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Inspection Agency

Agence canadienne
d'inspection des aliments

Industrial Treatment of Specified Risk Materials: A Qualitative Risk Assessment of BSE Transmission and Spread to Domestic Ruminants

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Animal Health Risk Assessment
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EXECUTIVE SUMMARY

The Canadian Food Inspection Agency (CFIA) has promulgated regulations to require the removal and redirection of specified risk material (SRM) from livestock feed. SRM are tissues that, in affected cattle, contain over 99 percent of the infectivity associated with bovine spongiform encephalopathy (BSE). As a result of these proposed regulations, various SRM treatment options are being considered for this material. The A/Director, Animal Health and Production Division, Animal Products Directorate, requested the Animal Health Risk Analysis Unit, Science Strategies, to assess the following options: risk reduction (controlled incineration, cement kiln, alkaline hydrolysis, thermal hydrolysis, gasification followed by incineration), containment (landfill and mass burial), technologies with uncertain efficacy (mass composting, gasification), and the land application of sludge (treated waste water from abattoir and rendering plants).

Scope of Risk Assessment

This series of qualitative risk assessments evaluated the risk of new cases of BSE in cattle and other domestic ruminants resulting from various methods of SRM treatment. The pathway assessed was the potential for environmental contamination of agricultural land with BSE infectivity and resultant exposure of domestic bovines. The potential for transmission to other animals (including wildlife species) as a result of environmental contamination was not assessed. Similarly, no potential implications for public health and the environment unrelated to BSE were considered.

General Approach

All of the following conditions must be satisfied before the BSE agent can be transmitted and spread through industrial treatment of SRM:

- ▶ Cases of BSE (clinical/preclinical or subclinical) must be present in the Canadian cattle population;
- ▶ BSE cases must be undetected by animal health authorities at slaughter or by farm veterinarians or producers, or there must be inadequate compliance with regulations governing treatment of confirmed BSE cases;
- ▶ Infective material from these cases must be disposed of by commercial treatment methods;
- ▶ Cattle must gain access to the infective material and consume an infective dose.

For further spread and amplification to occur, cases infected through improperly treated SRM must live long enough to develop significant infectivity, and transmit that infectivity primarily through the feeds system. Since a ruminant-to-ruminant feed ban has been in place for several years, and since SRM will now be removed from the feeds system (thereby reducing potential for cross-contamination with ruminant feeds), the likelihood of further amplification via ruminant feed would be very low.

The release assessment is based on the assumption that there are less than 2 clinical cases per million adult cattle per year in Canada, that SRM from a maximum of 5 preclinical cases and 100 subclinical cases would enter commercial treatment systems, and that the CFIA requires the removal and redirection of SRM from livestock feed as part of a full SRM feed ban.

Risk Assessment Process

The risk estimate is based on:

- ▶ the likelihood that the BSE agent will be released into the environment (Release Assessment);
- ▶ the likelihood that cattle and other domestic ruminants will be exposed and develop disease (Exposure Assessment); and
- ▶ the expected magnitude of the resulting consequences (Consequence Assessment).

The product of the release and exposure assessments plus the consequences, represents the risk estimate.

In some cases a range in the risk estimate has been presented, reflecting the uncertainties associated with the treatment process and its impact on infectivity.

The factors exerting the most influence on the risk estimates for industrial treatment of SRM are as follows:

- ▶ the estimated low prevalence of BSE in Canada;
- ▶ the lack of scientific evidence to support denaturation of BSE infectivity for some treatment options; and
- ▶ the maintenance of an effective feed ban.

Changes to these assumptions could substantially affect the risk estimates.

<i>Likelihood Definitions:</i>		<i>Probability Range:</i>	
Negligible	The event would be virtually unlikely to occur	10^{-7}	10^{-6}
Extremely low	The event would be extremely unlikely to occur	10^{-6}	10^{-5}
Very low	The event would be very unlikely to occur	10^{-5}	10^{-4}
Low	The event would be unlikely to occur	10^{-4}	10^{-3}
Small	The event would be minimally likely to occur	10^{-3}	10^{-2}
Moderate	The event would be fairly likely to occur	10^{-2}	10^{-1}
High	The event would likely occur	10^{-1}	1

The risk estimate is based on the probability of new cases of BSE agent in the domestic ruminant population and the expected magnitude of the resulting **consequences** (the costs and losses).

Summary Chart of SRM Treatment Methods

	Release Assessment	Exposure Assessment	Likelihood Assessment	Consequence Assessment	Risk Estimate
SECTION A: RISK REDUCTION OPTIONS					
1. Controlled Incineration (including Cement Kilns)	Negligible	Low for incineration with land spreading of ash / Negligible for incorporation into cement kiln products	Negligible	Moderate to High	Negligible
2. Alkaline Hydrolysis	Extremely low	Low (land spread)	Negligible	Moderate to High	Negligible
3. Thermal Hydrolysis	Very low	Low (land spread)	Negligible	Moderate to High	Negligible
4. Gasification followed by Incineration	Negligible	Low (land spread)	Negligible	Moderate to High	Negligible
SECTION B: CONTAINMENT OPTIONS					
5. Landfill and Mass Burial	Moderate	Negligible	Negligible	Moderate to High	Negligible
SECTION C: TECHNOLOGIES WITH UNCERTAIN EFFICACY					
6. Mass Composting	Moderate	Low (land spread)	Very Low	Moderate to High	Very low to Low
7. Gasification only	Moderate	Low (land spread)	Very Low	Moderate to High	Very low to Low

Note: For likelihood definitions and the corresponding probability range, see Appendix 1; for estimation of quantity of SRM produced, see Appendix 2

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TRACKING FORM

Process Initiation and Dates:

Request received to compile all SRM disposal risk assessments into a single document received from Linda Morrison A/Director, Animal Health & Production Division, Animal Products Directorate, CFIA, in September, 2005.

Status of this Document:

In progress.

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RISK ASSESSMENT REQUEST

From: Linda Morrison, A/Director, Animal Health and Production Division, CFIA
Date submitted: August and February 22, 2005

This document represents a compilation of industrial scale SRM disposal, treatment and containment options that were individually completed under the following single risk assessment request. During the completion of this document, proposed enhanced feed ban regulations were approved.

History, background and rationale of the request

The presence of bovine spongiform encephalopathy (BSE) has been confirmed in Canada. The BSE agent is presumed to have been present in Canadian rendered ruminant material and ruminant feed at an infective dose during the latter half of the 1990s. The mammalian (with the exception of pigs and horses)-to-ruminant feed ban was promulgated in August 1997 and gradually took effect as residual feed stores were used up. The current feed ban permits the use of production lines for both "prohibited material" (ruminant protein other than blood and milk) and "non-prohibited material" as long as cleanout procedures are undertaken.

In Canada SRM has been removed from cattle slaughtered for human consumption since 2003. These tissues of potentially higher BSE infectivity, as well as ruminant deadstock (the "high risk" animals), continue to be processed as inedible rendered products and could be present in non-ruminant feeds and pet food.

The CFIA is now proposing modifications to the feed ban that would prohibit the use of bovine SRM and bovine deadstock including animals not raised for food purposes in any animal feed. This requirement will necessitate the finding of suitable alternate disposal options for all such material to preclude their entry into feed. Permits will be issued by the CFIA to dispose of this material by recognised options and approved methods. The proposed regulations will also allow for the treatment of this material by CFIA-approved methods, and exempt bovine SRM and bovine deadstock that remain on-farm.

Description of commodity or activity to be assessed

A number of disposal proposals may be submitted for the CFIA's evaluation. To assess these industrial disposal methods, it would be beneficial to identify an acceptable level of infectivity reduction that such methods must attain to be approved.

The starting point is the baseline indicator of the level of risk presented by raw SRM and bovine deadstock. Once that is established, the target level for infectivity reduction needs to be identified (e.g. three log, six log reduction). Infectivity reduction could be considered for two end points. What is the reduction required if the end product has a non-agricultural use? What is the reduction required if the end product has an agricultural use (as defined by risk managers e.g., non-grazed land)?

With the establishment of these benchmarks (level of risk presented by raw SRM and bovine deadstock, and the level for infectivity reduction), the level of risk presented by the treatment methods (such as burial: containment only, no risk reduction) needs to be identified. The residual level of risk posed by each of these processes would determine if the end product would require further treatment or could be released without restriction.

BACKGROUND

Between May 2003 and May 2006, bovine spongiform encephalopathy (BSE) was diagnosed in 6 cattle born in Canada. A small number of cases continue to appear with two additional animals detected during the summer of 2006, bringing the total number of detected cases to 8. Canada has responded by significantly enhancing BSE surveillance and by examining the need for additional disease control procedures. As a result, public health safeguards were strengthened in 2003 through the removal of specified risk materials (SRM) from the food system. This was followed in July 2006 with the approval of regulations for an enhanced ruminant feed ban in which SRM are required to be removed from feeds, pet food and fertilizer. In so doing, SRM has now become byproduct material potentially carrying infectivity, and requiring an appropriate level of safeguard in its treatment.

Definition of Specified Risk Material (SRM)

In Canada, SRM is defined under the *Health of Animals Regulations* (Part 1.1 Specified Risk Material, section 6.1) as:

- (a) the skull, brain, trigeminal ganglia, eyes, tonsils, spinal cord and dorsal root ganglia of cattle aged 30 months or older, and;
- (b) the distal ileum of cattle of all ages (SOR/2003-264, s. 1).

Enhancing the Current Feed Ban Regulations

The existing framework of the 1997 feed ban will be maintained in the *Health of Animals Regulations* and has been enhanced by the addition of the following requirements (*Canada Gazette*, 2006):

- Prohibiting the use of proteins derived from SRM (from slaughter cattle) and SRM contained in condemned and deadstock cattle, in livestock feed; in BSE-infected cattle, SRM harbour the BSE agent. BSE infected deadstock or condemned carcasses of cattle may also harbour the agent;
- Segregating SRM by removal at slaughter or during further processing of other cattle tissues, and dedicating equipment that handles SRM to prevent the contamination of other inedible tissues;
- Identifying SRM and deadstock containing SRM through the addition of markers, stains, tracers or other means, and the tracking of movements of SRM and deadstock (via record-keeping requirements) from removal to final treatment or alternative use outside the food and feed production and distribution system, to increase the certainty that these materials do not re-enter the human and livestock food chains, and;
- Specifying the manner and conditions of destruction and treatment or alternative use for cattle SRM and deadstock control, e.g., containment, to effectively reduce or contain any potential BSE infectivity in these materials and prevent other cattle in Canada's herd from being exposed to the BSE agent.

The CFIA will control SRM (including deadstock) that leaves the premise of origin and the distribution, processing, destruction, treatment or alternative uses for these materials, by permits issued under the authority of the *Health of Animals Regulations*. Permits and standards for control measures will not be required for SRM or bovine deadstock if they are destroyed or disposed of on the premises of origin, but the disposition of these materials would still be subject to any provincial agricultural, environmental or public health control measures in effect.

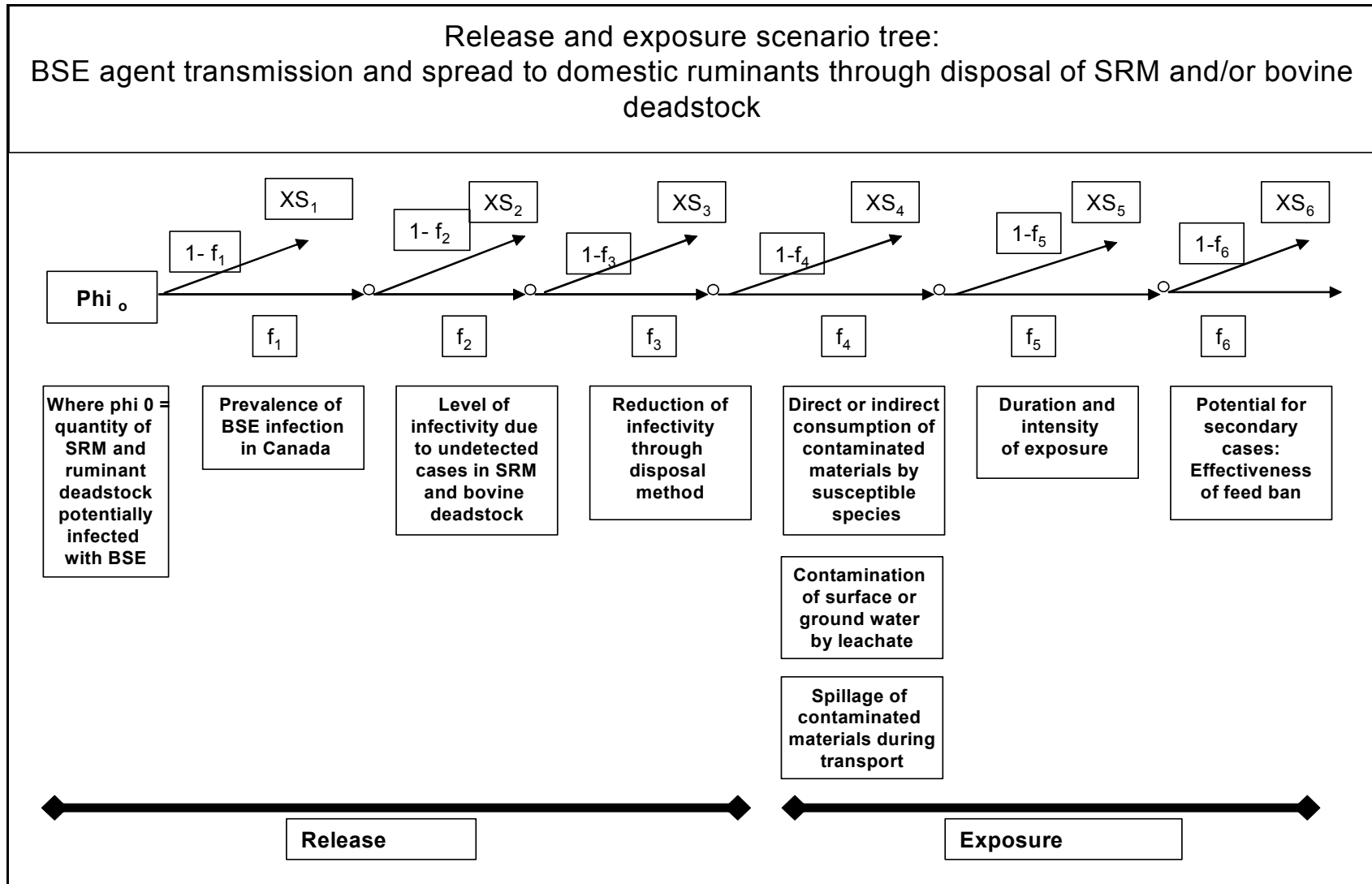
RISK ASSESSMENT ON SRM TREATMENT

HAZARD IDENTIFICATION

Hazard identification is the process of identifying the biological agents which could potentially be introduced with a commodity or activity and for which pathways exist for exposure of the agents to susceptible animals and humans.

- ▶ BSE is a fatal, progressive neurological disease of cattle and other ruminants. BSE is associated with an abnormal prion which, in cattle, accumulates almost exclusively in the brain, spinal cord and dorsal root ganglia, causing cell death and leading to symptoms of disease.
- ▶ The major route of spread is through the ingestion of prion-contaminated ruminant origin meat-and-bone meal (MBM). Maternal transmission is thought to be insignificant in the spread of disease but may account for a very small number of cases. Investigations are on-going in the United Kingdom to explain the cases (more than 60) born after the imposition of a ban on the use of all animal products in cattle feed. Epidemiological data to date suggest that horizontal transmission and environmental contamination do not play a significant role in the maintenance of the epidemic in cattle.
- ▶ The minimum infective dose for cattle is not definitively known. However, disease in cattle has developed after oral ingestion of as little as 0.001 grams of infective material (Matthews, 2003).
- ▶ It is estimated that clinical cases of BSE carry about 10 000 ID₅₀'s (the infectious dose at which 50% of exposed animals will develop disease).
- ▶ The average incubation period is 5 to 6 years, though incubation periods vary with the level of exposure: higher exposures are associated with abbreviated incubation periods, and vice versa.
- ▶ In addition to cattle and humans, other species known to be susceptible to natural infection include goats, felines, captive zoo primates and zoo ungulates. Several species, including sheep, have been shown to be susceptible under experimental conditions. Susceptibility of many species has not been tested.
- ▶ There is uncertainty with respect to routes of transmission in other species, although transmission through infective meat-and-bone meal is likely the major route for all species. BSE infection in sheep resembles scrapie in terms of tissue distribution. Infectivity has been shown to be present in sheep blood, and infection can be transmitted from sheep to sheep via blood. Infectivity has not been detected in bovine blood collected from live clinical cases and no transmission of disease occurs via blood under experimental conditions (note, this does not preclude the potential for transmission of disease via blood products contaminated with neural tissue as a result of stunning at slaughter). There is a likelihood that BSE in sheep may be transmitted similarly to scrapie, in which vertical and horizontal transmission occurs (primarily due to heavy contamination of the birthing environment), and environmental contamination may be a factor. Subsequent passage within the new host species is usually more efficient, indicating prion protein (scrapie [PrP^{Sc}]) adaptation.
- ▶ Prion protein is very resistant to denaturation. Only a few methods of treatment used under specified conditions—incineration, rendering at 133°C, 3 bar for 20 minutes and alkaline hydrolysis— have been demonstrated to significantly reduce the level of infectivity in treated product. Testing for residual infectivity is difficult: often surrogate measures are used and test sensitivity is poor.

Figure 1. Release and Exposure Scenario Tree



RELEASE ASSESSMENT

Release assessment consists of the potential of a risk source to release or otherwise introduce risk agents into an environment accessible to animal populations.

Estimated Prevalence of BSE in Canada and Level of Infectivity in SRM

- ▶ Of the amount of SRM produced in Canada, the proportion that contains infectivity is directly related to the prevalence of BSE in Canada. Between May 2003 and July 2006, BSE was detected in 8 cattle born in Canada. With a population of approximately 6 million to 7 million adult cattle, this represents less than 2 cases detected per million adult cattle per year.
- ▶ Since the detection of the first indigenous case, BSE surveillance has been enhanced significantly. In 2004, 23 thousand samples were tested. The target for 2005, of 30 thousand, was far surpassed with over 57.7 thousand samples tested by year end. The current (July 2006) total for BSE surveillance samples is now over 100 thousand. Surveillance is targeted at high risk animals, that is, mature cattle which are either showing clinical signs of BSE or are down, diseased, dying or found dead. The likelihood of detecting BSE in the high risk population is much greater than in the general cattle population.
- ▶ Disease control measures are designed to reduce the prevalence of disease. Since BSE is primarily spread through rendered materials originating from diseased cattle, the most important disease control measure is the reduction of infectivity in ruminant feeds. In 1997 a feed ban was implemented which prohibited the feeding of ruminant origin MBM to ruminants. Prior to the feed ban, this material was commonly used as a supplement in cattle feed. Ruminant origin MBM is permitted to be fed to other species, such as swine and poultry, leaving a small potential for cross-contamination of ruminant feeds with ruminant materials within the feeds preparation and distribution system. However, the removal and disposal of SRM (which contain 99% of the infectivity) would reduce this potential for cross-contamination in feeds to extremely low levels.
- ▶ The impact of the feed ban on the BSE epidemic curve was modelled and estimated to be as follows: a peak in cases born in or around 1997 when infectivity in the Canadian feeds system was likely at its highest level, followed by overall declining incidence in subsequent years. A key assumption in the model is that the ruminant to ruminant feed ban was not 100% effective and therefore, a small number of cases born after the implementation of the ban was anticipated.
- ▶ Four Canadian BSE cases were born from 1996 to 1998 and were likely infected prior to full implementation of the 1997 feed ban. Two cases born in 2000 and one in 2002 were probably indicative of cross-contamination within the feeds system. One atypical case occurred in an elderly cow born well in advance of the feed ban.
- ▶ A risk assessment on BSE in cattle in Canada (AHRA, 2002 and 2004) determined that the risk of exposure to BSE infectivity prior to the feed ban was very low. Although there was some infectivity in the feeds system, it was likely present at very low levels and may have been largely restricted to one area in Canada (four of the Canadian cases were born in one area of Alberta and one was born in Saskatchewan immediately adjacent to the same area of Alberta). Two recent cases found in British Columbia and Manitoba, still in Western Canada, are being investigated for linkages with a feed source common to the previous cases.
- ▶ The prevalence of BSE is difficult to estimate for the following reasons: BSE is a rare disease; it has a prolonged incubation period and is only detectable late within the course of the disease, using currently available tests. High risk populations are targeted for testing to maximize the chance of detecting disease. Detectable cases (those which are clinical or late in the incubation period) represent only a proportion of the infected population at any point in time. For every clinical case,

there may be several subclinical cases. It is therefore necessary to rely on a combination of surveillance data and an evaluation of risk factors to obtain a reasonable estimate of BSE prevalence.

- ▶ For the purposes of this risk assessment, it was assumed there were a total of 10 cattle which were preclinical (e.g., detectable upon testing) or clinical in Canada in 2005. This is based on a case scenario of just under 2 detectable cases per million adult cattle, and a model which was developed as a tool to assess the efficacy of Canada's feed ban (Murray, 2004). Due to the effects of the feed ban, it is expected that the rate of new infections would decline with each ensuing year.
- ▶ For each case, it was assumed there would be 10 subclinical cases in the cattle population, for a total of 100 subclinical cases. A proportion of these animals would be slaughtered or destroyed (in most cases, it was assumed that the subclinical animals were not retained as replacements and therefore, would have been slaughtered or destroyed).
- ▶ Anderson et al. (1996) estimated that 729 thousand asymptomatic cattle entered the United Kingdom food system in the BSE epidemic up to 1995. During that time, 166 thousand cattle were detected (a 4.3 to 1 ratio of asymptomatic to detected).
- ▶ For the purposes of these risk assessments, the following hypothetical scenario was proposed: 50% of clinical or preclinical (e.g., late in the incubation period) cases would be detected through the surveillance program and disposed of under controlled conditions. No subclinical animals would be detected with current testing technology.
- ▶ Detectable cases were estimated to contain 10 000 ID₅₀ (one ID₅₀ is the infectious dose at which 50% of exposed cattle would be expected to contract the illness). Subclinical animals were assumed to carry 300 ID₅₀ per animal (AHRA, 2002).
- ▶ Five clinical/ preclinical cases would contain 50 000 ID₅₀ (10 000 ID₅₀ x 5) and 100 subclinical cases would contain 30 000 ID₅₀ (300 ID₅₀ x 100). Thus, a maximum of 80 000 ID₅₀ would be present in SRM destined for control (i.e., containment, treatment or alternate use).
- ▶ Infectivity from the cases would not be uniformly distributed and diluted in all of the SRM produced in Canada but would appear as packets of infectivity from a maximum of 105 cases (5 clinical/ preclinical cases and 100 subclinical cases) randomly distributed throughout Canada. Although there is some evidence suggesting a clustering of disease in Alberta, there are no movement controls on cattle within Canada, and cattle and their products could enter the SRM control process anywhere in Canada.

Analysis and Summary – Estimated Prevalence of BSE in Canada and Level of Infectivity in SRM

For 2005, it was estimated that 10 clinical or preclinical cases of BSE in cattle would be present in Canada, based on a possible scenario of just under 2 clinical/ preclinical cases per million adult cattle per year. It was estimated there would be 10 subclinical cases in the population for every case, for a total of 100 subclinical cases. Removal of SRM from the feed system would reduce infectivity to extremely low levels. It is likely that the prevalence of BSE is declining in Canada and will continue to decline over time.

For the purposes of this risk assessment, the following hypothetical scenario is proposed: 50% of clinical or preclinical (e.g., late in the incubation period) cases would be detected through the surveillance program and disposed of under controlled conditions, and 5 clinical or preclinical cases (together with a maximum of 100 subclinical cases) would be undetected and disposed of through commercial means.

Five clinical/ preclinical cases would contain 50 000 ID₅₀ (10 000 ID₅₀ x 5) and 100 subclinical cases would contain 30 000 ID₅₀ (300 ID₅₀ x 100). Thus, a total of 80 000 ID₅₀ would potentially enter into materials sent

for treatment in 2005. This material would not be uniformly distributed throughout the total SRM production for Canada, but would appear as randomly distributed packets of infectivity.

Effect of Environmental Conditions on Infectivity

- ▶ Very little information is available regarding the fate of transmissible spongiform encephalopathy (TSE) agents in the environment. The agents responsible for TSEs (such as BSE in cattle, scrapie in sheep, chronic wasting disease [CWD] in deer and elk and Creutzfeldt-Jakob disease [CJD] in humans) are highly resistant to inactivation processes effective against bacterial and viral disease agents. TSE agents have been demonstrated to be highly resistant to inactivation by chemical and thermal means, as well as ionizing, ultraviolet and microwave irradiation processes (Taylor, 1996; Taylor, 2000). CJD-infected brain tissue remained infectious after storing at room temperature for 22 months (Tateishi et al., 1988 in SCC, 1999). Scrapie agent is known to remain viable after at least 30 months of desiccation (Wilson et al., 1950 in SCC, 1999 in Nutsch & Spire, 2004).

Taylor (2001) indicated that “the present evidence suggests that TSE infectivity is capable of long-term survival in the general environment, but does not permit any conclusions to be drawn with regard to the maximum period that it might survive under landfill conditions” (Nutsch & Spire, 2004).

Studies are underway in the United Kingdom, and in many other countries, to determine the fate of the BSE agent in the environment. Definitive results are not expected to be available for several years.

- ▶ The relationship between carcass or SRM decomposition in the environment and the reduction of BSE infectivity is not known. Organic material is normally decomposed by microbial and chemical processes, some of which might have an impact on prion degradation. However, the rate of degradation of materials and microbial populations can vary considerably between sites, and is dependant on temperature, moisture and burial depth, as well as pH, soil type and drainage, species and size of carcass, humidity/ aridity and rainfall, among other things (McDaniel, 1991; Pounder, 1995; Mann, Bass & Meadows, 1990).
- ▶ Several species of protease-producing bacteria have shown potential to degrade resistant prion under small scale experimental conditions (Tsirounnikov et al., 2004). Studies are not yet sufficiently advanced to draw conclusions about the impact of soil bacteria on prion degradation under the various environmental conditions.
- ▶ In one small experiment, the scrapie agent was demonstrated to retain at least a portion of its infectivity following burial for three years (Brown & Gajdusek, 1991). Scrapie-infected hamster brain was mixed with soil, packed into perforated petri dishes that were then embedded within soil containing pots, and buried in a garden for 3 years. Between 2 and 3 log units of the input infectivity of nearly 5 log units survived this exposure, with little leaching of initial infectivity into deeper soil layers. These results have implications for environmental contamination by scrapie and by similar agents, including those of bovine spongiform encephalopathy. It is uncertain if it would be valid to extrapolate this result to BSE.

Analysis and Summary – Effect of Environmental Conditions on Infectivity

There is evidence to support the degradation of abnormal prion through microbial action in the environment, but the current fund of knowledge is insufficient to draw conclusions about the rate of degradation and longevity of prion in the environment. Research studies are underway in the United Kingdom, and in other countries, however, results will not be available for several years. Until further evidence is available, it is assumed there is no degradation of the BSE agent in the environment.

Release Assessment Summary

- Five undetected clinical cases containing a total of 50 000 ID₅₀ (10 000 ID₅₀ x 5) and up to 100 subclinical cases containing 30 000 ID₅₀ (300 ID₅₀ x 100) could enter into the commercial SRM treatment system annually.
- Infectivity would appear in the SRM control system as packets (5 containing 10 000 ID₅₀ each and 100 containing 300 ID₅₀ each), randomly distributed in time and space.
- It is assumed there is no degradation of the BSE agent in the environment.
- Since a proportion of ruminant origin materials and SRM is processed under conditions which do not reduce infectivity, the impact of rendering on infectivity is assessed as negligible to very low.
- Based on the assumptions that cases of BSE do exist at a low level in Canadian cattle, and there is no degradation in the environment, the release assessment is estimated as **Moderate**, unless the treatment or SRM control method selected can be shown to reduce infectivity.

EXPOSURE ASSESSMENT

Exposure assessment consists of describing the relevant conditions and characteristics of animal exposure to risk agents produced or released by a specified source of risk.

Please note that the exposure assessment, as well as in other published risk assessments for environmental transmission of BSE (Cummins et al.; 2002; DNV, 1997; Grist E (PM), 2005) is based principally on assumptions, as little experimental data are available.

Exposure pathways include direct exposure through consumption of infective material by domestic cattle and indirect exposure through the contamination of groundwater and/or surface water. Consumption of infective material by animals other than cattle has not been considered.

Likelihood that Cattle Would Ingest SRM Disposed of on Agricultural Land

- ▶ Susceptible domestic livestock could be exposed to residual infectivity through ingestion of infectious material from processed SRM spread on pasture land, through consumption of contaminated forage crops harvested from land on which infectious material was spread, and from decomposed improperly buried raw or processed SRM or deadstock left for scavenging on land accessible to cattle. Some of the products of SRM treatment may be palatable to cattle (e.g., meat-and-bone meal and other highly processed products from various treatments) and others may be inadvertently consumed while grazing (e.g., incinerator ash, compost).
- ▶ Leachate potentially carrying infectivity from decomposing or composting SRM may contaminate surrounding agricultural land and surface water. This would apply to SRM burial, treatment in landfill or composting.
- ▶ There is a small potential for exposure to occur as a result of spillage of infective materials during transportation and application to land.
- ▶ The extent of cattle exposure would depend on the end-use of the SRM. For example, containment of SRM (e.g., burial) would be expected to affect only cattle in the local vicinity. Treated/ processed SRM used as fertilizers, such as composted SRM, could be distributed over much greater areas.
- ▶ Cattle behaviour affects the likelihood that SRM would be ingested. Cattle tend to be non-selective in their foraging activity. Through the process of grazing, they may inadvertently ingest quantities of foreign material, including processed SRM (e.g., incinerator ash or compost) spread on grazing land. If a processed SRM is palatable, cattle may preferentially consume the material. Cattle experiencing mineral or salt deficiencies in their diet may ingest earth or chew on bones. Lush plant growth around decomposing carcasses may be preferentially grazed by cattle. All of these behaviours may result in potential exposure to SRM.
- ▶ The period of time in which SRM would remain accessible (either as particulate matter or as a water contaminant) to cattle on agricultural land is uncertain, and would vary according to local conditions.
- ▶ Indirect exposure may occur through the contamination of ground water. Prions are insoluble and are bound to particulate material in an aqueous environment (DEFRA, 2001; Gale et al., 1998). Removal of particulate material from water reduces potential infectivity in proportion to the particulate material removed. Dilution of infectious material in water would also reduce the likelihood of consumption of an infectious dose.

Some proportion of the prion infectivity disposed of on land may infiltrate into ground water. The transfer of prion through the ground was estimated to range from 0.0225 to 1, depending upon the geological conditions (DEFRA, 2001). Transfer is reduced with increasing levels of organic material in

the soil, since prion will preferentially attach to that material. The rate of transfer would also depend upon the depth of the underlying aquifer. Any prion which does leach into groundwater would be further diluted within the water body. For exposure to occur, groundwater would have to be withdrawn and an amount containing an infective dose would have to be provided to susceptible animals. This assumes that there is little or no degradation of BSE prions in the environment.

- ▶ Since the rate of degradation of prions in the environment is unknown, it is assumed that the potential exposure to infectivity would also be for an indefinite period of time.
- ▶ There is no evidence to support aerosol transmission of BSE, nor is there any evidence to suggest uptake of prion protein by plants (with subsequent contamination of livestock feeds).
- ▶ Exposed cattle would need to ingest a sufficient amount of infectivity to develop disease. In experimental studies, a small proportion of cattle developed disease after ingestion of as little as 0.001 grams of infected brain (Matthews, 2003). The minimum infective dose has not been determined. Based on epidemiological evidence, young cattle (under one year of age) appear to be more susceptible to becoming infected.
- ▶ Environmental contamination is important in the transmission of chronic wasting disease, a prion disease of cervids. Unlike BSE, there is evidence that the prion associated with chronic wasting disease is actively excreted by infected animals and that sufficient quantities persist in the environment to infect other cervids. Environmental contamination has been demonstrated to play a role in the spread of scrapie among sheep which are housed together. Although the major route of transmission for BSE in cattle is through the feeding of contaminated MBM, it is speculated that environmental contamination may have contributed to some of the more than 60 BSE cases in the United Kingdom born after the complete feed ban (SEAC, 2004). There is, however, no epidemiological evidence (due to the small number of cases) to support this contention. Further studies are underway in the United Kingdom to determine the source of infection for cattle born after the complete feed ban.

Assessment and Summary – Likelihood that Cattle Would Ingest SRM Disposed of on Agriculture Land:

Because of the various routes (direct and indirect) of potential exposure, the several end-uses of SRM, cattle behaviour and uncertainties surrounding the viability of the prion agent into the environment (soil and water), the exposure assessment is estimated as from **Negligible** to **Low**.

CONSEQUENCE ASSESSMENT

The consequence assessment consists of describing the relationship between the specified exposures to a risk agent, and the health (animal and human populations) and the economic consequences of those exposures.

Assuming SRM is removed from the feeds system and the effective enforcement of the Canadian feed ban, the occasional case of BSE in cattle and other domestic ruminants arising from ingestion of infectious material would have negligible animal health consequences, since there would be little to no opportunity for transmitting (other domestic ruminants being exposed to) the disease. Any such cases would be self-limiting. For disease to spread further, additional cattle would have to be exposed to infective material. The primary means of spread is through contaminated meat-and-bone meal. Canadian regulations prohibit the feeding of all mammalian origin meat-and-bone meal to ruminants, with the exception of porcine meal, equine meal and milk, blood, gelatin and rendered animal fat from any species. Wild animals and other ruminants and cervids are not permitted in ruminant feeds. As a result of this feed prohibition, amplification of the infectivity through the feeds system and further expansion of the epidemic would be curtailed.

The occurrence of three cases born after the 1997 feed ban indicates that some level of cross-contamination has existed in the Canadian feeds system. The current regulatory changes requiring the removal of SRM from the feeds system will reduce the level of BSE infectivity in non-ruminant feeds by more than 99%, therefore minimizing the potential for cross-contamination of ruminant feeds.

Public health consequences resulting from occasional cases of BSE in ruminants would be very limited, since SRM (which contains 99% of the infectivity in a carcass) is removed at slaughter and destroyed, thereby removing it from the human food chain.

There could, however, be economic consequences due to trade restrictions and decreased public confidence if cases in the domestic ruminant population continue to occur on a sporadic basis and Canada is unable to explain the origins. If the objective is to achieve negligible risk status, a few cases may have major implications. Trade restrictions may become less of an issue if international trade policies continue to moderate with respect to BSE. In addition, confidence in the effectiveness of Canada's measures to reduce/ eradicate may also be reduced if cases continue to be detected several years after new controls have been implemented.

The domestic market is a potentially serious issue. The Canadian public has demonstrated its confidence in, and support of, the Canadian beef industry from the start of the BSE crisis. The domestic market was a mainstay of the industry following the loss of export markets. The loss of public confidence in the safety of the beef supply could have serious economic consequences for an already battered industry.

Based on the foregoing, the consequence assessment is estimated as **Moderate to High**.

RISK ESTIMATION

Risk estimation consists of integrating the results from the release assessment, exposure assessment and consequence assessment, to produce measures of risk to health and the environment. The product of the likelihood of disease introduction and the consequences represents the risk estimate.

The overall risk of transmission of BSE through treatment of SRM with no mitigating measures, is **Negligible to High**

PART A: INFECTIVITY REDUCTION OPTIONS

1. CONTROLLED INCINERATION (Including Cement Kiln)

Background Information on Controlled Incineration in Canada: (Thompson, 2005)

The numbers and types of incinerators operating in Canada were not readily available. It was determined that use of incineration has been curtailed in many provinces due to the introduction of tight controls on pollution and ensuing compliance and inspection costs.

According to one expert (Thompson, 2005), the most common types of incinerator in Canada are:

Starved Air Incinerator.

- ▶ the most common type of incinerator in Canada
- ▶ most operate within 800°–1000°C;
- ▶ two stages; first starved air, second complete combustion;
- ▶ batch mode.

Rotary Kiln

- ▶ operating temperature 800°–1600°C;
- ▶ rotates wastes in cylindrical container, mixes with air;
- ▶ can operate in batch mode.

Fluidized Bed

- ▶ operating temperature 760°–980°C;
- ▶ contains inert granular material that expands and acts as a fluid when gases are injected through material bed.

Liquid Injection

- ▶ wastes sent through nozzles and reduced into small droplets to allow for mixing with air;
- ▶ operating temperature 640°–1600°C.

Burn time is variable and dependant, among other things, on the type of waste. Burning of non-rendered material may be problematic with some incinerators because of water content.

The most common category of incinerator used in North America is the fixed-facility incinerator. This includes on-farm units, incinerators at waste treatment plants, crematoria, veterinary colleges, etc.

Operating temperatures in Canadian incinerators depend greatly on the design of the unit. Most incinerators are designed to achieve an initial temperature of between 800° and 1000°C; however, there is no guarantee that incinerators in use would operate at a required temperature for a variety of reasons (design, lack of maintenance, waste streams, etc.).

National and provincial operating criteria exist for incinerators. Canada requires a minimum temperature of 1100°C for hazardous waste incineration (*CCME National Guidelines for Hazardous Waste Incinerator Facilities*: under revision). Provincially, only British Columbia, Ontario and Quebec have any incineration standards (see below). No data were located on the level of compliance and enforcement of these standards.

British Columbia: *Emission Criteria for Biomedical Waste Incinerators*

- ▶ 1000°C minimum in final combustion zone.
- ▶ minimum residence time of 1 sec @ 1000°C.

Ontario: *Combustion, Air Pollution Control and Monitoring Requirements for Biomedical Waste Incinerators in Ontario*

- ▶ States “although dependant on design, generally in range of 1000°C or higher to ensure high efficiency combustion/destruction. Should be capable of sustaining, on a continuous basis, an incineration temperature of about 100°C greater than design operating temperature.

Quebec: *Environmental Quality Act*

- ▶ States that the design of a biomedical waste incinerator must offer at all times a gas residence time of at least 1.0 seconds in the final combustion chamber at a temperature of 1000°C.

In comparison, a 1997 report by DNV listed the following types of incinerators used in Britain:

- ▶ high-temperature incinerators, burning at over 1200°C, used for hazardous waste;
- ▶ municipal solid waste incinerators, burning at 800°–1100°C;
- ▶ crematoria (human remains), burning at 750°–900°C;
- ▶ hospital incinerators (clinical waste);
- ▶ animal carcass incinerators, of which there are nine: one has a capacity of two tonnes/hour, the remainder less than one tonne/hour. All BSE cases are incinerated in animal carcass incinerators (no burn temperature was reported).

Background Information on Cement Kiln Incineration

No commercial cement kiln plants operating in Canada use SRM at this time. Lafarge North America is the largest Canadian and American diversified supplier of construction materials. Lafarge and other cement companies have expressed interest in obtaining contracts for the incineration of SRM, based on the European experience through the formulation of waste-derived fuels (Lafarge official Internet site: www.lafarge.com).

Combustion of MBM in cement kilns is used in France, Switzerland and Germany (European Commission [EC], 2000). Burning of hazardous industrial wastes in cement kilns has become a well-accepted method for the treatment of hazardous wastes in a number of other European countries (Environment Australia, 1997). In France, the maximum amount of MBM which can be used in a cement kiln is estimated to be approximately 10% of the cement production. The maximum amount of MBM which can be used for cement production is limited by the phosphorus and chloride content of the MBM. The limits vary according to the cement production system and the other raw materials used (EC, 2000).

Details on Cement Kiln Processing

- ▶ A cement kiln typically comprises a long cylinder of 50 to 150 metres (3 – 4% gradient) which rotates at about one to four revolutions per minute. The solid material passes down the kiln, rolling and slipping as the kiln rotates. The material flows counter-current to the combustion gases, and fuel is fired at the lower (front) end of the kiln (Woodcroft, 1992). Gases discharged from the kiln are normally cleaned of particulate matter by passing them through an electrostatic precipitator. Dust collected in the precipitator can be returned to the process.
- ▶ The raw materials are transformed into clinker (the precursor to portland cement) in several stages: up to 550°C, the mixture is dried and the clay dehydrates; from 550° to 900°C, pre-heating and decarbonization takes place (calcining); from 900° to 1300°C, the di-calcium silicates, aluminates and ferro-aluminates are formed; and, from 1300° to 1450°C, the formation of tri-calcium silicate takes place (Schrieber, 1992; Environment Australia, 1997; Foy et al., 1996). When the powder is homogenized and heated to 1450°C in the kiln, the lime molecules combine with the silica, alumina and iron oxide molecules to form clinker. Clinker can only form at this temperature (Environment Australia, 1997).

- ▶ Extremely high temperatures (1450° to 1500°C) are achieved, which effectively destroy and combust all organic matter. There is no residual material for treatment because all of the inorganic residual from the MBM is incorporated into the clinker (Irish Government, 2003).
- ▶ Kilns consume a large amount of energy to produce the extremely high temperatures necessary for the process to convert raw input material into clinker. The clinker is ground with gypsum in a separate process to produce the portland (classical) cement product. The heat and turbulence inside the cement kiln are intense: at some point the 3400°F flame must heat the raw materials to at least 2700°F (approx. 1400°C) (Cement Association of Canada, personal communication, August 2005).
- ▶ The cement kiln provides a flame temperature of more than 2000°C with long retention times for both gases and raw materials. The processing of large quantities of raw materials provides a high degree of thermal stability, which is not easily affected by variations in raw material or interruptions in fuel flow (Schrieber, 1992).
- ▶ Rendered SRM is considered liquid waste or low ash waste, and can be relatively easily burnt in cement kilns. The material can be fed in dry or in slurry form (especially with the 'wet' process), or as a fuel supplement into the burning zone of the kiln. In this zone, the temperature of 1450°C can effect a high destruction efficiency as the gas passes through the kiln (Environment Australia, 1997).

The preferred position to introduce the SRM material is about 45% of the kiln length, uphill of the discharge. The kiln temperature at this point is approximately 1100°C, and it increases as the materials pass further down the kiln (Hansen, 1992).

- ▶ According to DNV (1997), ash particles in the combustion flue gas are carried through the furnace, where 99.7% of the particulate is captured by fly ash extractors and the rest is emitted in the flue gas stream. The ash that remains is released as bottom ash, while a small percentage is released as dust. It was assumed that this dust is extracted by cleaning water and the particulate matter is screened and returned to the bottom ash, while a small fraction is emitted with the effluent.
- ▶ According to information received on the cement kiln process in Canada (Cement Association of Canada, personal communication, 2005), it has been assumed in this risk assessment that no residual material is generated in the process that would require landfilling. Dust collected in the precipitator can be returned to the process.
- ▶ The SRM-derived MBM is loaded into the furnace at the cement kiln plant. According to Cumming et al. (2002), an allowance has to be made for the fact that some material may be spilled during the loading process (0.05%) and there may be material attached to the handling equipment. It was assumed that 0.05% of the material may be washed away into the effluent from cleaning the raw-material handling equipment.
- ▶ Based on a case study done in Japan by Lafarge's cement plant (Lafarge, 2006), SRM-derived MBM may be kept in a completely closed circuit involving transport to the cement plant in hermetically sealed road tankers, followed by storage in dedicated containers and injection directly into the combustion chamber. If similar practices were employed in Canada, as assumed, this would reduce the risk of exposure of residue into the environment.

Release Assessment

Inactivation of Prion Under Various Time-Temperature Gradients

- ▶ Experimental studies have shown great variability in prion destruction by dry heat under various conditions and using a variety of strains of abnormal prion. As a result, results of various heat treatment experiments are of limited value unless they specifically replicate incinerator conditions.
- ▶ Brown et al. (2004) investigated the effectiveness of 15 minute exposure to 600° and 1000°C in continuous flow normal (oxidative conditions or combustion) and starved-air (reducing conditions or pyrolytic) incineration-like conditions to inactivate samples of pooled brain macerated from hamsters infected with the 263K strain of scrapie. Bioassays from heating one gram of tissue samples yielded a total of two transmissions of the disease among 21 inoculated mice from the ash of a single specimen burned in normal air at 600°C. No disease transmissions were detected from samples heated at either 600°C under starved-air conditions or at 1000°C under both air conditions (normal and starved). They concluded that there is apparently a threshold transmission from tissues incinerated at about 600°C. The low transmission rate and very long onset time for the symptoms suggest that it is close to the extinction temperature. At temperatures approaching 1000°C, it was concluded that infectivity was completely deactivated. In a previous experiment by Brown et al. (2000), five out of 18 hamsters developed disease after inoculation with residue of hamster-adapted 263K strain of scrapie which had been exposed to heating at 600°C for 15 minutes. Oddly, the same experiment in which the residue had been heated for only five minutes did not result in any disease transmission. There is some uncertainty with respect to the efficacy of burning at 600°C on reduction of prion infectivity to negligible levels.
- ▶ Testing for low amounts of residual infectivity is difficult. There are no quick, inexpensive and reliable tests. Mouse bioassay has been used for experimental studies, but it is prohibitively expensive. Although bioassay is very sensitive, there is an estimated species barrier of 500, and even this test cannot detect total elimination of infectivity. Current tests inform about clearance factors, but do not inform on the elimination of infectivity (DNV, 2003a).
- ▶ Destruction of protein (since prions are proteins) has been used as a surrogate marker for the destruction of resistant prion. The reductions of protein in incinerated material from incinerators and power stations in the United Kingdom were determined by analyzing residual ash for amino acid content (DNV, 1997). A reduction of 10^4 in total protein was obtained. As some amino acids known to be present in prion protein could not be detected in the ash, it was the considered opinion of the Spongiform Encephalopathy Advisory Committee (SEAC, 1996) of the United Kingdom that controlled incineration likely reduced prion contamination by a factor of 10^6 or more. This is generally accepted within the published literature.

In 1996, SEAC concluded that incineration, either in power stations or cement kilns (in which temperatures could reach at least 1400°C) or in dedicated incinerators which reached 850°C, would be sufficient to ensure that there was no risk in relation to the ash which could safely be landfilled. It was noted that some ash from power stations was used in aggregate and that the method of firing cement kilns inevitably resulted in some ash being incorporated in the final product. The Committee concluded that, given the nature of these processes, these and any other uses of the ash were perfectly acceptable. In summary, the Committee did not feel that there were any reasons related to BSE which mitigated against the use of tallow or MBM as a fuel source for either the power generation or cement industries, or that required any special precautions to be taken in relation to the protection of the environment, either from smoke discharges or from the resulting ash. (<http://www.seac.gov.uk/statements/state07jun96.htm>) (SEAC, 1996).

Reduction of Infectivity in SRM Subjected to Controlled Incineration

- ▶ It is assumed that infectivity associated with incinerator flue gas, filter sludge and wash water is negligible (DNV, 1997).

- ▶ A reduction of 10^6 was assumed for a controlled burn at 850°C, based on the standards used by the European Union and research findings cited above, which suggest 600°C as the threshold temperature for prion degradation. A failure probability due to improper operation has been assumed, yielding a slightly reduced clearance factor of 2.1×10^5 (Cummins, 2002; DNV, 1997).
- ▶ European legislation governing standards for the incineration of BSE-risk material can be found in Appendix 3. In brief, the European Union requires material containing SRM to be disposed of in an approved incinerator which is operated in such a way that:
“gas resulting from the process is raised in a controlled and homogeneous fashion ... to a temperature of 850°C as measured near the inner wall ... for two seconds.” (Regulation [EC] No 1774/2002)

Furthermore, incinerators must be equipped with at least one auxiliary burner.

“This burner must be switched on automatically when the temperature of the combustion gases after the last injection of combustion air falls below 850°C. It must be used during plant start-up and shutdown operations to ensure that the temperature of 850°C is maintained at all times during these operations and as long as unburned material is in the combustion chamber.”

If waste content contains over 1% halogenated organic substance (chlorine), the temperature must be raised to 1100°C (European Regulation Directive 2000/76/EC).

- ▶ Assuming there were five batches of raw SRM containing 10 000 ID₅₀ each, incineration would reduce the infectivity to 0.04 ID₅₀ per batch. This is a negligible amount. Similarly, one hundred batches containing 300 ID₅₀ each would contain negligible infectivity.
- ▶ Detailed knowledge of existing programs to ensure Canadian incinerators comply with the standards designated by the EU was not readily available. The efficiency of incineration facilities in reducing infectivity is dependant on ensuring the operation meets the minimum requirements of temperature and time, and ensures evenness of burning. Incineration studies have been carried out using laboratory scale models under carefully controlled conditions. From time to time, incinerated material may contain small amounts of residual infectivity if incineration is not conducted properly.
- ▶ Based on the above statements, for both techniques, the release assessment is estimated as **Negligible**.

Exposure Assessment

- ▶ Susceptible domestic livestock could be exposed to residual infectivity through ingestion of infectious material spread on pasture land, or through the potential contamination of feed crops harvested from land on which infectious material was spread. This would result from surface contamination of forage and soil within a limited time after residues are spread (there is no evidence to suggest there is any uptake of prion by plants).
- ▶ Indirect exposure may occur through the contamination of surface water or groundwater. Prions are insoluble and are bound to particulate material in an aqueous environment (DEFRA, 2001; Gale et al., 1998). The transfer of prion through the ground was estimated to range from 0.0225 to one (a very small amount), depending on geological conditions (DEFRA, 2001). Transfer is reduced with increasing levels of organic material in the soil, as prion will preferentially attach to that material. The rate of transfer would also depend upon the depth of the underlying aquifer. Any prion which does leach into groundwater would be further diluted within the water body.
- ▶ The rate of degradation of prions in the environment is unknown.

- ▶ Because of the lack of palatability, land-spread ash would not be consumed by cattle. However, inadvertent consumption may occur, therefore the exposure is estimated as **Low**.
- ▶ Because the products of cement kilns are ultimately incorporated into cement products, the exposure to cement kiln products is estimated as **Negligible**.

Consequence Assessment

- ▶ No impact: **Moderate to High** (see description on page 14)

Risk Estimate

- ▶ The probability of new cases of BSE resulting from spreading incinerated SRM on agricultural land is **Negligible**. The probability of new case of BSE arising from the use of SRM in the production of cement kiln products is **Negligible**.

2. ALKALINE HYDROLYSIS

Process:

Hydrolysis is the breaking of the bonds between two atoms by inserting a water molecule between them (<http://www.soe.uoguelph.ca/bio-1/hydrolysis.html>). The process occurs in nature when animal tissues and carcasses are buried in soil of neutral or alkaline pH, where hydrolysis is aided by the digestive processes of soil organisms (Kaye et al., 2004).

Alkaline hydrolysis uses potassium hydroxide or a mixture of potassium and sodium hydroxide (50% concentrated NaOH stock solution is unstable at temperatures below 20°C) to catalyze the hydrolysis of biological material (protein, nucleic acids, carbohydrates, lipids, etc.) into a sterile and aqueous solution consisting of small peptides, amino acids, sugars, soaps and electrolytes (Thacker, 2004) and (www.wr2.net/process/2005). The alkali itself is consumed in the process by generating the salts of the hydrolysis products. To accelerate the process, heat is applied (100° to 180°C) under a pressure of 4.8 bar for a period varying from three to six hours, depending on the pathogens of concern (Thacker, 2004).

The only solid by-product of alkaline hydrolysis is the mineral constituents of the bone and teeth of vertebrates, which represents two percent of the original weight and volume of a carcass (www.wr2.net/process/2005). This by-product is sterile and easily crushed into a powder that may be used as a soil additive.

The output of alkaline hydrolysis is a solution which can be released into a sanitary sewer in accordance with local and federal guidelines regarding pH and temperature (Kaye, 2003 in Thacker, 2004). For Kaye et al. (2004), this undiluted hydrolyzate is a valuable and versatile nutrient source that can be used as fertilizer (either liquid or dried), as an additive to composting systems, or as input material for anaerobic digestion biogas generation plants which produce methane steam, heat and electric power. Biodiesel applications for the hydrolyzate are also being explored. It could be also diluted with potable water (after cooling) and disposed of in the sanitary sewer or in landfill (Richmond et al., 2003).

In Canada, Health Canada is using a 100-Lab-30 WR² Tissue Digester for their Prion Research Facility in Winnipeg. It is also used in several cities in the US, as well as in Europe. Any WR² Tissue Digester standard cycle exposes all materials to the equivalent of 1M NaOH for three hours at 150°C (302°F) (<http://www.wr2.net/process/prions.html>).

Prion protein is very resistant to denaturation. Only a few methods of treatment—incineration and alkaline hydrolysis—have been demonstrated to have a predictable effect on the level of infectivity in treated product. Testing for residual infectivity is difficult: often surrogate measures are used and test sensitivity is poor.

Recommendations by World Health Organization (WHO) and United States Department of Agriculture (USDA)

- ▶ WHO guidelines recommend hot alkaline hydrolysis, in addition to incineration, as the preferred method for decontaminating TSEs (Nolte et al., 2002; WHO, 1999).
- ▶ The USDA and the US Environmental Protection Agency have recommended alkaline hydrolysis as one of only two acceptable treatment and treatment methods for animal tissues and carcasses infected with, or suspected of containing, prions (the other being incineration at >900°C). Alkaline hydrolysis tissue digesters are currently being used in the USDA's major chronic wasting disease elimination programs. Moreover, large-scale treatment and treatment units are being developed for treatment of SRM that the USDA has defined (revised regulations 9CFR301-9) in response to the first confirmed case of BSE in the US (Kaye et al., 2004).

Release assessment

Reduction of Infectivity Through Alkaline Hydrolysis

- ▶ Alkaline hydrolysis ultimately leads to the breaking of all peptide bonds in proteins, the major solid constituent of all animal cells and tissues. The protein coats of viruses are destroyed and the peptide bonds of prions are broken under the extreme conditions of temperature and alkali concentration used in the WR² Process (www.wr2.net/techdata.htm, visited July 2005).
- ▶ In a literature review with regard to the inactivation of TSE agents by either autoclaving or alkaline hydrolysis, or combinations of heat and alkaline hydrolysis, Taylor (2001) concluded:
 - There are no known autoclaving cycles that can be regarded as reliably effective for the inactivation of TSE agents.
 - There have been no hydrolytic processes described that can reliably inactivate TSE agents.
 - All papers reviewed indicate that alkaline hydrolysis at elevated temperature processes are extremely efficient in inactivating TSE agents, even at 100°C. However, there is a significant difference between inactivating TSE infectivity in a whole infected cattle carcass, compared with laboratory studies involving small amounts of TSE-infected brain material.
- ▶ Using 50 mg of a macerated pool of mouse brain infected with the 22A strain of scrapie agent (Taylor et al., 1997a) has confirmed the findings of Tagushi et al. (1991) with the Creutzfeldt-Jacob disease (CJD) agent, that no infectivity can be recovered when 2M NaOH treatment is followed by gravity-displacement autoclaving at 121°C for 30 minutes (Taylor et al., 1997a). Indeed, Taylor et al. (1997a) found that mice did not develop scrapie after injection with infected brain tissue that had been autoclaved in NaOH, regardless of whether autoclaving was carried out immediately after the addition of NaOH, or after a one-hour holding period at room temperature.
- ▶ Taylor et al. (1999 in Taylor, 2000) showed that boiling in 1M NaOH solution for one minute inactivated the most thermostable strain of mouse-passaged BSE (301V).
- ▶ Inactivation of TSE agent by NaOH occurs at the beginning of the treatment, significantly, within one minute (Taylor et al. 1999 in Grobbsen et al., 2004), and mostly during the first 15 minutes of the treatment (Brown et al. 1986 in Grobbsen et al., 2004).
- ▶ In the manufacturing process of bone gelatine, Grobbsen et al. (2004) showed that the first part of the alkaline process (exposure of demineralized bone to saturated lime [Ca(OH)₂] solution for at least 20 days) reduces infectivity of the 301V agent (10^{8.4} mouse ic ID₅₀/kg) by a clearance factor of 3.7 logs. The complete alkaline process reduced infectivity to undetectable levels, giving a clearance factor of >= 4.9 logs.
- ▶ The Scientific Steering Committee (SSC) was requested to address the safety of alkaline hydrolysis treatment (150°C for three hours) and liquid residues from this treatment in relation to the BSE risk. The Committee concluded (SSC, 2002) that:
 - Under controlled laboratory conditions in a single experiment, the treatment of animal waste by means of high temperature (150°C, three hours) and high pressure alkaline hydrolysis has been shown to reduce the infectivity of TSE/BSE by a factor of 10^{3.5}–10^{4.5}. Because of constraints specific to this experiment, further studies on the combination of heat, pH and time in clearance studies are needed before any final assurance can be given regarding the safety of the process with respect to TSE risks.

No infectivity was found after six hours. This may indicate that the clearance after six hours processing time is higher than after three hours. However, these experiments can only give a

measure of the minimum clearance possible and do not permit the quantification of the clearance factor after six hours.

- On the basis of the data available, by-products of the three-hour process could carry a risk of BSE/TSE infectivity and this risk may decrease with the duration of processing. Further data would be needed to make a definitive statement (SSC, 2003).
- ▶ In this risk assessment, we assumed that alkaline hydrolysis (1M NaOH) would reduce the infectivity of TSE/BSE by a factor of $10^{3.5}$ – $10^{4.5}$ by means of high temperature (150°C, three hours) and high pressure (4.8 bars).
- ▶ Assuming there are five batches of raw SRM containing 10 000 ID₅₀ each, alkaline hydrolysis would reduce the infectivity to approximately 1 ID₅₀ per batch. This represents an extremely low amount.
- ▶ Similarly, the infectivity in five batches of rendered SRM containing 1000 ID₅₀ each would be reduced to approximately 0.1 ID₅₀ per batch. This represents a negligible amount.
- ▶ Based on the above statements, the release assessment is estimated as **Extremely low**.

Exposure Assessment

Residue Spread on Agricultural Land

- ▶ Susceptible domestic livestock could be exposed to residual infectivity through ingestion of infectious material spread on pasture land, or through consumption of hay harvested from land on which infectious material was spread. This would result from surface contamination of forage and soil within a limited time after residues are spread (there is no evidence to suggest there is any uptake of prion by plants).
- ▶ Indirect exposure may occur through the contamination of surface water or groundwater. Prions are insoluble and are bound to particulate material in an aqueous environment (DEFRA, 2001, Gale et al., 1998). The transfer of prion through the ground was estimated to range from 0.0225 to one (a very small amount), depending on geological conditions (DEFRA, 2001). Transfer is reduced with increasing levels of organic material in the soil, as prion will preferentially attach to that material. The rate of transfer would also depend upon the depth of the underlying aquifer. Any prion which does leach into groundwater would be further diluted within the water body.
- ▶ The rate of degradation of prions in the environment is unknown.
- ▶ Assuming no restrictions on its use and that inadvertent consumption may occur, there is a **Low** likelihood that susceptible animals would ingest liquid residue derived from SRM after alkaline hydrolysis treatment.

Consequence Assessment

- ▶ No impact: **Moderate** to **High** (see description on page 14)

Risk Estimate

- ▶ Based on the above, the probability that ruminant livestock would become infected with BSE as a result of exposure to SRM and/or bovine deadstock treated by alkaline hydrolysis, is **Negligible**.

3. THERMAL HYDROLYSIS

Process

Thermal hydrolysis consists of exposing organic waste to steam at a temperature of 160° to 180°C and a pressure of up to 40 bar (for pharmaceutical grade magnesium stearate) for 60 minutes, during which the materials are continuously agitated and denatured, followed by a dehydration stage (Schieder et al., 2000; Taylor and Woodgate, 2003). The thermal hydrolysis process is similar to a rendering system except it operates at a higher temperature and a much higher pressure.

By reacting with water, thermal hydrolysis fractures long chain molecules of organic material, including proteins, into smaller fragments. This increases the availability of nutrients in the end product while denaturing and destroying most pathogens. The resulting outputs include a high temperature liquid (potentially suitable for irrigation or other use) and sterilized solid non-toxic residue (white powder with 8% moisture), which could be used as an organic fertilizer in land remediation or as a component in animal feed (Note: if input materials contain ruminant protein or SRM, these end uses would not be permitted in Canada, unless it was determined that all potential infectivity had been destroyed) (DNV, 2003; Frasier & Talka, 2005). According to expert opinion, the thermal hydrolysis process has at least the same capability to destroy the BSE agent as rendering at 133°C and 3 bars for 20 minutes (Taylor, 2005). However, the extent of infectivity reduction has yet to be confirmed.

In Canada, Biosphere Technologies in Alberta has developed a process called Biorefinex™ which takes large volumes of food and carcass waste, destroys the pathogens and then refines them into valuable products (www.foodincanada.com 2005). This process, which works at 180°C and a pressure of 12 bar for 40 minutes, has been validated for a variety of pathogens but not as yet for TSE agents. This work was started in 2003 and is expected to be completed at the beginning of 2006 (Schmidt, 2005; www.biorefinex.com).

Throughput is 30 tonnes per day based upon five tonnes per cycle and a four-hour cycle time. A two vessel system is capable of processing approximately 13 thousand tonnes per year, assuming the output is processed to the level whereby input material might be considered suitable for end use as fertilizer (DNVb, 2003).

This process is used in Canada by companies involved in treating different kinds of organic waste on a large scale to maximize the generation of green power and thermal energy, produce a highly valuable organic fertilizer and greenhouse gas credits (www.bioalberta.com), as well as to treat cyanide in industrial waste waters (Cyanide Destruct Systems Inc., www.strategis.ic.gc.ca).

Release Assessment

Estimated Reduction of Infectivity in SRM after Rendering

- ▶ Rendering systems involving autoclaving (steam at 133°C under a pressure of three bars for 20 minutes) appeared to be effective in reducing infectivity of the BSE agent (Taylor et al., 1995 and 1997b). Most rendering processes have been shown to reduce infectivity by one to three logs (AHRA, 2002); however, this process does not reliably inactivate high titres of BSE-like agents, even when the exposure times are extended (Taylor, 2001). Vacuum systems have not been demonstrated to reduce infectivity.
- ▶ Taylor et al. (1995) showed that BSE-agent infectivity was reduced after exposure to hyperbaric (2–4 bar) steam cycle at 133°C for 30 minutes
- ▶ Results of an experiment (Schreuder et al., 1998) showed that under the European Union (EU) recommended process (at 133°C under a pressure of three bars for 20 minutes), BSE infectivity was

reduced by about 1000 fold when measured in the diluted and undiluted form, respectively. The BSE agent appeared to be more resistant to heat inactivation procedures than the scrapie agent, particularly in processes involving lower temperatures for a shorter period of time.

- ▶ Infectivity would be present only in those batches containing an infected animal. Assuming there are five clinical/ preclinical cattle and 100 subclinical cattle, a total of 105 batches of SRM could potentially contain infectivity (this assumes that none of the contaminated SRM is split into separate batches).
- ▶ These batches are assumed to be randomly distributed in space and time.

Reduction of Infectivity of Raw and Rendered SRM Through Thermal Hydrolysis

- ▶ For the purposes of this risk assessment, only the infectivity associated with residues is considered. Infectivity loss through flue gas, filter sludge and wash water is not considered.
- ▶ Steam sterilization studies on BSE and scrapie strains demonstrated a reduction factor of up to ten million fold after heating at 138°C (Taylor et al., 1994). It seems likely that the thermal hydrolysis process can achieve complete inactivation, as it has been shown to effectively break down proteins into amino acids and peptides (Taylor & Woodgate, 2003). A research project, funded by the United Kingdom government and Biosphere, to validate the effectiveness of thermal hydrolysis to inactivate TSE infectivity was undertaken by the Institute for Animal Health at Edinburgh in 2003, but definitive results are not yet available.
- ▶ Rendering by pressure cooking (at 133°C under a pressure of three bars for 20 minutes) as recommended by the EU inactivates ≥ 3 logs of TSE infectivity in MBM. As no data has been published yet on TSE inactivation by the thermal hydrolysis process (steam at 180°C under a pressure of 12 bar for 40 minutes) and, even if we expect that TSE infectivity inactivation would be greater than that the European Community recommended rendering, the worst-case scenario would consider that thermal hydrolysis would inactivate TSE infectivity by at least three logs.
- ▶ Assuming there are five batches of raw SRM containing 10 000 ID₅₀ each, thermal hydrolysis would reduce the infectivity to a small amount of 10 ID₅₀ per batch. One hundred batches containing 300 ID₅₀ each would be reduced to negligible levels.
- ▶ Based on the above statements, the release assessment is estimated as **Very low**. Studies are ongoing on the extent of prion degradation.

Exposure Assessment

Residue Spread on Agricultural Land

- ▶ As described with alkaline hydrolysis, the exposure of land-spread residues of thermal hydrolysis may be inadvertently consumed by cattle. It was assumed no residues would be used in animal feeds, therefore, the exposure assessment is estimated as **Low**.

The likelihood of exposure if residues are disposed of in landfill is discussed in the section "Containment Options". The exposure is estimated as **Negligible**.

Consequence Assessment

- ▶ No impact: **Moderate to High** (see description on page 14)

Risk Estimate

- ▶ Based on the above, the probability that ruminant livestock would become infected with BSE as a result of exposure to SRM and/or bovine deadstock disposed of by thermal hydrolysis, is **Negligible**.

4. GASIFICATION FOLLOWED BY INCINERATION

Process and Canadian Context

Gasification is a technology that converts carbonaceous materials through a process involving partial oxidation of the feedstock in a reducing atmosphere at temperatures sufficient to convert the feedstock to a synthetic gas (syngas). The gasification process operates by feeding carbon-containing materials into a heated and pressurized chamber (gasifier) along with a controlled and limited amount of oxygen (USDE, 2000).

The term 'gasification' includes thermic treatments known as pyrolysis and gasification. As opposed to common incineration, which involves a sufficient quantity of oxygen to fully oxidize the fuel used in the combustion, pyrolysis and gasification are thermal degradations in the absence of oxygen (pyrolysis) or with a partial amount of oxygen (EC, 2003; DEFRA, 2005). As such, incineration is an oxydative condition process, gasification a partial oxydative process and pyrolysis a reductive process. The end products of gasification are solid residues (char) and a synthetic gas (syngas).

No criteria are set specifically for gasification processes in Canada, as no commercial gasification plants are operating. As mentioned for incineration, Canada requires a minimum temperature of 1100°C for hazardous waste incineration (*CCME National Guidelines for Hazardous Waste Incinerator Facilities*: under revision). Provincially, only British Columbia, Ontario and Quebec have any incineration standards. No data was located on the level of compliance and the enforcement of these standards.

One Cindar Gasification System plant is planned for Ontario, and it may be tested by 2006. A company based in Quebec has developed a gasification technology intended for municipal wastes, but not for animal flour/MBM (Chornet, personal communication, 2005). This company has one plant currently in test mode in Canada.

Specific Gasification Processes

The Brookes Gasification Process is achieved by placing organic material inside a sealed vessel (primary chamber) and externally applying heat via a secondary chamber, where the set point temperature is a minimum of 850°C. After loading the material into the primary chamber, the temperature is raised slowly over a period of 12 to 14 hours until it reaches or exceeds the secondary chamber set point. This peak temperature is reached at the end of the process. The gases produced during the Brookes Gasification Process as a result of combustion enter the secondary chamber, where they are further oxidized (Infectrol, 2005). It should be noted that the combustion can occur here in a normal, starved or enriched oxygen atmosphere (EC, 2003), meaning the term 'gasification' may not be strictly appropriate.

The Cindar Gasification System is a mixture of the gasification and incineration processes. MBM is first gasified in the absence of oxygen (pyrolysis) and then the residue (char) is incinerated. Both gases from the gasification chamber and incinerator chamber are over 1000°C (Gallant, personal communication, 2005). This system, as well as most European gasification plants for MBM/SRM materials, can be described as an incineration system where incineration occurs during final processing of the residues created during gasification, in comparison with the Brookes Gasification Process which is a straight gasification system.

The plants conducting gasification are defined by the European Council Directive 2000/76/EC as incineration plants (EC, 2000b):

"Incineration plant means any stationary or mobile technical unit and equipment dedicated to the thermal treatment of waste. This includes thermal treatment processes such as pyrolysis gasification or plasma processes in so far as the substances resulting from the treatment are subsequently incinerated."

As such, they have to follow the same requirements. Plants that are operating a pyrolysis and gasification system without incineration are not covered by this Directive, but are closely regulated by European regulations on landfill use and environmental regulations (DEFRA, 2004).

The EU requires treatment of materials containing SRM in an approved incinerator, which is operated in such a way that “gas resulting from the process is raised in a controlled and homogeneous fashion to a temperature of 850°C as measured near the inner wall for two seconds.” (Regulation (EC) No 1774/2002).

This is further acknowledged and clarified by the Integrated Pollution Control Guidance of the United Kingdom Environment Agency in their *Guidance Note for the Combustion of Meat and Bone Meal (MBM)* (2003) in which the requirements for MBM combustors are a minimum of 850°C for two seconds at 6% O₂ applicable to all MBM burning. The residence time and optimum percentage of oxygen depend on the type of combustion (e.g., combustion or gasification). Gasification can be considered as a kind of incineration where materials are partially oxidized (gasification) or reduced (pyrolysis) instead of completely oxidized (incineration). As such, this process has to follow the same standards as incineration.

Release Assessment

Reduction of Infectivity in Raw and Rendered SRM Processed by Gasification

- ▶ For the purpose of this risk assessment, only the infectivity associated with residual ash is considered. Infectivity loss through flue gas, filter sludge and wash water is not considered.
- ▶ Gasification processes, including a final incineration of the residues at 850°C, can be compared to incineration. As no data are available for prion destruction under partial oxidation, a worst-case scenario was chosen in which the amount of prion is the same before and after gasification, and before the incineration process.
 - The pyrolysis part of the Cindar system is considered as equivalent to an 850°C controlled incineration regarding prion destruction (is estimated to reduce infectivity by 5 to 6 logs).
- ▶ The efficiency of incineration (and gasification) facilities in reducing infectivity is dependant on ensuring the operation meets the minimum requirements of temperature and time, and ensures evenness of burning. Incineration and gasification studies have been carried out using laboratory scale models under carefully controlled conditions. From time to time, incinerated material may contain small amounts of residual infectivity if incineration/ gasification is not properly implemented.
- ▶ A reduction of 10⁶ is assumed for a controlled burn at 850°C (EC, 1999). A failure probability due to improper operation has been assumed, yielding a slightly reduced clearance factor of 2.1 x 10⁵ (DNV, 1997; Cummins et al., 2002). A pyrolysis process is considered equivalent to a controlled burn.
- ▶ Assuming there are five batches of raw SRM containing 10 000 ID₅₀ each, incineration would reduce the infectivity to 0.04 ID₅₀ per batch. This is a negligible amount.
- ▶ Similarly, the infectivity in five batches of rendered SRM containing 1000 ID₅₀ each, would be reduced to 0.004 ID₅₀ per batch. This is a negligible amount.
- ▶ Based on the above statements, the release assessment is estimated as **Negligible** (gasification followed by controlled incineration of residues at 850°C, is estimated to reduce infectivity by 5 to 6 logs).

Exposure Assessment

- ▶ As described with the incineration method, due to the lack of palatability of the residue, land-spread ash would not be consumed by cattle (assuming no residue would be used in animal feeds). However, inadvertent consumption may occur, therefore the exposure is estimated as **Low**.

Consequence Assessment

- ▶ No impact: **Moderate to High** (see description on page 14)

Risk Estimate

- ▶ Based on the above, the probability that secondary infections in ruminant livestock would become infected with BSE as a result of exposure to SRM and/or bovine deadstock disposed of by gasification (followed by incineration), is **Negligible**.

PART B: CONTAINMENT OPTIONS

5. LANDFILL AND MASS BURIAL

The assessment of two closely similar methods is conducted in this section. The major differences between the two are the level of regulation, control, planning and monitoring.

Landfill

Landfill sites are highly regulated and planned. They are engineered and built with technically complex systems designed to protect the environment. Landfill environmental protection systems are generally more robust than those for burial sites, and would likely be less prone to failure when challenged by high organic loading, as in the treatment of large quantities of carcass material.

Mass Burial

Mass burial refers to a process whereby large numbers of animal carcasses (e.g., during a disease outbreak) and/or large quantities of SRM (e.g., from a slaughterhouse) are disposed of by burial. Mass burial sites would be pre-approved and engineered to incorporate systems and controls to collect, treat and/or dispose of leachate and gas. Leachate would be managed as well as monitored, for both composition and migration.

Carcasses must be buried deep enough that carnivorous animals cannot dig them up and water table contamination is prevented. The advantage of a pre-approved site by regulatory bodies is that the licensing process addresses groundwater protection and includes guidelines that govern distances to water tables, drinking water, etc. (Freedman & Fleming, 2003).

Table 1. Provincial Regulations for the Treatment of Deadstock and SRM in Landfill

British Columbia	There are 78 landfill sites in British Columbia, for which 54 have some regulatory approval for deadstock and or slaughter waste. Of these, 28 could handle SRM material.
Alberta	Provincial regulations permit burying MBM, as well as animal carcasses and raw material, in landfill. However, with respect to carcasses and raw material, operators of the two industrial landfills in Alberta can choose to refuse this material.
Saskatchewan	Municipalities accepting slaughterhouse remains or by-products at landfill sites must first ensure that the landfill is suitable for this waste, and that they have the equipment and land available to deal properly with the waste.
Manitoba	There are 18 Class 1 and Class 2 landfill sites in the province. Some accept deadstock, but others are subject to municipal requirements for burial.
Ontario	There are 58 landfill sites (Ontario major municipalities and private sites). Only a few take bovine carcasses and SRM, but within limits. A few others accept MBM only—not carcasses or raw meat waste.
Quebec	Municipal landfills are not available for bovine carcasses or SRM disposal.
New Brunswick	There are six landfill sites in the province, none of which accept bovine carcasses or SRM material.
Nova Scotia	Not specified.
Prince Edward Island	There is one landfill in the province, classed as a “second generation landfill”, in which MBM and raw animal wastes are not permitted.
Newfoundland and Labrador	Not specified.

(Ref: Appendix 4: Provincial Regulations for the Handling and Disposal of Deadstock)

Release Assessment

Landfill and Mass Burial: Level of Infectivity from Bovine Deadstock and SRM Potentially Destined for Disposal by Mass Burial or Landfill, per Year

- ▶ Detectable cases (that is, those late in the incubation period) are estimated to contain 10 000 ID₅₀ (one ID₅₀ is the infectious dose at which 50% of exposed cattle would be expected to contract the illness). Subclinical animals are assumed to carry 300 ID₅₀ per animal.
- ▶ Five clinical/ preclinical cases would contain 50 000 ID₅₀ (10 000 ID₅₀ x 5) and 100 subclinical cases would contain 30 000 ID₅₀ (300 ID₅₀ x 100). Thus, a maximum of 80 000 ID₅₀ would enter into materials potentially destined for disposal by mass burial or landfill sites.
- ▶ Assuming materials from carcasses of infected animals are randomly distributed in space and time, there would be a maximum of 105 burial sites (five clinical/ preclinical cases and 100 subclinical cases), one infected carcass by site, as a worst-case scenario in Canada. This assumes the maximum number of potentially infected sites, therefore, the potential for release of infectivity in a larger number of areas.

Effects of Landfill or Mass Burial Disposal on Infectivity

- ▶ Very little information is available regarding the length of time TSE agents persist in the burial environment, or the potential for dissemination from the burial site (United Kingdom Department of Health, 2001). Until more evidence is available on degradation of the BSE agent in the environment (Tsiroulnikov et al., 2004), landfill or mass burial disposal of bovine carcasses and SRM should be considered as a containment system. Studies are underway in the United Kingdom and in many other countries to determine the fate of the BSE agent in the environment; however, definitive results are not expected to be available for several years.
- ▶ Buried organic material is normally decomposed by microbial and chemical processes; however, the relationship between carcass or SRM decomposition and the reduction of BSE infectivity is not known. The rate of degradation of materials following burial can vary considerably between sites, and is dependant on temperature, moisture and burial depth, as well as pH, soil type and drainability; species and size of carcass; humidity/aridity, rainfall; and other factors (McDaniel, 1991; Pounder, 1995; Mann et al., 1990).
- ▶ The agents responsible for transmissible spongiform encephalopathies (TSEs) such as BSE in cattle, scrapie in sheep, CWD in deer and elk and CJD in humans, are highly resistant to inactivation processes effective against bacterial and viral disease agents. TSE agents have been demonstrated to be highly resistant to inactivation by chemical and thermal means, as well as ionizing, ultraviolet and microwave irradiation processes (Taylor, 1996 and 2000). CJD-infected brain tissue remained infectious after storage at room temperature for 22 months (Tateishi et al., 1988 in SCC, 1999). The scrapie agent is known to remain viable after at least 30 months of desiccation (Wilson et al., 1950 in SCC, 1999 in Nutsch & Spire, 2004).
- ▶ In one small experiment, the scrapie agent was demonstrated to retain at least a portion of its infectivity following burial for three years (Brown & Gajdusek, 1991). Scrapie-infected hamster brain was mixed with soil, packed into perforated petri dishes that were then embedded within soil containing pots, and buried in a garden for three years. Between two and three log units of the input infectivity of nearly five log units survived this exposure, with little leaching of initial infectivity into deeper soil layers. These results have implications for environmental contamination by scrapie and by similar agents, including those of BSE. It is uncertain if it would be valid to extrapolate this result to BSE.

Taylor (2001) indicated that “the present evidence suggests that TSE infectivity is capable of long-term survival in the general environment, but does not permit any conclusions to be drawn with regard to the maximum period that it might survive under landfill conditions” (Nutsch & Spire 2004).

- ▶ Based on the above information, the rate of degradation of the BSE agent in the environment (burial sites with various conditions) is unknown, therefore, the release assessment is estimated as **moderate**.

Exposure Assessment

Landfill and Mass Burial Disposal

- ▶ Landfill and mass burial disposal refer to processes whereby animal carcasses and/or large quantities of SRM (e.g., from a slaughterhouse) are disposed of by burial in particular sites. For the purposes of this risk assessment, it is assumed that those sites would be pre-approved and engineered to incorporate systems and controls to collect, treat, and/or dispose of leachate and gas. Leachate would be managed as well as monitored for both composition and migration. Appropriate planning and site evaluation would be conducted before burial, and would have to conform with federal, provincial and municipal laws with respect to hazard management and pollution control.
- ▶ Deep burial is required to prevent any potential disturbance of the burial site by scavengers. Domestic ruminants would not have access to the buried material, and therefore, would not be exposed to infectivity.
- ▶ Although leachates and other pollutants may persist for many years (United Kingdom Environment Agency, 2002; DN V, 2003), the management and monitoring of leachate would reduce the likelihood of surface water and groundwater contamination.
- ▶ In controlled landfills in the United Kingdom (where the leachate is controlled and there is no exposure to drinking water supplies), the “highest individual risk” (cumulative risk from regular exposure) was estimated around 3×10^{-6} to 10^{-7} cattle ID₅₀ per year, depending on the specific site (DNV, 1997 in SCC, 1999). The potential infectivity escaping from the site is around 50 cattle ID₅₀ per year, thus making the infected material likely to last for many years.
- ▶ There is a potential to spread the disease agent during transport. This potential is related to leachate from the trucks, from the site of origin to the buried sites. Because BSE infectivity is associated with biological membranes and infectious prions are insoluble, the likelihood that leachates from trucks would contain certain levels of infectivity could be reduced to negligible levels.
- ▶ Assuming sites are appropriately selected and managed, including the monitoring and control of leachate and surface water, SRM would be adequately contained. Therefore, the exposure assessment is estimated as **Negligible**.

Consequence Assessment

- ▶ No impact: **Moderate to High** (see description on page 14)

Risk Estimate

- ▶ Based on the above, the probability that secondary infections in ruminant livestock would become infected with BSE as a result of exposure to SRM and/or bovine deadstock disposed of in a landfill or into a mass burial pit, is **Negligible**.

PART C: TECHNOLOGIES WITH UNCERTAIN EFFICACY

6. MASS COMPOSTING

Process

Carcass composting is a natural biological decomposition process that takes place in the presence of oxygen. Under optimum conditions during the first phase of composting the temperature of the compost pile increases, but it does not usually raise material temperatures over 71°C. The decomposition of a mature cattle carcass may take about four to eight months. The remaining bony matter is soft and easily broken up for land application or other final disposal (Mukhtar et al., 2004; APHIS, 2003; Looper, 2001).

It was assumed that protection to prevent any potential disturbance of the composting sites by scavengers would be in place. Similarly, grazing animals would not have access to the composted material. According to the Composting Council of Canada (2005), in the interest of environmental protection, most Canadian composting facilities are required to manage any potential leachate produced on site as a key part of their environmental protection plan targeting ground and surface water safety. In mass composting disposal, it is assumed that sites would be appropriately planned and managed to prevent the formation of leachate. We also assumed that sites would be engineered to incorporate systems and controls to collect, treat and/or dispose of leachate. The management and monitoring of mass composting would reduce the likelihood of surface water and groundwater contamination. For more details, please refer to *Carcass Disposal: A Comprehensive Review*, National Agricultural Biosecurity Center Consortium, USDA APHIS Cooperative Agreement Project, Carcass Disposal Working Group (August 2004). Chapter 3. Composting. (<http://fss.k-state.edu/research/books/carcassdisfiles/PDF%20Files/CH%203%20-%20Composting.pdf>).

Composting Standards

In Canada, three organizations are responsible for the development of standards and regulations for compost and composting.

- ▶ CFIA regulates compost under the authority of the *Fertilizers Act and Regulations*. All compost that is sold in Canada must comply with the requirements of the *Fertilizers Act*. The *Act* includes provisions for product safety, benefit claims and labelling.
- ▶ The provincial and territorial governments regulate the disposal and use of waste, including its production and use. Consequently, compost which is produced and used is regulated within this jurisdiction. The Canadian Council of Ministers of the Environment (CCME) assists in the coordination of provincial and territorial initiatives wherever possible.
- ▶ The Bureau de normalisation du Québec (BNQ), acting on behalf of the Standards Council of Canada, establishes voluntary industry standards and endorses products which meet these standards (Composting Council of Canada, 1999). For more information, see the Composting Regulations and Guidelines Across Canada document (<http://www.compost.org/pdf/ccr.sw&r.legislation.PDF>).

These groups define compost as: “a solid mature product resulting from composting, which is a managed process of bio-oxidation of a solid heterogeneous organic substrate including a thermophilic phase” (Composting Council of Canada).

Release Assessment

Level of Infectivity from Bovine Deadstock and SRM Potentially Destined for Disposal by Composting Caused by Undetected Cases

- ▶ Detectable cases (clinical or preclinical) are estimated to contain 10 000 ID₅₀ (one ID₅₀ is the infectious dose at which 50% of exposed cattle would be expected to contract the illness). Subclinical animals are assumed to carry 300 ID₅₀ per animal.
- ▶ Five clinical/ preclinical cases would contain 50 000 ID₅₀ (10 000 ID₅₀ x 5) and 100 subclinical cases would contain 30 000 ID₅₀ (300 ID₅₀ x 100). Thus, a maximum of raw SRM from slaughterhouses from 105 clinical and/or preclinical cases of bovine carcasses (80 000 ID₅₀) would enter into materials sent directly by transport for disposal by mass composting.

Reduction of Infectivity Through the Composting Disposal Method

- ▶ The agents responsible for TSEs, such as BSE in cattle, scrapie in sheep, CWD in deer and elk and CJD in humans, are highly resistant to inactivation processes effective against bacterial and viral disease agents. TSE agents have been demonstrated to be highly resistant to inactivation by chemical and thermal means, as well as ionizing, ultraviolet and microwave irradiation processes (Taylor et al., 1995; Taylor, 2002). CJD-infected brain tissue remained infectious after storage at room temperature for 22 months (Tateishi et al., 1988 in SCC, 1999). The scrapie agent is known to remain viable after at least 30 months of desiccation (Wilson et al., 1950 in SCC, 1999 in Nutsch & Spire, 2004).
- ▶ Very little information is available regarding the length of time TSE agents persist in compost (Tsirounikov et al., 2004; Huang et al., 2005), or the potential for dissemination from the composting site. Composting is problematic with regard to BSE infectivity, as it may reduce but not destroy infectivity (Cliver, 2003). Composting does not usually raise the material's temperature over 160°F (71°C)—a temperature the BSE agent is known to survive for long periods. Further research is needed to characterize the effectiveness of composting with regard to BSE.
- ▶ Huang et al. (2005) at CFIA's Ottawa Laboratory (Fallowfield) conducted composting studies and an *in vitro* test tube simulation study to assess the influence of these processes on the degradation of abnormal prion protein (PrP^{Sc}) of scrapie. In the composting study, they attempted to destroy scrapie PrP^{Sc} (from specimens including central nervous system and lymphoid tissues from three scrapie infected sheep) by thermophilic microbial activity during laboratory composting conditions (60°C for 2 weeks). Specimens were removed from piles for testing after 108 days or 148 days. After composting, tissues were dry and significantly reduced in weight. PrP^{Sc} was not detected by ELISA, but was detected in reduced amounts in some specimens by Western blot after 148 days.

The authors concluded that PrP^{Sc} was degraded under specific laboratory conditions during composting and that thermophilic microbes were presumed to have played a role in its degradation. Bioassays are planned to estimate its log reduction. After personal discussions with Dr. Huang, it seems these studies are just beginning. The results cannot be extrapolated to BSE and the field situation. Studies are underway in Canada to optimize the compost conditions for efficient degradation of PrP^{Sc} and to measure the remaining infectivity.

- ▶ In one small experiment, the scrapie agent was demonstrated to retain at least a portion of its infectivity following burial for three years (Brown & Gajdusek, 1991). Scrapie-infected hamster brain was mixed with soil, packed into perforated petri dishes that were then embedded within pots containing soil, and buried in a garden for three years. Between two and three log units of the input infectivity of nearly five log units survived this exposure, with little leaching of initial infectivity into deeper soil layers. These results have implications for environmental contamination by scrapie and

similar agents, including those of BSE. It is uncertain if it would be valid to extrapolate this result to BSE.

The present evidence suggests that TSE infectivity is capable of long-term survival in the general environment, but does not permit any conclusions to be drawn with regard to the maximum period that it might survive under composting conditions.

- ▶ Several studies have demonstrated prion degradation by using proteases in laboratory conditions (Tsiroulnikov et al., 2004; McLeod et al., 2004; Sutton, 2005). In those studies, results demonstrated proteolytic inactivation of TSE agents, under specific conditions; however, their applicability to large scale disposal operations is questionable for reasons which include difficulties in ensuring contact over prolonged periods (DNV, 2003a). Further research is needed to characterize the effectiveness of this biological technology with regard to BSE.
- ▶ There are some obvious challenges in using composting for raw SRM and/or bovine deadstock disposal potentially contaminated with BSE, including the need for complete mixing, potential difficulties in accessing neural tissue encased within bone (brain in skull and spinal cord in vertebral column) for bovine deadstock, and ensuring the correct conditions are maintained, both in relation to the temperatures achieved and levels of microbial degradation (DNV, 2003a).
- ▶ Based on the foregoing high level of uncertainties, the lack of published papers specific to BSE and until further evidence is available, it is assumed that composting does not destroy any BSE infectivity. Even though normal composting procedures involve the addition of nutrient sources (e.g., straw, sawdust, manure) which increases the volume of compost created and which could result in a dilution factor of the BSE agent, the release assessment is estimated as **Moderate**.

A very limited number of studies suggest composting may reduce infectivity. Further research is required to define specific conditions for prion degradation

Exposure Assessment

Mass Composting Disposal

- ▶ For the purposes of this risk assessment, it is assumed that appropriate planning and site evaluation would be conducted according to the Composting Council of Canada (2005) before mass composting, which would have to conform with federal, provincial and municipal laws with respect to hazard management and pollution control. Appropriate disposal of deadstock and/or raw SRM will reduce the possibility that domestic ruminants will come into contact with the BSE agent, as well as protection to prevent any potential disturbance of the composting sites by scavengers and grazing animals so they would not have access to the composted material.
- ▶ There is a potential to spread the disease agent during transport. This potential is related to leachate from the trucks, from the site of origin to the composting sites.

Compost Spread on Land as Fertilizer

- ▶ Susceptible domestic ruminants could be exposed to infectivity through the ingestion of infectious material spread on pasture land or through the consumption of hay harvested from land on which infectious material was spread. This would result from surface contamination of forage and soil within a limited space of time after contaminated compost is spread.
- ▶ There is a small potential for the adjoining land to be contaminated by runoff of surface water contaminated with infectious material.

- ▶ Indirect exposure may occur through the contamination of surface water or groundwater.
- ▶ The rate of degradation of prions in the environment is unknown. Long-term experiments are currently underway in the United Kingdom with results expected in about ten years. For the purposes of this risk assessment, it is assumed that prion remains in the environment indefinitely.
- ▶ Given the lack of infectivity reduction achieved through composting and the high level of uncertainty associated with several environmental pathways—assuming no restriction on compost use—and the fact that inadvertent consumption may occur, the exposure assessment is estimated as **Low**.

Consequence Assessment

- ▶ No impact: **Moderate to High** (see description on page 14)

Risk Estimate

- ▶ Based on the above, the probability that secondary infections in ruminant livestock would become infected with BSE as a result of exposure to SRM and/or bovine deadstock disposed of by composting, is **Very low to Low**.

7. GASIFICATION

As described in the gasification followed by incineration section (page 27), gasification is a technology that burns carbonaceous materials under deprived oxygen to produce solid residues (char) and a synthetic gas (syngas).

Specific Gasification Process

As previously described on page 27, the Brookes Gasification Process is achieved by placing organic material inside a sealed vessel (primary chamber) and externally applying heat via a secondary chamber. After loading the material into the primary chamber, the temperature is raised slowly over a period of 12 to 14 hours until it reaches or exceeds the secondary chamber set point. This peak temperature is reached at the end of the process. The gases produced during the Brookes Gasification Process as a result of combustion enter the secondary chamber, where they are further oxidized (Infectrol, 2005)

Release Assessment

Reduction of Infectivity in Raw and Rendered SRM Processed by Gasification

- ▶ For the purpose of this risk assessment, only the infectivity associated with residual ash is considered. Infectivity loss through flue gas, filter sludge and wash water is not considered.
- ▶ No scientific evidence is available yet for the effectiveness of the Brookes Gasification Process used alone, without incineration. A worst-case scenario is therefore used, assuming no reduction in BSE infectivity of SRM.
 - The Brookes process, having no final incineration procedure, takes a long time to reach its peak temperature, and the recycling of the gases produced has to be considered separately.
- ▶ Based on the above, the release assessment is estimated as **Moderate**.

Exposure Assessment

- ▶ As with gasification followed by incineration, the lack of palatability of the residue means that land-spread ash would not be consumed by cattle (assuming no residue would be used in animal feeds). However, inadvertent consumption may occur, therefore the exposure is estimated as **Low**.

Consequence Assessment

- ▶ No impact: **Moderate to High** (see description on page 14)

Risk Estimate

- ▶ Based on the above, the probability that secondary infections in ruminant livestock would become infected with BSE as a result of exposure to SRM and/or bovine deadstock disposed of by gasification, is estimated as **Very low to Low**.

REFERENCES

- Alberta Regulations for the Disposal of Deadstock by Composting ([http://www1.agric.gov.ab.ca/\\$department/deptdocs.nsf/all/agdex6081?opendocument](http://www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/agdex6081?opendocument)).
- Alberta, Provincial regulation for the handling and disposal of the deadstock, *Livestock Diseases Act and Regulations*. ([http://www1.agric.gov.ab.ca/\\$department/deptdocs.nsf/all/agdex6081?opendocument](http://www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/agdex6081?opendocument)) ([http://www1.agric.gov.ab.ca/\\$department/deptdocs.nsf/all/rsb9096](http://www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/rsb9096)).
- Anderson RM, Donnelly CA, Ferguson NM, Woolhouse MEJ, Watt CJ, Udy HJ, MaWhinney S, Dunstan SP, Southwood TRE, Wilesmith JW, Ryan JBM, Hoinville LJ, Hillerton JE, Austin AR, & Wells GAH. 1996. Transmission dynamics and epidemiology of BSE in British cattle. *Nature* Vol 382: 779–788, August 29, 1996.
- Animal and Plant Health Inspection Service (APHIS). 2003. Proposed rules. Risk reduction strategies for potential BSE pathways involving downer cattle and deadstock of cattle and other species. 2703–2711.
- Animal Health Risk Assessment Unit (AHRA). 2002. Risk Assessment on Bovine Spongiform Encephalopathy in Cattle in Canada, J16. Canadian Food Inspection Agency, Ottawa.
- Animal Health Risk Assessment Unit (AHRA). 2004. Risk Assessment on BSE in Cattle in Canada—Update, M33. Canadian Food Inspection Agency, Ottawa.
- British Columbia *Regulations for the Disposal of Deadstock by Composting*. Provincial regulation for the handling and disposal of deadstock, Code of Practice, Part 8, Sections 23 and 24 of the Agricultural Practice for Waste Management. (http://www.qp.gov.bc.ca/statreg/reg/W/WasteMgmt/131_92.htm).
- Brown P & Gajdusek DC. 1991. Survival of scrapie virus after three years internment. *The Lancet*, 337 (8736), 269–270.
- Brown P, Rau EH, Johnson BK, Bacote AE, Gibbs Jr CJ & Gajdusek DC. 2000. New studies on the heat resistance of hamster adapted scrapie agent: Threshold survival after ashing at 600°C suggests an inorganic template of replication. *Proc. Soc. Natl. Acad. Sci. US*, 97, 3418–3421.
- Brown P, Rau EH, Lemieux P, Johnson BK, Bacote AE & Gajdusek DC. 2004. Infectivity Studies of Both Ash and Air Emissions from Simulated Incineration of Scrapie-Contaminated Tissues. *Environmental Science and Technology* 38, 6155–6160.
- Canada Gazette, Government of Canada, Vol. 140, No. 14 — July 12, 2006, Registration SOR/2006-147 June 23, 2006 (website viewed - July 28, 2006: <http://gazetteducanada.gc.ca/partII/2006/20060712/html/sor147-e.htm>).
- Cement Association of Canada (Personal Communication). August 2005. (<http://www.cement.ca/cement.nsf>). Retrieved August 2005.
- Chornet V. 2005. Personal Communication. Enerkem Technologies Inc.
- Clover D. 2003. Personal Communication. (<http://forests.org/articles/reader.asp?linkid=23169>).
- Composting Council of Canada. 1999. The Composting Process: Leachate Management. Composting Fact Sheets. Available on-line (July 15, 2005): (http://www.compost.org/pdf/sheet_6.PDF). Composting guidelines can be found at: (http://www.nr.gov.nl.ca/agric/soil_land/envseries/poultry/fs_poultry.pdf). Agriculture and Agri-Food Canada and Environment Canada. Support Document for Compost Quality

Criteria: National Standard of Canada (CAN/BNQ 0413-200) The Canadian Council of Ministers of the Environment (CCME) Guidelines and Agriculture and Agri-Food Canada (AAFC) Criteria.

Cummins EJ, Grace PM, Fry DJ, McDonnell KP, Colgan SF & Ward SM. 2002. Quantitative exposure assessment for the combustion of meat and bone meal derived from specified risk material in the context of BSE in Ireland. *J Agric Saf Health*. Nov; 8(4):365–83.

Department for Environment, Food and Rural Affairs, United Kingdom (DEFRA). 2001. Risk Assessment for the Disposal of Treated Rendering Plant Ruminant Condensate to Agricultural Land. (<http://www.defra.gov.uk/animalh/bse/index.html>).

DEFRA. 2004. Guidance on: Directive 2000/76/EC on the incineration of waste, Edition 2. (<http://www.defra.gov.uk/corporate/consult/ppc-wid/guidance.pdf>). Accessed on August 26, 2005.

DEFRA. 2005. Advanced Thermal Treatment of Municipal Solid Waste. (www.defra.gov.uk/environment/waste/wip/newtech/pdf/AdvancedThermalTreatment.pdf). Accessed on August 25, 2005.

Det Norske Veritas (DNV) Consulting (1997). Overview of Risks from BSE via Environmental Pathways for the Environmental Agency. (C7243). DNV Ltd., 3 Cathedral Street, London SE1 9DE, United Kingdom.

DNV. 2003a. Review of Disposal Options for Prion Contaminated Animals, Food and Feed Products. Commissioned by the Canadian Food Inspection Agency, AHRA, 3851 Fallowfield Road, Ottawa, ON. CFIA Report (C20036300) .

DNV. 2003b. "Independent environmental and public health risk assessment of DEFRA Foot and Mouth Disease Disposal Site" (No. 20073900). In Nutsch A. and Spire M, 2004 *Carcass disposal: A comprehensive review*. Chap 1. Burial.

Environment Australia. 1997. Appropriate Technologies for the Treatment of Scheduled Wastes. Review Report Number 4, November.

European Commission (EC). 1999. Scientific Report on the Risks of Non-Conventional Transmissible Agents, Conventional Infectious Agents or Other Hazards such as Toxic Substances Entering the Human Food or Animal Feed Chains via Raw Material from Fallen Stock and Dead Animals (including also: Ruminants, Pigs, Poultry, Fish, Wild/Exotic/Zoo Animals, Fur Animals, Cats, Laboratory Animals and Fish) or via Condemned Materials. (http://europa.eu.int/comm/food/fs/sc/scc/out58_en.html). Accessed on August 26, 2005.

EC. 2000. Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste. (http://europa.eu.int/comm/environment/wasteinc/newdir/2000-76_en.pdf). Accessed on August 25, 2005.

EC. 2002. No 1774/2002 of the European Parliament and of the Council - October 2, 2002. Health Rules concerning animal by-products not intended for human consumption. (http://www.defra.gov.uk/animalh/by-prods/publicat/en_2002R1774_do_001.pdf)

EC. 2003. Opinion on six alternative methods for safe disposal of animal by-products. (http://europa.eu.int/comm/food/fs/sc/ssc/out352_en.pdf). Accessed on August 25, 2005.

EC. 2005. Commission Regulation (EC) No 92/2005 of 19 January 2005 implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards means of disposal or uses of animal by-products and amending its Annex VI as regards biogas transformation and processing of rendered fats. (http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/l_019/l_01920050121en00270033.pdf). Accessed on August 25, 2005.

- Foy BR, Waldthausen, K, Sedillo MA & Buelow SJ. 1996. Hydrothermal Processing of Chlorinated Hydrocarbons in a Titanium Reactor. *Environmental Science and Technology*, Vol. 30, No. 9, pp. 2790–2799.
- Frasier D & Talka J. 2005. Facility design considerations for select agent animal research. *ILAR Journal*. Vol 46. No 1.23–33.
- Freedman R & Fleming R. 2003. Water quality impacts of burying livestock mortalities. In Nutsch A and Spire M, *2004 Carcass disposal: A comprehensive review*. Chap 1. Burial.
- Gale P, Young C, Stanfield G & Oakes D. 1998. Development of a Risk Assessment for BSE in the Aquatic Environment. *Journal of Applied Microbiology* 1998, 84, 467–477.
- Gale P. 1999. BSE Inquiry: Statement on Behalf of the Environment Agency concerning Thruxted Mill. The BSE Inquiry-Statement No 493. (<http://www.bseinquiry.gov.uk/files/ws/s493.pdf>).
- Gallant J. 2005. Personal communication. Cindar Power Developments Inc.
- George Morris Centre. 2004. Economic Impacts of Potential Regulations on the use of Bovine Materials in Animal Feeds, Informa economics and AGRA Informa company.
- Grist E (PM). 2005. An evaluation of United Kingdom Environmental Bovine Spongiform Encephalopathy Risk Assessment. *Integrated Environmental Assessment and Management*. Vol 1, (2). 152–159.
- Grist EP. 2005. Transmissible spongiform encephalopathy risk assessment: the UK experience. *Risk Analysis* 2005 Jun; 25(3):519–32.
- Grobben AH, Steele PJ, Somerville RA & Taylor DM. 2004. Inactivation of the bovine spongiform encephalopathy (BSE) agent by the acid and alkaline process used in the manufacture of bone gelatine. *Biotechnol. Appl. Biochem* (2004) 39, 329–338.
- Hansen E. 1992. Burning Solid Waste in Cement Kilns Proc. Kilburn '92, Brisbane, Sept. 10–11.
- Huang H, Spencer JL, Soutyrine A, Guan J, Rendulich J & Balachandran A. 2005. Application of Composting for Degradation of Abnormal Prion Protein in Tissues from Scrapie Infected Sheep. *Molecular Mechanisms of Transmissible Spongiform Encephalopathies (Prion Diseases)*. January 11–15, 2005 (Utah).
- Infectrol Brookes Gasification Process Programs. (www.infectrol.com/bgp_programs_agriculture.html). Accessed on August 17, 2005.
- Irish Government. 2003. Report of interdepartmental/agency committee on disposal options for meat and bone meal (MBM). 4 December.
- Lafarge Group. 2006. Kanda, Japan: Energy recovery from meat and bone meal. [http://www.lafarge.com:sustainable development](http://www.lafarge.com:sustainable%20development)
- Kaye GI, Weber P and Wetzell WM. 2004. Alkaline Hydrolysis. <http://www.animallab.com/articles.asp?pid=76>
- Looper M. 2001. Whole Animal Composting of Dairy Cattle. (www.dairybusiness.com/western/Nov01/NovWDBcompost.htm).
- Manitoba, Provincial regulation for the handling and disposal of the deadstock, *Livestock Manure and Mortalities Regulation* under the *Environment Act*. (<http://web2.gov.mb.ca/laws/regs/pdf/e125-042.98.pdf>).

Mann RW, Bass WM & Meadows L. 1990. Time since death and decomposition of the human body: variables and observations in case and experimental field studies. *Journal of Forensic Sciences*. Vol 35, Issue 1 (1 January 1990) 9pgs. Paper ID: JFS351900103.

Matthews D. 2003. Paper presented at: TSE — Fact or Fiction, Fort Collins, Colorado. Sponsored by the International Forum for TSE and Food Safety (TAFS), Sept 10–11, 2003. (<http://www.cvmbs.colostate.edu/aphi/Pubs/TSEProc.pdf>). Accessed on August 26, 2005.

McDaniel HA. 1991. Environmental protection during animal disease eradication programmes. *Revue scientifique et technique Office international des Épizooties*, 10 (3), 867–884.

McLeod AH, Murdoch H, Dickinson J, Dennis MJ, Hall GA, Buswell CM, Carr J, Taylor DM, Sutton JM & Raven ND. 2004. Proteolytic inactivation of the bovine spongiform encephalopathy agent. *Biochem Biophys Res Commun*. May 14;317(4):1165–70.

Mukhtar S, Kalbasi A & Ahmed A. 2004. *Carcass disposal: A comprehensive review*. Chap 3. Composting.

Murray N. 2004. BSE Regulatory Options: Enhanced Feed Ban Options—Risk Reduction Model and Analysis, CFIA, Ottawa.

New Brunswick Regulations for the Disposal of Deadstock by Composting.

New Brunswick, Provincial Regulations for the Handling and Disposal of Deadstock.

Newfoundland and Labrador, Regulations for the Disposal of Deadstock by Composting.

Nolte KN, Taylor DG & Richmond JY. 2002. Biosafety considerations for autopsy. *Am J Forensic Med Pathol* 23:107–122.

Nutsch A & Spire M. 2004. *Carcass disposal: A comprehensive review*. Chap 1. Burial.

O’Leary P & Walsh P. 1995. University of Wisconsin-Madison Solid and Hazardous Waste Education Center. US EPA, Office of Solid Waste and Emergency Response, 1995; as reprinted from *Waste Age*, 1991–1992.

Ontario, Provincial Regulations for the Handling and Disposal of Deadstock, *Dead Animal Disposal Act*, (http://www.gov.on.ca/OMAFRA/english/livestock/swine/facts/info_pm_mortal.htm).

Ontario, Provincial Regulations for the Disposal of Deadstock by Composting (http://www.gov.on.ca/OMAFRA/english/livestock/swine/facts/info_pm_mortal.htm); (<http://www.gov.on.ca/OMAFRA/english/livestock/deadstock/>).

Pounder DJ. 1995. Postmortem changes and time of death. Retrieved August 11, 2003, from Web site (<http://www.dundee.ac.uk/forensicmedicine/llb/timedead.htm>). In Nutsch A and Spire M. *Carcass disposal: A comprehensive review*. Chap 1. Burial. Electronic site. Retrieved August 11, 2003.

Prince Edward Island, Provincial Regulations for the Disposal of Deadstock by Composting (<http://www.gov.pe.ca/af/agweb/index.php3?number=73049>); (<http://www.gov.pe.ca/af/agweb/index.php3?number=74540>).

Prince Edward Island, Provincial Regulations for the Handling and Disposal of Deadstock, (<http://www.gov.on.ca/OMAFRA/english/livestock/deadstock/>).

Quebec, Provincial Regulations for the Handling and Disposal of Deadstock, according to the Agricultural Products, *Marine Products and Food Act*. Quebec Regulations for the Disposal of Deadstock by

Composting (<http://www2.publicationsduquebec.gouv.qc.ca/home.php#>)
(<http://communiqués.gouv.qc.ca/gouvqc/communiqués/GPQF/Mars2005/09/c2907.html>).

Richmond JY, Hill RH, Weyant RS, Nesby-O'Dell SL, and Vinson PE. 2003. What's Hot in Animal Biosafety? *ILAR Journal* Vol 44, No 1:21–27.

Saskatchewan, Provincial Regulations for the Handling and Disposal of Deadstock.
(http://www.agr.gov.sk.ca/DOCS/livestock/pork/production_information/agop-deadanimal.asp#MODA).

Saskatchewan, Provincial Regulations for the Disposal of Deadstock by Composting.
(http://www.agr.gov.sk.ca/DOCS/livestock/pork/production_information/agop-deadanimal.asp#MODA);
(http://www.agr.gov.sk.ca/docs/livestock/beef/production_information/CompostingAnimalMortalities.pdf).

Schmidt E. 2005. Personal communication. Canadian Meat Council's 85th annual conference. February 1–4, Québec. (www.foodincanada.com).

Schieder D, Schneider R & Bischof F. 2000. Thermal hydrolysis (TDH) as a pretreatment method for the digestion of organic waste. *Waste Science Technology*. Vol 41. No 3. 181–187.

Schreiber RJ. 1992. Cement Kiln Recycling: An Innovative Approach to Waste Management. *Proc. Kilburn '92*, Brisbane, Sept. 10–11.

Schreuder BE, Geertsma RE, van Keulen LJ, van Asten JA, Enthoven P, Oberthur RC, de Koeijer AA & Osterhaus AD. 1998. Studies on the efficacy of hyperbaric rendering procedures in inactivating bovine spongiform encephalopathy (BSE) and scrapie agents. *Vet Rec*. 1998 May 2;142(18):474–80.

Scientific Steering Committee (SSC). 1999. Scientific report on the risks of non conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals (Including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials.

SCC. 2002. Final Opinion and Report on: A treatment of Animal Waste by Means of High Temperature (150°C, 3 hours) and High Pressure Alkaline Hydrolysis. 10–11 April 2003. SEAC. 2001. Public summary of meeting held on 30th March 2001.

SSC. 2003. Opinion on the use of burial for dealing with animal carcasses and other animal materials that might contain BSE/TSE.

Spongiform Encephalopathy Advisory Committee (SEAC). 1996. Recommendations on the handling of waste material from cattle incineration: Statement: 7th June 1996.
(<http://www.seac.gov.uk/statements/state07jun96.htm>). Accessed on August 29, 2005).

SEAC. 2004. Origin of BSE in Relation to Born After the Reinforced Ban (BARB) BSE Cases.
(http://www.seac.gov.uk/papers/seac80_4.pdf).

Sutton M. 2005. Proteolytic Inactivation of Prions; a biological solution to TSE decontamination. Food and Drug Administration. Transmissible Spongiform Encephalopathies Advisory Committee. February 24, 2005.

Taylor DM. 1996. Inactivation studies on BSE agent. *British Food Journal*, 98 (11), 36–39.

Taylor DM. 2000. Inactivation of transmissible degenerative encephalopathy agents: A review. *The Veterinary Journal*, 159 (1), 10–17.

- Taylor DM. 2001. Issues involving the disposal of TSE infected animals. Proceedings One hundred and fifth annual meeting of the United States Animal Health Association. 2001. Hershey, Pennsylvania.pp 70–75.
- Taylor D. 2002. Inactivation of the BSE agent. *C R Biol.* 2002 Jan; 325(1):75–6.
- Taylor DM, Fraser H, McConnell I, Brown DA, Brown KL, Lamza KA & Smith GR. 1994. Decontamination studies with the agents of bovine spongiform encephalopathy and scrapie. *Arch Virol.* 1994; 139(3–4):313–26.
- Taylor DM, Woodgate SL & Atkinson MJ. 1995. Inactivation of the bovine encephalopathy spongiform agent by rendering procedures. *Veterinary Record*, Dec. 9; 137(24), 605–610.
- Taylor DM, McConnell I & Fernie K. 1996a. The effect of dry heat on the ME7 strain of mouse-passaged scrapie agent. *J Gen Virol.* Dec; 77 (Pt 12):3161–4.
- Taylor DM & Fernie K. 1996b. Exposure to autoclaving or sodium hydroxide extends the dose-response curve of the 263K strain of scrapie agent in hamsters. *J Gen Virol.* 1996 Apr; 77 (Pt 4):811–3.
- Taylor DM, Fernie K & McConnell I. 1997a. Inactivation of the 22A strain of scrapie agent by autoclaving in sodium hydroxyde. *Veterinary Microbiology* 58. 87–91.
- Taylor DM, Woodgate SL, Fleetwood AJ & Cawthorne RJ. 1997b. Effect of rendering procedures on the scrapie agent. *Vet Rec.* 1997 Dec 20–27; 141(25):643–9.
- Taylor DM & Woodgate SL. 2003. Rendering practices and inactivation of transmissible spongiform encephalopathy agents. *Rev Sci Tech.* 2003 Apr; 22(1):297–310. Review.
- Thacker LH. 2004. Alkaline Hydrolysis in Carcass Disposal: A Comprehensive Review. *The Veterinary Journal*, 159 (1), 10–17.
- Thompson S. 2005. Information gathered through internal documentation (CFIA) and through personal communication particularly concerning the information on Canadian incineration.
- Tolusso S. Personal Communication (February 2005 to 2006), Program Coordinator Feed Section, Canadian Food Inspection Agency (CFIA).
- Tsiroulnikov K, Rezai H, Bonch-Osmolovskaya E, Nedkov P, Gousterova A, Cueff V, Godfroy A, Barbier G, Metro F, Chobert JM, Clayette P, Dormont D, Grosclaude J & Haertle T. 2004. Hydrolysis of the amyloid prion protein and nonpathogenic meat and bone meal by anaerobic thermophilic prokaryotes and streptomyces subspecies. *Journal of Agricultural and Food Chemistry.* Oct 6; 52(20):6353–60.
- United Kingdom Department of Health. 2001. A rapid qualitative assessment of possible risks to public health from current foot and mouth disposal options - main report and annexes. Under the Environmental Protection Act, (<http://www.gov.pe.ca/af/agweb/index.php3?number=73049>)
- United Kingdom Environment Agency. 2002. Assessing the groundwater pollution potential of cemetery developments.
- United Kingdom Environment Agency. 2003. Processes Subject to Integrated Pollution Control: Combustion of Meat and Bone Meal (MBM). (<http://www.environment-agency.gov.uk/commondata/acrobat/ipcs2105a.pdf>). Accessed on August 25, 2005.

United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS). 2003. Proposed rules. Risk reduction strategies for potential BSE pathways involving downer cattle and deadstock of cattle and other species. 2703–2711.

USDA, APHIS Cooperative Agreement Project. 2004. National Agricultural Biosecurity Center Consortium *Carcass disposal: A comprehensive review*. Chap 1. Burial and Chap. 3. Composting.

United States Department of Energy (USDE) National Energy Technology Laboratory (NETL). 2000. A Comparison of Gasification and Incineration of Hazardous Wastes. (http://www.netl.doe.gov/publications/others/techrpts/igcc_wp.pdf). Accessed on August 26, 2005.

WHO (World Health Organization). 1999. WHO Global Action Plan for Laboratory Containment of Wild Poliovirus. Geneva: WHO (www.who.int/gpv-documents/).

Woodcroft DE. 1992. Introduction to Cement Technology. Proc. Kilburn, Brisbane, September 10–11.