia from as early as three months before the onset of clinical signs. Other tissues, such as the distal ileum, may carry infectivity before it is detected in the central nervous system. This has been the rationale for the removal of certain tissues known as SRM from cattle carcasses at slaughter. These tissues are reported to account for more than 99% of BSE infectivity.

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17 *Canada Gazette Part II, Vol. 140, No. 14,* SOR/2006-147, Regulatory Impact Analysis Statement (RIAS) on the Omnibus Regulation that Strengthened Canada's Safeguards against Bovine Spongiform Encephalopathy (BSE), http://publications.gc.ca/gazette/archives/p2/2006/2006-07-12/pdf/g2-14014.pdf (accessed on December 31, 2013)

3. Linkage of BSE to other TSES

Source: 2006 RIAS

The 2006 RIAS specified that these diseases, some of which are believed to have existed for centuries, include human varieties (Creutzfeldt-Jakob disease, Kuru, Gerstmann-Staussler-Scheinker syndrome, and fatal familial insomnia), as well as scrapie in sheep, transmissible mink encephalopathy, chronic wasting disease of deer and elk, feline spongiform encephalopathy, and BSE. These diseases have long incubation periods, and there is no known prophylaxis or treatment.

Many scientific uncertainties still exist about BSE and its causative agent. These are being rigorously addressed in the scientific community, particularly since the 1996 confirmation of vCJD in humans and its link to BSE. Both experimental and epidemiological evidence now indicates that vCJD is likely caused by the BSE agent, and although the oral route of exposure seems most likely for transmission to cattle and humans, many questions remain regarding other routes of exposure, infective dose, relative infectivity of tissues, genetic susceptibility, accumulated infectivity, and species barriers.

4. BSE and Animal Feed

Source: 2006 RIAS

As explained in the 2006 RIAS, the incorporation of rendered protein from cattle infected with BSE into cattle feed, is considered the primary means by which the BSE epidemic spread in the United Kingdom (UK). The export of infected cattle and feed from the UK is also believed to have been responsible for introducing BSE to other European countries, including, among others, Switzerland, France, and Italy. The practice of rendering ruminant by-products into proteins and incorporating them as ingredients in ruminant feed is therefore a known risk factor that could contribute to the spread of BSE.

With the emergence of BSE as a disease of cattle in the 1990s, the primary BSE prevention measure was strict import controls for animals, and animal products and by-products from countries that posed a risk of having and transmitting BSE. Cattle that had been imported from the UK before the import restrictions came into effect were placed under a monitoring program. Subsequent to the detection of BSE in one of these imported UK cattle in 1993, Canada eliminated all remaining UK cattle from the Canadian herd.

As a secondary firewall, Canada implemented a mammalian-to-ruminant feeding ban (with exceptions) in 1997 by amending and adding provisions to the federal *Health of Animals Regulations*. The feed ban was implemented in accordance with a World Health Organization (WHO) recommendation in 1996 that all countries ban the feeding of

ruminants with MBM, derived from other ruminants to help check the spread of BSE. At the time, Canada was thought to be BSE free.

Canada's 1997 feed ban prohibits the feeding of ruminant animals (cattle, sheep, goats, deer, elk, and other species) with most proteins derived from mammals (except proteins derived from only swine and equines, as well as milk, gelatin, animal fat, and blood products). The regulatory framework of the 1997 feed ban required manufacturers, users, vendors, and feeders of animal proteins and feeds to have procedures and records in place to demonstrate that

- segregation of prohibited animal proteins is maintained to prevent feeding to ruminants and adulteration or cross-contamination of ruminant feeds;
- labels of products, comprising or containing prohibited proteins carry warnings against feeding the products to ruminants; and
- records of distribution for proteins and feeds are being kept to facilitate tracing throughout the animal feed and animal production chain.

5. Implications of BSE in North America

Source: 2006 RIAS

The 2006 RIAS provided details on these implications, which are summarized in this Review. In May 2003, as part of Canada's national active targeted surveillance program for BSE, the provincial government in Alberta sampled a cow that had been condemned at slaughter and found unsuitable for human consumption. This cow subsequently tested positive for BSE and was considered to be sentinel for the presence of BSE in North America. This cow was born in March 1996, before the introduction of the 1997 feed ban.

Additional cases of BSE were confirmed in Alberta on January 2, 2005, January 11, 2005, and January 22, 2006, and in British Columbia (B.C.) in April 16, 2006. With respect to the case reported on January 2, 2005, the investigation that followed determined that the infected animal was born in October 1996. The CFIA confirmed that the affected animal was exposed to feed rations containing MBM produced before the 1997 feed ban. At that time, regulations were in effect, which permitted the inclusion of MBM in ruminant feeds. With respect to the latter three cases, the investigation that followed determined that the infected animals were born after the implementation of Canada's 1997 ruminant feed ban regulations.

In the U.S., a case of BSE was detected in a cow in Washington State in December 2003. The investigation that followed determined that the cow had been born and raised, prior to the introduction of the feed ban, for a few years in Canada, before being exported to the U.S. Two indigenous U.S. BSE cases were reported in June 2005 and March 2006. The U.S. investigations indicated that the positive animals were born prior to the implementation of the 1997 feed ban, instituted by the Food and Drug Administration (FDA).

Based on the findings of the five comprehensive investigations, conducted in response to Canada's cases of BSE and the one conducted following the December 2003 Washington State case, it was concluded that

- BSE was likely introduced into Canada by one or a few imported UK cattle that died or were slaughtered and whose by-products were subsequently rendered and used in feeds for cattle prior to the 1993–94 cull of remaining imported UK animals;
- before the implementation of Canada's feed ban in 1997, cattle (and other susceptible species) were exposed to infectivity recycling in the feed supply for a number of years; and
- while measures, such as the 1997 feed ban have been demonstrated to curtail BSE amplification and spread, the potential for feed cross-contamination remained. Detection of BSE-affected animals born after the introduction of the 1997 feed ban is not unique to Canada.

When the feed ban was implemented in 1997, it was believed that one gram of infected cattle by-product material could cause the infection of another bovine. Measures to prevent cross-contamination are even more critical, as it is now believed that as little as 0.001 g (1 mg) of infected material can transmit the disease. The testing of ruminant feeds for compliance with the ban (i.e. to check for the absence of prohibited proteins) has been impossible, due to limitations of the testing detection methods available.

The 1997 feed ban, implemented without benefit of additional resources, might have been acceptable without the incidence of BSE in the country; however, with it, there was a need to strengthen the key points that are crucial to preventing disease spread. This was consistent with international expectations. No other country has become BSE positive and avoided the need for additional feed control measures. Most other countries that have become BSE positive have implemented a complete animal protein feeding ban.

6. International Panel of BSE Experts

Source: 2006 RIAS

As reported in the 2006 RIAS, following the detection of BSE in Alberta in May 2003, an international panel of animal health experts were invited to review the Canadian BSE situation. The panel made four key recommendations: enhancement of cattle identification; increased surveillance testing for BSE; and complete removal and redirection of cattle SRM from the entire human food and the animal feed chain. The review team stressed the importance of preventing opportunities for cross-contamination or cross-feeding of ruminants with prohibited proteins. A similar recommendation was made by the team in February 2004 in reviewing the U.S. BSE experience with the infected cow detected in Washington State.

As of the beginning of 2006, the Government of Canada had responded to three of the four recommendations by implementing several new or enhanced measures regarding human food safety, animal traceability, and BSE surveillance in the cattle population. The Government amended the federal *Food and Drug Regulations* and the *Health of Animals Regulations* to define and ban SRM from human food in July 2003. This was the single most important step that could be taken immediately following BSE detection to protect public health. In those amendments, the list of tissues defined as SRM that are required to be removed from the human food supply are as follows: skull, brain, trigeminal ganglia, eyes, tonsils, spinal cord, and dorsal root ganglia of cattle over thirty months of age (OTM); and the distal ileum (portion of the small intestine) of cattle of all ages.

The fourth recommendation was addressed by the EFB in 2007.

7. Risk Analysis and Benefits and Costs

Source: 2006 RIAS. To note: only some relevant sections from the 2006 RIAS are included and the order has been modified.

The analysis of the benefits and costs of the EFB in the 2006 RIAS stated that: “the relative probabilities of further transmission of BSE to other animals is reasonably low, and, indirectly, exposure to people through food or other human uses of ruminant animal tissues is lower yet.” However, it was recognized that: “the potential animal health, public health, and/or economic consequences remain very substantial.” This has been demonstrated (i.e. the UK) by human deaths due to vCJD in Europe and, in Canada's case, by the billions of dollars in economic damage that was incurred subsequent to the detection of BSE in a Canadian-born cow in May 2003.

Given the magnitude of potential negative consequences and the global context in which Canada operates as a large net exporter of beef and beef products, livestock and livestock products, the Government was seeking to enhance its high level of animal and public health protection. The analytical framework used to assess the benefits and costs of excluding SRM from the animal feed chain was as follows:

To prevent further exposure of susceptible animals to BSE and effectively eradicate the disease in the shortest practically achievable time frame, the enhanced feed restrictions should:

- cause SRM to be removed from the animal food chain in a manner that minimizes risks associated with potential
    - adulteration or cross-contamination of ruminant animal feed with prohibited protein of ruminant origin, and
    - on-farm misuse of feed containing prohibited protein of ruminant origin.

The enhancements should achieve this result in a manner that

- is credible domestically, in that it contributes to public and animal health protection and efficient functioning of the domestic market for livestock and livestock products;
- is credible internationally in that it contributes to the safety of livestock and livestock products exported from Canada and related market access opportunities;
- considers opportunities for re-integration of the North American market; and
- does not unnecessarily contribute to disposal challenges.

An analysis regarding the anticipated impacts, resulting from the implementation of a full SRM feed ban, as well as to those potentially posed should the Government have chosen to adopt a partial SRM feed ban in lieu of the full SRM option, was performed in the 2006 RIAS. This analysis is summarized in the next sections (8 to 11) of this Review.

8. Benefits of the Amendments – Animal Health Benefits

Source: 2006 RIAS

The analysis in the 2006 RIAS stated that the regulatory amendments, which built on the existing regulatory framework, would be very effective in preventing further exposure of susceptible animals to BSE in Canada. By removing essentially all of the known tissues that could contain infectivity (over 99%) at the beginning of the animal food supply chain, these measures were expected to effectively minimize the risk of transmitting BSE due to either a) potential adulteration or cross-contamination of ruminant animal feed with prohibited protein of ruminant origin during manufacturing and distribution, or b) potential on-farm misuse of feed containing prohibited protein of ruminant origin on those farms with multiple species.

It was noted that partial SRM removal would leave tissues representing approximately 10% of known potential infectivity in abattoir waste and eligible for use as MBM within a diverse and complex animal feed chain.

Relative to a partial SRM feed ban, a full SRM feed ban would provide better animal health protection for Canada by reducing to a minimum both 1) the number of years to eradicate BSE (about 10) and 2) any ongoing potential for more cattle (or other susceptible species) to be born and infected with BSE after the enhanced ban, as Canada proceeds toward this end point. It fully matched recommendations of the international panel and the OIE requirements for a country to achieve a "controlled" (and potentially thereafter "negligible") BSE risk categorization.

While it may be possible to achieve a level of protection with partial SRM removal that approaches that of a complete SRM exclusion, the required supplementary risk-mitigating measures that would be required downstream along the feed chain were impractical and difficult to achieve in a Canadian context (e.g. achieving a nationally standardized minimum level of infectivity reduction during rendering, precise segregation in feed milling, absence of misuse on farm, etc.).

9. Benefits of the Amendments – Public Health Benefits

Source: 2006 RIAS

The 2006 analysis, included in the RIAS, portrayed BSE as a zoonotic disease of mammals that can transfer from infected cattle tissues to humans and other species. It is also described as a disease that poses a public health risk that is not yet fully understood. The primary route of potential public health exposure, in the short term, was addressed in July 2003, by requiring the removal of SRM from beef for food purposes.

Contrary to previous evidence, recent scientific publications indicate that vCJD can potentially be transmitted from person-to-person through blood transfusions and that a larger proportion of the human population is genetically susceptible to this disease. These two recent scientific findings have extended the scope of public health concerns and thus emphasize the importance of taking advantage of this opportunity to accelerate BSE eradication.

Because of the scientific uncertainty, the feed ban was considered as key to breaking the BSE cycle in a way that more fully addresses public health risk in Canada. Compared with a partial SRM feed ban, a full SRM feed ban, with the associated permit controls, would provide greater public health protection by 1) controlling access for all SRM to remaining pathways of potential human exposure not already covered by SRM removal from the beef supply and 2) eradicating BSE as soon as possible from the animal population which, because of uncertainties regarding human epidemiology, was the public health measure of choice.

10. Benefits of the Amendments – Domestic and International Market Benefits

Source: 2006 RIAS. To note: only some relevant sections from the 2006 RIAS are included and the order has been modified.

The 2006 analysis presented Canada's beef industry as the largest single commodity source of farm cash receipts with the sale of cattle and calves valued at $6.4 billion in 2005, accounting for 17% of total farm cash receipts (down from $7.6 billion or 21% of the total farm cash receipts in 2002, but up from $5.1 billion in 2004). Beef production's contribution to the Canadian economy overall was $20 billion in 2004 (down from $30 billion in 2002), including processing, retail, food service, and transportation sectors.

Canada's export sales of live cattle and beef in 2002 were about $4.0 billion. However, mainly due to reduced access to foreign markets because of BSE-related restrictions, exports fell to $1.9 billion in 2004, and climbed to $2.5 billion in 2005. Of total exports in 2005, 85% went to the U.S., with Mexico accounting for 10%, Asia 3% (Japan, Macau, Hong Kong), and 2% to other markets.

Although exports were critically important to the Canadian beef industry, the domestic market remained its single most important one, accounting for some $8.2 billion in beef sales.

By volume in 2004

- 65% of production was consumed domestically (compared with 40% in 2002).
- 35% of production was exported (mainly as beef) (compared with 60% in 2002, with a significant share being exports of live cattle for slaughter in the U.S.).

The economic recovery of beef and other ruminant sectors was founded on public confidence in the regulatory system. Any slide in consumer confidence could be difficult to reverse and have potentially devastating impacts. For example, the loss of only 10% of beef consumption in Canada would represent approximately $800 million in lost domestic sales. This would result in excess product and would necessitate selling to international markets with lower price expectations, provided there was no corresponding loss in international market access.

If borders were to close, Canada would be forced to dramatically curb slaughter. The ramifications of significantly reduced demand and lost outlets for Canadian meat would again ripple throughout the value chain. Unlike the situation in the summer of 2003, it cannot be assumed that such a loss of market confidence or export market access could be recovered in as short a period of time, especially if it were linked to a perceived failure of Canada's feed ban.

To maintain and expand markets for beef, the 2006 analysis insisted that confidence in the safety of the product was critical. Removal of all SRM from the animal food system (including pet food and fertilizer) in Canada was expected to be viewed positively, both by Canadians and Canada's trading partners, as a scientifically sound approach to completing Canada's domestic risk management response to BSE detection. The general public in Canada perceived a strong correlation between animal health and food safety/human health. Public polling has consistently indicated that one-half of consumers (whether or not fully informed about the suite of BSE risk-mitigation measures) considered the 1997 feed ban as the most important measure for food safety. Public and consumer confidence, although strong since the detecting BSE in Canada in 2003, cannot be taken for granted. Polling indicated limited tolerance for additional cases of BSE, especially if the cattle are born after the initial 1997 feed ban.

It was argued that the complete removal and redirection of all SRM from the animal food chain would conform fully to the recommendations of the international panel. These amendments were to reinforce public and consumer confidence domestically and provide strong assurances to downstream suppliers of beef products direct to retail that BSE (and therefore market) risks are being effectively mitigated. Removing the same list of known potentially BSE infective tissues from feed, as for food, would lend itself to effective risk communication.

Requiring the exclusion of SRM from all animal food would buttress Canada's scientific case for progressively regaining more secure access to the U.S. market under both current and anticipated USDA minimal BSE risk rules. One of the risk factors considered in assessing a country as minimal risk under the current USDA rule is the effectiveness of the exporting country's animal feed restrictions.

Full SRM removal would promote export market diversification by responding to other trading partners' expectations, while remaining compatible with North American integration. More especially, high-value Asian markets were following the issue of Canada's feed ban with great interest. Implementing a complete SRM ban was expected to eliminate or neutralize their concerns. Full removal of SRM would play a key role in helping to pave the way for earlier normalization of trade.

11.2006 Regulatory Amendments

Source: 2006 RIAS

In 2007, the Government proceeded to make several enhancements to the 1997 feed ban regulations, as presented in the 2006 RIAS.

The Government took an outcome-based approach that is based on the level of animal health protection afforded by the removal of all tissues of known potential infectivity from the feed chain.

- Principally, the enhancements required the removal and redirection of the same list of SRM tissues from animal feed, pet food, and fertilizers ("full SRM feed ban"), which are prohibited from use in human food. These measures (described in the paragraph below) strengthen existing animal feed controls and further protect Canada’s cattle from BSE.
- The regulations are outcome based, where the responsibility for demonstrating equivalence of alternative implementation systems rests with regulated parties, and removal or inactivation of BSE infectivity takes place at the top of the feed chain (e.g. prior to use in manufacturing feed). The CFIA considers such alternative systems (e.g. destruction), where they can be scientifically supported, as achieving the same level of protection as full SRM removal and are verifiable in practice.

The *Health of Animals Regulations* were enhanced by adding the following requirements for this purpose:

- prohibiting the use of materials derived from cattle SRM, removed at slaughter or from condemned or dead stock cattle, in animal food, including pet food, and in fertilizers;
- segregating, identifying, and requiring record-keeping for SRM removed at slaughter or during further processing of other cattle tissues, as well as dedicating equipment to handle SRM to prevent the contamination of other inedible tissues; and
- having the CFIA control all activities that concern the movement of SRM from abattoirs and of dead stock from farms, as well as their distribution, processing, destruction, disposal, or alternative uses by a system of permits issued under the authority of the *Health of Animals Regulations*. Permits and control measures are not required for SRM or dead stock, if they are destroyed or disposed of on the premises where they originate, but the disposition of these materials is subject to any provincial agricultural, environmental, or public health control measures that are currently in effect.

  The permit system addresses:

  - the tracking of movements of SRM and dead stock via record-keeping requirements from the point at which SRM is removed and collected through to final destruction, disposal, or alternative use; these measures are intended to increase the certainty that these materials do not re-enter the human and animal food chains or the fertilizer system; and
  - the manner and conditions of destruction and disposal or alternative use for cattle SRM and dead stock that are removed from abattoirs or the farms to effectively reduce or contain any potential BSE infectivity in these materials and to prevent other cattle in Canada's herd from being exposed to the BSE agent.

In addition to introducing these new SRM controls, the framework of the 1997 feed ban was enhanced through a series of further amendments. These apply to the non-SRM animal protein that is eligible for use in feed, but is prohibited from being fed to ruminants. These additional amendments were made to the *Health of Animals Regulations*, the *Feeds Regulations* (1983), the *Fertilizers Regulations*, and the *Meat Inspection Regulations* (1990) to coordinate regulatory control measures and to improve the consistency and enforcement of controls on commodities subject to this legislation.

The CFIA's Meat Hygiene Manual of Procedures, Chapter 17, Annex D[18] provides additional information on the procedures associated with SRM controls at federally registered establishments.

[18] CFIA, Annex D: Specified Risk Materials, http://www.inspection.gc.ca/food/meat-and-poultry-products/manual-of-procedures/chapter-17/annex-d/eng/1369768468665/1369768518427 (accessed on December 31, 2013).

ANNEX 3: SUMMARY OF THE ISSUE PAPER ON SRM USE IN FERTILIZERS

1. The Risks and Considerations on SRM Use in Fertilizers

The CFIA's Fertilizer Safety Office has developed a position and an issue paper on the "Risks and Considerations on the Use of SRM in Fertilizers," summarized in this Annex, which may inform some of the issues that are discussed in this review.

2. Enhanced Feed Ban

The Enhanced Feed Ban (EFB) prohibits SRM use SRM in fertilizers and supplements in Canada, unless authorized by a permit issued under the *Health of Animals Regulations* (HofA). The permits are issued by the CFIA on a case-by-case basis and contain specific conditions to minimize any potential for cross-contamination with animal feed and to reduce the risk to animal and human health.

3. The Issue

The cattle industry and some stakeholders consider the current restrictions too prohibitive and restrictive; they are believed to limit dead stock and SRM disposal options. Approximately 200,000 tonnes of SRM are produced in Canada annually, and the implementation of the EFB has created logistical challenges and increased disposal costs. Further, there is a lack of infrastructure supporting alternative SRM deactivation methods, which limits the available positive value outlets for SRM. Also, the U.S. FDA has taken a disparate approach to its feed ban that does not restrict SRM use in fertilizer. The divergent regulatory approaches taken by Canada and the U.S. have been perceived by Canada's cattle industry as economically disadvantaging. Stakeholders would prefer to better manage increasing SRM volume and attenuate high disposal costs by incorporating SRM into fertilizer and supplement products. The cattle industry previously requested the CFIA to review current policies and reconsider and re-evaluate the potential for SRM inclusion in fertilizers and supplements, and thereby review the current feed ban.

4. Aim of the Paper

While the focus of the paper is not a review of the EFB, it does discuss the scientific uncertainty surrounding the issue of BSE transmission and offers a qualitative conclusion about the safety of SRM use in fertilizers in an agricultural setting. Worker or bystander exposures, environmental routes of BSE transmission, and food safety risks are considered. In addition to scientific considerations, this paper takes into account historical, regulatory, technological, and economic factors. In addition, legislative protective measures are discussed.

The goal of this paper is to highlight the key risks and considerations that are associated with SRM use in fertilizers and supplements and to serve as a basis for an informed discussion among all affected stakeholders (cattle, fertilizer and supplement industries, agricultural producers, and other users) in developing a path forward and in identifying potential use patterns for fertilizers containing SRM that pose negligible or manageable risks to BSE spread.

5. BSE Transmission Potential

There are a number of scientific uncertainties, with no conclusive evidence demonstrating the spread of SRM in fertilizer is without risk. This variability has been attributed to incomplete characterization of CJD strains, inconsistencies in variant Creutzfeldt-Jakob disease (vCJD) clinical diagnoses, and differences in population susceptibilities. Some epidemiological studies and risk assessments suggest that none of the following use patterns appear to be associated with appreciable risk for workers or bystanders: 1) non-food, non-feed, non-grazing land (examples are land reclamation, forestry, Christmas tree farms, site preparation for turf, sod farms); 2) agricultural land used for growing crops that are subject to further processing prior to human consumption (e.g. canola for oil production); and 3) application to land used for crops grown for direct human consumption (e.g. vegetables and fruits), and grazing or pasture land. However, others have demonstrated an association between ingestion of raw SRM and increased vCJD risk. Further, the environmental impact to the health of animals from SRM spread in fertilizers may present some concerns. Applying fertilizers that contain SRM may potentially contribute to transmissible spongiform encephalopathy (TSE) or BSE infection in both domesticated and wild species through contamination of hay, forage crops, or even water as a result of leaching and the persistence of the BSE agent in the environment. From a food safety perspective, Health Canada (HC) maintains that alternative uses of SRM must remain comparable to the current measures for mitigating risks to animals and humans; however, they do not directly remark on a policy that would allow land application of SRM as fertilizer to non-food, non-feed, and non-grazing land.

6. Market Access Considerations

Alternative uses for SRM, their control, and impact on market access are also discussed in the paper. Trading partners would deem the lowering of BSE controls as premature, and given the current Canadian risk status, market closures and diminished confidence in Canadian beef products, field, oilseed, and grain crops may ensue. Subsequently, confidence in the safety of Canadian fertilizer products may be compromised. In short, these effects may impact not only the agricultural sector and on-farm profitability, but multiple Canadian industries as well. Similarly, the Canadian domestic market, shown to exhibit considerable aversion to risk, may react negatively to the spread of fertilizers containing SRM, citing concerns over the safety of the food supply. Further, land onto which SRM fertilizers have been applied may be subject to reduced re-sale value, which, in turn, may lead to negative economic consequences, particularly for small family farms and Aboriginal lands.

7. Infectivity Reduction Methods and Disposal Cost

Table 1 is a summary of the cost analysis that is associated with the various methods.

TABLE 1 **Cost analysis**

Method	Cost per tonne ($)	Annual Cost ($)	OTM Cost per head ($)
Landfilling	55 to 221	13.8 to 55.1 million	3.19 to 12.79
Rendering	83 to 163	20.7 to 40.9 million	4.80 to 9.48
Composting	95 to 271	23.8 to 67.8 million	5.51 to 15.72
Incineration	107 to 2011	26.7 to 503 million	6.19 to 116.66

OTM = over thirty months of age

Currently available treatment methods that are recognized as capable of sufficiently addressing BSE infectivity are also the most costly. At present, the CFIA recognizes the following methods as those that reduce potential BSE infectivity in SRM: controlled incineration, alkaline hydrolysis, and thermal hydrolysis. Likewise, the methods recognized by the Agency as adequate for BSE containment include mass burial and landfill. Costs associated with the treatment and disposal of SRM are direct costs (fixed and variable, operating costs), and indirect costs (the consequences of changing regulatory, societal, and trade climates).

8. Decision

Given the considerations summarized in the issue paper and the uncertainty associated with TSE transmission, the CFIA's EFB policy pertaining to fertilizers and supplements was maintained. Permits may be issued under specific conditions that include, but are not limited to, land use restrictions on non-food, non-feed, and non-grazing land only.

ANNEX 4: INTERNATIONAL TRENDS AND TRADE

1. United States

The U.S. has had only three reported BSE cases, all of which were "atypical BSE" with two born before their 1997 feed ban and one born in 2001. In May 2013, the World Organisation for Animal Health (OIE) granted the U.S. negligible risk status for BSE.

The U.S. has imposed a partial SRM ban, whereby it prohibits the incorporation of brain and spinal cord from over thirty months of age (OTM) cattle in animal feed. In terms of SRM removal and disposal, the U.S. essentially has the same age cut-off and list of SRM as Canada does, as far as the human food supply is concerned, except that tonsils from cattle of all ages are included as SRM, whereas in Canada, tonsils are only considered as SRM if they from OTM cattle. With respect to surveillance, the focus of the surveillance program in the U.S. is much the same as in Canada. They continue to test 40,000 OTM 4Ds each year.

2. European Union

In recent years, several BSE-affected European countries have qualified as negligible BSE-risk (Austria, Belgium, Denmark, Finland, and Sweden). The most recent example was Belgium, which had 133 cases overall. Its first indigenous case was detected in 1997, and the most recently affected birth year of a BSE case was 1998.

In the EU, the BSE measures are stringent. More specifically, there is a total ban on feeding MBM to farm animals; animal feeds are tested for the presence of prohibited material; and SRM is either incinerated directly or rendered under high temperature and pressure (133°C at 3 bars of atmospheric pressure for 20 minutes) and then incinerated or buried in an approved landfill. With respect to SRM removal, the tonsils and entire intestinal tract (including the mesentery) is excluded from animals of all ages; brain, skull, eyes, trigeminal ganglia, and spinal cord from cattle over 12 months; and the vertebral column, including the dorsal root ganglia, from OTM cattle.

In terms of surveillance, based on a demonstrably improving situation (including an increasing age profile of BSE cases), the EU increased the age limit for animals referred to as 4Ds in Canada to 48 months, while for healthy slaughter cattle, it has increased progressively to 72 months. Even though the age limits have increased, all cattle in the respective subpopulations must still be tested. Further targeting in the EU over the next few years may include testing a sample from each subpopulation (e.g. clinical suspects, fallen stock)

The EU's TSE roadmap (originally released in 2005 and recently updated in 2010) foresaw the eventual easing of some BSE-related restrictions. Although some adjustments have been made based on the accumulation of a sufficient amount of evidence, as well as sound scientific advice, they are relatively minor.

3. Japan

Japan is part of the controlled BSE-risk category. With respect to surveillance, until recently, Japan tested all slaughtered cattle, regardless of age. Although the national government recently increased the age of testing to 20 months, many prefectures continue to subsidize testing of younger animals, primarily due to concerns over consumer confidence. In terms of SRM removal and disposal, Japan has the most stringent requirements, whereby the full list of SRM from animals of all ages is destroyed by incineration.

4. International Comparisons

Based on the OIE's requirement that the last indigenous case must have been born more than 11 years ago, it is likely that, up to 13 countries, including Japan and many other European countries (even perhaps the UK and Ireland), could qualify as negligible BSE-risk ahead of Canada. As a result, Canada could be one of only several BSE-affected countries that remain in the controlled risk category, and the only one among its key beef export competitors, including the U.S.

ANNEX 5: FINDINGS OF THE INTERNAL CFIA'S EVALUATION OF THE EFB

1. Findings – Relevance: Continued Need for Program

The evaluation concluded that the circumstances and factors that prompted the introduction of the EFB have not changed significantly and warrant continuation of the EFB as currently designed and structured.

The continuation of the current EFB is justified to a large extent by the fact that it is a requirement for Canada's BSE status, as determined by the World Organisation for Animal Health (OIE). In the case of BSE, an effective feed ban is one of the conditions for maintaining Canada's controlled risk status as classified by the OIE, as well as for eventually qualifying for the negligible BSE risk status.

The view that the EFB should continue was also shared by the majority of internal and external stakeholders interviewed. The reasons cited for continuing the EFB were twofold. Internal stakeholders and, to a lesser extent, external stakeholders noted that it was too early to assess the efficacy of the EFB in eliminating potential BSE infectivity in the Canadian cattle herd (as well as the associated animal and public health risks), due to the long incubation period of BSE, which ranges from 30 months to 8 years. Therefore, many stakeholders (especially internal) argued that the EFB should continue until enough time has passed to assess its effectiveness (i.e. after 2015).

The other rationale centered on market access and was mentioned more frequently by external stakeholders. Some major export markets remain only partially open to Canadian beef products, whereas international market access for Canadian feed and pet food products, regulated by the EFB, continues to be restricted, with a few exceptions. As explained above, ongoing and future exports of these products are partially contingent on Canada continuing to meet OIE standards as a "controlled risk" country for BSE, which requires the demonstration of an effective feed ban.

2. Findings – Relevance: Alignment with Government Priorities

The evaluation found that the current EFB is aligned with federal government priorities and the CFIA mandate. However, there is a lack of awareness of the market access component of the CFIA mandate, both internally and externally.

Interviews with internal and external stakeholders, as well as a review of the Speech from the Throne, and related documents and websites, confirmed that the EFB is consistent with federal government priorities.

When discussing the alignment between the mandate of the CFIA and the objectives of the EFB, the majority of internal and external stakeholders referred to several aspects of

the mandate of the CFIA, such as protecting Canadian livestock from diseases and pests, contributing to the safety of Canada's food supply, and safeguarding Canadians from preventable health risks.

Market access was seldom mentioned or linked to the mandate of the CFIA by stakeholders. However, there is an increasingly important interrelationship between product safety and market access in a global economy.

3. Are the EFB Activities producing the Expected Outcomes?

The evaluation claimed that, based on available information, the immediate intended outcomes of the EFB have largely been met, but it is too soon to assess the achievement of longer-term outcomes (i.e. the effectiveness of the EFB).

As indicated before, the number of BSE cases identified in Canada has been low in recent years (one case confirmed per year since 2009). However, this decline cannot be directly attributed to the EFB, because the EFB is only one of the components of the CFIA Enhanced BSE Programming. More importantly, due to the long incubation period of BSE, it is too early to determine the extent to which the strengthened EFB regulations, along with enhanced compliance and enforcement measures, will have contributed toward the achievement of this long-term intended EFB outcome. Consequently, this outcome fell outside the scope of this evaluation.

ANNEX 6: SUMMARY OF THE PROVINCIAL/MUNICIPAL INTERPRETATION OF POLICIES FOR SRM HANDLING/COMPOSTING

(As supplementary information to section 10.2.1 of the Review)

1. Additional Provincial Input on the Disposal and Use of Compost on Land

In general, the production and disposal (i.e. land application) of composted animal tissues is regulated by provinces and territories. Provincial and territorial regulations typically contain provisions about environmental protection, appropriate agronomic practices, and restrictions for compost end use, but they may also contain provisions about compost quality, and pathogen reduction.

- **Alberta:** The disposal and use of compost is not regulated by the province. The provincial *Destruction and Disposal of Dead Animals Regulation* pertains to on-farm composting of dead animals and requires setback distances from, for instance, well waterways, coulees, livestock facilities, and residences. It also requires that scavengers are excluded. There are environmental regulations for commercial compost facilities that regulate how the composting is carried out, but there are no requirements on the disposal or use of the compost. Compost produced at these facilities must meet the quality requirements that are described in the Guidelines for Compost Quality, published by the Canadian Council of Ministers of the Environment.

- **Manitoba:** Composting SRMs on-farm and applied on-farm to non-food use land is exempt from CFIA regulations. Refer to Manitoba regulations regarding composting of SRM.[19]

  Manitoba Conservation regulates the disposal of dead stock under the *Livestock Manure and Mortalities Management Regulation*. Under this regulation the approved mortality disposal options in Manitoba are as follows:
  - burial
  - incineration
  - composting
  - rendering

  A summary of the most relevant sections is as follows:

  Composting of mortalities is described under 15(1):

[19] Government of Manitoba. Livestock Manure and Mortalities Regulations, amendment, http://web2.gov.mb.ca/laws/regs/2009/172.pdf (accessed on December 31, 2013)

- 15.1(1) No person shall compost livestock mortalities on the property of an agricultural operation unless:
  (a) the composting site is located at least 100 m from
    (i) any surface watercourse, sinkhole, spring or well, and
    (ii) the operation's boundaries;
  (b) the mortalities are composted in a manner that does not cause pollution of surface water, groundwater or soil; and
  (c) the composting facilities and process are acceptable to the director.
- 15.1(3) No person shall apply composted mortalities to land between November 10 of one year and April 10 of the following year.

Since composting has not proven to destroy the presence of prion in SRM, composted SRM is still considered SRM. If carcasses or SRM are composted, the compost should not be spread on land grazed by ruminant livestock for the following five years.

Off-farm SRM composting is subject to SRM disposal permitting requirements. Mass composting is only permitted if the CFIA has control of the end site of the SRM. The use of the end product of mass SRM composting (i.e. spreading on land not grazed by ruminant livestock for the following five years) will be permitted by the CFIA on a case-by-case basis.

- **Ontario:** This province regulates the use of compost generated by provincially licensed abattoirs, provided the compost is classified as Category 3 non-agricultural source material (NASM) under the *Nutrient Management Regulation*, which governs the use of land-applied nutrients. In addition, abattoirs with SRM compost are advised not to apply it to pasture land or land directly used to graze domestic ruminants. If SRM is spread on pasture or grazing land, then the generator is prohibited from allowing ruminant's access to the fields for at least five years. Provincial rules prohibit SRM compost from being sold or removed from the abattoir premises without approval from the CFIA. The Nutrient Management Act (NMA) – On-farm Disposal of Dead Farm Animals Regulation pertains to on-farm composting of dead animals and requires setback distances from, for example, well waterways, neighbouring livestock facilities, and residences. In Ontario, all on-farm compost must remain on the farm of origin. Likewise, information pertaining to the preferred use of on-farm SRM compost has been communicated to farmers through stakeholder sponsored "Best Management Practices" dead stock disposal handbook.

- **Quebec:** Composting is not allowed for beef at the farm level. If composting is done at the slaughterhouse, it must not include SRM.

2. Additional Provincial Input on the Regulatory Requirements for Composting Process, Conditions, Restrictions and Application

In general, the production and disposal of SRM compost off the farm of origin (the farm at which the SRM was generated) is also regulated by the federal *Health of Animals Regulations*. The *Health of Animals Regulations* require permits if SRM is being transported, processed (i.e. composted), disposed of, or destroyed off the farm of origin. The CFIA is the agency with the authority to issue SRM permits. While the composting of SRM is an effective volume reduction step, the resulting mature compost is still considered as SRM, as current science indicates that composting is an ineffective prion destruction method.

If the production and disposal of SRM compost occurs on the farm of origin, SRM permits are not required by the *Health of Animals Regulations*, although the Regulations prohibit the application of SRM compost on land that is cultivated for human consumption. The CFIA also strongly recommends that if compost is being land applied, domestic ruminants do not graze on the land or obtain feed from the land for at least five years after the SRM compost has been applied.

- **Ontario:** This province regulates the composting of bovine dead stock on-farm, bovine dead stock off-farm, and SRM generated at provincially licensed abattoirs under the following Acts and Regulations:
  (a) Bovine dead stock composted **on-farm** is regulated under the Nutrient Management Act (NMA) – Regulation 106/09.
  (b) Bovine dead stock composted **off-farm** is regulated under the Food Safety Quality Act (FSQA) – Regulation 105/09.
  (c) SRM composted at a provincial abattoir is regulated under the FSQA, Regulation 31/05 and is not carried out, unless approved by a regional veterinarian.