A Cost-Benefit Analysis of Voluntary BSE Testing of Cattle

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January, 2011
Executive Summary

The purpose of this study was to evaluate the costs and benefits of voluntary testing for BSE in cattle at, or before, slaughter. To that end, the following were undertaken:

- The veterinary epidemiology literature on BSE was reviewed
- Selected agricultural economics literature on BSE was reviewed
- A survey of industry participants was conducted to evaluate demand for a BSE-tested product
- The cost of implementing BSE testing using post mortem and ante mortem testing procedures was estimated
- Consumer research was conducted in Canada to evaluate the demand for BSE-tested product
- The policy and regulatory context for a BSE test was reviewed
- An overview of the strategic context for a BSE test was developed

Results

The results showed the following:

- Given the scope of Canadian SRM removal (which is the key approach to safeguarding the human food supply) and the age at which fed cattle are slaughtered, post mortem BSE testing of them is extraordinarily unlikely to identify infected animals or indicate progress toward BSE eradication. Its value is essentially determined by the preferences of customers for, and value assigned to, tested product. An ante mortem test has less certain prospects, as only one of the approaches appears to be close to commercial reality, and practically speaking this could easily take five or more years for it to reach the Canadian market if validated. It is similarly unclear whether live BSE tests in development could detect positive BSE cases in younger cattle than the existing post mortem tests.
- The US and Canadian consumers appear only weakly inclined to pay for BSE testing, compared with certain other countries like Japan. BSE testing is not a panacea- it is not a market access opener by itself, and it is not the only way of enhancing perceived safety in the system as there are other approaches such as tracking and tracing. As noted, the major ways of protecting human foods from BSE are through implementation of the Enhanced feed ban, removal of specified risk materials (SRM), and traceability.
- The essential economic basis upon which to evaluate testing is the following:
  - What benefit can be expected from testing due to increased market access and/or price premiums, relative to
  - Adverse market impacts resulting from testing, such as lower prices or decreased market access for non-tested product, and
  - The direct cost of implementing testing.
- Canadian processors and exporters are not seeing requests for BSE-tested product. However, one major Japanese importer has directly requested it, and a senior meat trader knowledgeable with the Japanese market saw BSE testing as a potentially
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effective strategy to exploit Canada’s niche in Asian markets. On balance, there appears to be customer interest in a tested product, but it will require marketing effort and development as importers are unlikely to take the lead.

- Given the current estimates about the low prevalence of BSE in our national herd and the even lower likelihood of detecting infection in animals under 24 months of age, BSE testing under a voluntary test is expected to be relatively inexpensive. For the *post mortem* test, the anticipated cost is just over $40/head, comprised almost entirely of the cost of the test kit and sample analysis. For the prospective *ante mortem* test, the expected cost is $15/head with the dominant proportion of the cost associated with veterinary oversight of sample collection.

- Canadian consumers indicated some willingness to purchase a beef product that had been tested for BSE, but BSE testing is not viewed as “trumping” other aspects of a beef product; there remains a clear tradeoff between BSE testing and other product attributes, notably freshness and price. Labeling of beef products that had been tested for BSE did appear to confuse more broadly held perceptions regarding the safety of Canadian beef, as about 20% of consumers appeared to have a more negative attitude regarding the safety of Canadian beef when product labeled tested was available. Conversely when exported product was tested but domestic product was not, only about 13% perceived untested domestic product as less safe than tested exports.

- The Canadian Food Inspection Agency (CFIA) has extensive approval authority in regards to a BSE test, as well as extensive discretion regarding how that authority is used. Current CFIA policy and perspective is not supportive of a test; it is quite conservative in nature. CFIA approval for the test would not be readily forthcoming.

- The Alberta government appears also to have a view on the merits of BSE testing consistent with that of CFIA.

- Canada is among the smallest of the significant beef exporting countries. Among the major exporters, none currently test for BSE beyond surveillance measures. Australia and New Zealand have livestock identification systems in place, but the other major exporters do not. It is not expected that the other major exporters will begin testing for BSE apart from surveillance because they are either negligible risk for BSE, or lack a livestock identification system to manage the process.

- In most Asian markets, Canada’s effective competitors are Australia and New Zealand supplying mostly grass-fed product, and the US supplying grain-fed product; South American competitors are faced with access issues relating to foot and mouth disease (FMD). Meanwhile, the Canadian cow herd is in structural decline, but the Canadian cattle slaughter has remained relatively constant. This has occurred as the segments of the cattle industry have been reeling from losses due to a structurally stronger Canadian currency and feed costs that are structurally stronger than that in the US.

- The economic results observed in this study are supportive of a latent export market for tested product. The evidence supporting this includes written testament by would-be Japanese buyers to an Alberta processor, as well as presentations and appeals made by Japanese meat importers. This market
potential would be as a niche, and the nature of these markets is such that its potential would need to be developed proactively.

- A range of considerations arise in terms of potential adverse market impacts with voluntary BSE testing and would need to be appropriately addressed.
  - *Testing works against Canada’s position that trade rules be science based.* However, if it is viewed as marketing based on customer preference rather than abandoning a scientific perspective, it is unclear that this is a significant issue nor that it sets an ominous precedent. Prior examples include a willingness on behalf of Canada to adopt hormone-free protocols for beef exported to the European Union (EU), and a willingness to segregate certain genetic modification (GM)-free grains.
  - *Some consumers perceive non-tested product as unsafe.* This possibility was tested in consumer research in this study, and it was observed that only a core committed subset of Canadians would adopt this view. However, the risk of potential domestic consumer pushback of allowing testing for export marketing purposes suggests caution and would require close monitoring and management.
  - *There are no price premiums for tested product.* The detailed analysis done by Rancher’s Beef in 2005 suggested that, for a range of cuts preferred in Japan, prices are higher than in Canada. The anticipation here is that Canadian tested beef could be well positioned to take market share from grass-fed beef in the Japanese market. According to the USDA Foreign Agricultural Service, Japanese beef consumption in 2010 was about 1.2 million metric tonnes; with Canadian exports to Japan currently at about 10,000 tonnes, even if Canadian exports sharply increased it should not be expected to materially affect prices in Japan.
  - *CFIA is not supportive of testing.* CFIA has taken a very conservative position relative to testing, and Canadian proponents of voluntary BSE testing would need to engage the CFIA on this. If it is indeed the case that testing could create significant benefit at low risk and low cost, this analysis should be presented to CFIA and advocated as being in the public interest; at a minimum, it must be acknowledged by the CFIA that the current situation itself constitutes risk in terms of lost market opportunity and associated revenue impacts.
  - *Trade risks from testing.* The principal risk associated with voluntary testing from a trade perspective is that it results in more positive cases being observed. This risk is understood to be very low in cattle aged Under Thirty Months (UTM). However, if this occurred it could diminish Canada’s reputation and prolong its “controlled risk” status. At the same time, there is a trade risk associated with not testing, arising from not expanding exports to the Japanese market, and perhaps other export markets.
  - The costs associated with implementing a BSE test are relatively low. Based on actual budgeted costs for a plant in Alberta and on required changes in plant
engineering/operations, the quantifiable costs of a post mortem test is expected to be just over $40/head. A prospective ante mortem test is expected to cost about $15/head.

These results suggest that the economic potential is likely to exist to successfully market a BSE-tested product in Asian export markets, with Japan the focus here. This market potential would be as a niche, and the nature of these markets is such that the potential that may exist for tested product will need to be developed proactively; it will not be motivated nor developed by importers themselves with a request then coming to exporters. Thus, a latent market benefit to a BSE-tested product is envisioned, but clearly more work is required to understand its nature and measure its potential size.

Implications and Conclusions

The results of this study are consistent with an economic benefit from allowing a voluntary test for BSE, with some qualifications. The target market for the tested product is Japan, it is by nature a market niche, and developing a market for tested product will require initiative and effort on behalf of Canadian beef marketers; based on analysis relating to Japan, Asian importers are unlikely to provide the initiative. As with the roll out of any new product, due diligence is required and, as such, more formal market research is warranted in Asian target markets prior to proceeding. The positioning of such an initiative domestically requires some sensitivity, as the results show that the prospect of a BSE tested product in export markets could negatively affect the perception of beef on behalf of a small proportion (13%) of Canadian consumers surveyed.

The Japanese market has long been seen as a premium market for beef. It supplies well under half of its domestic market, and has been testing cattle for BSE since 2001. Beef in Japan was labeled as tested until about 2007 but this has fallen away. Domestic product remains a premium product in Japan, but there is some preference in favour of grain-fed import products.

The benefits of allowing testing foreseen here relate to better satisfying market demand and increasing sales, leading to improved market access, in export markets where BSE testing is a valued attribute. In this study Japan was the focus, and it was clear that a latent interest exists in accessing Canadian BSE tested product. Under post mortem testing technology, the costs of implementing testing in fed cattle appear surprisingly low, contingent on a low prevalence of positive cases. It is also evident that the presence of a BSE tested export product would not significantly cannibalize the domestic market for non-tested product, as 70% of respondents perceived untested beef in Canada as no less safe and perceived that tested exports are either safer or no less safe; 13% perceived non-tested product available in Canada as less safe and tested exports to be safer. Ante mortem testing presents less certain prospects (EFSA, 2006, 2007), but is expected to be less costly to implement.

The drawbacks of allowing testing relate to the potential to negatively impact consumer attitudes toward untested beef, lack of support from regulators, and the prospect that
testing, especially under a future *ante mortem* test, might identify positive cases and adversely impact Canada’s BSE risk status.
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1. Introduction

Canada is heavily leveraged toward exports of cattle and beef; if it rescaled itself to be limited to the domestic market it would be a shadow of its former self. However, in the post-BSE environment, Canada has been challenged in growing or even maintaining export market access, and thus its economic viability at current scale. Among the best illustration of these effects is the price spread between slaughter cattle in the US and Canada, as shown in Figure 1.1 below. In the period immediately following the May, 2003 Canadian case of BSE, and its ensuing border closures, Alberta slaughter cattle values declined dramatically relative to those in the US High Plains, and took several years to recover. Indeed, it can be argued that it was not until late 2007 when the US allowed imports of Canadian cattle over thirty months of age that the previous market mechanism came back into operation fully. However, even since 2007 Canadian slaughter cattle prices relative to the US are more volatile than prior to BSE, in part due to the post-BSE policy environment.

A potential means of alleviating this situation is to engage the BSE issue directly by allowing testing of Canadian product. By allowing interested firms and supply chains to credibly test animals for BSE, it could allow Canadian product to more readily penetrate export markets with consumer preferences attuned to BSE, spurring the demand for Canadian beef. Moreover, by doing so, it could create recognition of a premium product in certain market segments and supplant competitors’ products at a higher price. The specific benefits that might accrue in international markets are unknown, however.

At the same time, doing so creates direct costs associated with testing, as well as important risks. First, voluntary testing of this nature does not currently occur on a post mortem basis, and the efficacy of a potential ante mortem test is unknown. Second, it is unclear to what extent national and international agencies might recognize the voluntary tests, and what risks might be placed on the credibility of Canada’s current BSE position as a result. Finally, the risk exists that by allowing BSE-tested beef as a niche product to be marketed in competition with product tested under Canada’s existing rules, it could cannibalize the market for standard product. This could result in all product having to be tested to meet consumer demands, despite the fact that the science does not justify mandatory testing, creating considerable additional costs in the system.

These benefits, costs, and risks need to be understood as public policy develops regarding a voluntary testing for BSE. In particular:

- What is known about the nature, scientific rationale, and efficacy of BSE testing youthful animals that form export demand for Canadian beef?
- What is the economic criteria upon which to base a decision on BSE testing?
- What is the demonstrated consumer interest in BSE tested product?
- What are the direct costs of existing BSE tests and prospective ante mortem tests?
- How would voluntary testing influence consumer perceptions?
- What is the nature of the regulatory framework governing BSE testing?
- How would testing interface with a Canadian beef trade strategy?
1.1 Purpose and Objectives

The purpose of this study is to evaluate the costs and benefits of voluntary testing of cattle for BSE in fed cattle. The objectives are

- To characterize the prospective demand interest for BSE-tested beef product
- To provide an evaluation of the costs and benefits of existing post mortem testing for BSE as well as the potential costs and benefits of an ante mortem test
- To assess potential competitive marketing benefits of voluntary BSE testing, both domestically and internationally
- To evaluate Canadian consumers’ attitudes toward BSE testing of beef destined for export
- To characterize and assess the consistency of a voluntary BSE testing regime with the existing Canadian position on BSE, and with international rules
- To evaluate the risks, apparent policy alternatives for BSE testing and the potential liability implications of alternatives
1.2 Organization of the Report

Section 2 below provides an overview of the knowledge base relating to the epidemiology of BSE and vCJD. Section 3 surveys the economic body of knowledge relating to BSE. Section 4 provides a discussion of the demand interest in a BSE-tested product. Section 5 provides an analysis of the costs associated with a voluntary post-mortem and ante mortem BSE tests. Section 6 provides an analysis of the prospective consumer benefits of a tested product. Section 7 presents the policy and regulatory implications of a voluntary BSE test. Section 8 develops the strategic context for BSE testing. Section 9 concludes the report.
2. **BSE and vCJD: Epidemiology, Control Efficacy, and Testing Protocols**

2.1 **Initial Discovery and Observations**

Bovine Spongiform Encephalopathy (BSE), a progressively fatal disease of the central nervous system (CNS), was first described in England in 1986 and since that time approximately 185,000 cases in cattle have been confirmed in the United Kingdom (UK) (Harman and Silva, 2009; Adkin et al., 2010). Given the huge scale of this epidemic, several investigations of its source, its control, and the potential for spread to humans have been held (see http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/bse/index.htm and http://www.seac.gov.uk/publicats/). A major observation was that because the average incubation period (time from exposure to clinical signs) of BSE (the average is 4-5 years) exceeds the average survival time for most cattle, the confirmed cases represent only the tip of the iceberg and thus it has been estimated that approximately 2,000,000 cattle have developed BSE in the UK (Harman and Silva, 2009).

Since the BSE epidemic represented a new syndrome that was at the time not well understood, the causal agent was difficult to identify. However, it is now accepted that “prion protein is the only disease specific macromolecule consistently isolated in BSE-affected animals. The prion theory assigns infectivity to a structurally modified form of the prion protein (PrP) which in tum promotes the conversion of other prion molecules to the same, abnormal form. The accumulation of these abnormal isoforms (PrPsc) within the affected cell cytoplasm, interferes with normal cell function, contributes to the characteristic spongiform changes, and eventually results in cell death.” (http://www.inspection.gc.ca/english/anima/heasan/man/bseesb/1e.shtml#m1.1).

Capobianco et al., 2007 demonstrated conversion of atypical BSE to the classical form and suggest this as one possible source of the UK epidemic (For more complete discussion of this see reports on The United Kingdom Department of the Environment, Food and Rural Affairs (DEFRA) website).

The “epidemic” spread from the UK to other countries and currently, native born cattle in at least 25 countries have been affected with BSE (Bradley et al., 2006; Harman and Silva, 2009; Ducrot et al., 2008). With respect to the source of BSE in cattle, Bradley et al., in 2006 noted that “It is virtually certain that the vehicle of infection was meat-and-bone-meal (MBM) fed as a dietary supplement predominantly to dairy calves. MBM, and its associated by-product tallow, were derived mainly from the carcasses of fallen stock and other animal and poultry material rejected or unwanted for human consumption. The starting materials were subjected to “rendering”, a cooking process in which water was...
extracted, fat was separated as tallow, and the remaining protein-rich material ("greaves") was ground to make MBM for animal feed or agricultural and plant fertilizer. MBM was marketed primarily in the UK, but considerable amounts went abroad.

Although the largest epidemic occurred in the UK, much of the EU was affected also (Bradley et al., 2006). The role of the European Food Safety Authority and lists of its contributions to the control of BSE and prevention of vCJD are available at http://www.efsa.europa.eu/en/biohaztopics/topic/bse.htm. This website includes the scientific opinion on the "Risk for Human and Animal Health related to the revision of the BSE Monitoring regime in some Member States". The international control efforts have taken some time to "roll-out", hence in stating dates, we are referring to the UK legislation unless otherwise indicated. In 1988, legislation was passed in the UK banning the feeding of ruminant protein to ruminants. Unfortunately MBM could still be fed to pigs, and poultry and the interchange of these feeds with feed destined for cattle led to a great deal of cross-contamination. Furthermore, the ban did not apply to ruminants in zoos and wildlife parks which allowed the disease to take foot in a number of these sites. Similarly, MBM was used in pet foods, and as a result several cats developed neurologic disease. Dogs appear to be resistant to the disease (Harman and Silva, 2009). The episodic (geographically localized or temporally limited) feeding of contaminated feedstuff from specific producers did lead to clusters of BSE cases (eg Ireland---Sheridan et al., 2005; Netherlands---Heres et al., 2008; 2007; France---Abrial et al., 2003)

In November 1989, in an attempt to prevent human exposure to BSE, the use of specified bovine offal (SBO) in human food was prohibited (SBO denotes tissues that can be infected with the agent of BSE, namely brain and spinal cord, spinal ganglia, retina, and terminal small intestine). Initially, this legislation was largely based on what was known about scrapie in sheep and goats and did not become fully effective until 1995 (Bradley et al., 2006) when the SBO ban was extended to protect the foods of all species of mammals and birds. During the 1990s, the entire head, except the tongue, of cattle more than 6 months of age was banned from human foods; head meat was again permitted in the food chain in May, 2006. In 1996, meat from cattle over 30 months of age was removed from the food chain and this practice was continued until November, 2005 (Adkin et al., 2010).

As the epidemic grew, it became apparent that cattle less than 6 months of age had the greatest sensitivity to becoming infected (Arnold and Wilesmith, 2004). Animals between 6 and 18 months of age had a reduced susceptibility. Current estimates are that 1 mg of infected tissue is sufficient to infect cattle in their first year of life. Cattle older than 18 months appear to be more resistant to infection via the oral route; but can still become infected (Harman and Silva, 2009). This age-susceptibility feature was of great importance in understanding the epidemiology of BSE and in tracing the likely sources of infection.

Preventing the feeding of MBM to ruminants and identifying infected cattle at slaughter greatly reduced the subsequent frequency of BSE cases and protected human health. Testing of cattle at slaughter also proved to be a more sensitive indicator of breaks in the exposure-prevention practices than passive surveillance (see previous European Food
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Safety Authority (EFSA) website, 2008). However, the BSE control programs were very expensive. The costs of combating BSE have been enormous (in Europe, the discounted present value of BSE control has been about €92 billion). The loss to the EU livestock industry has been estimated at 2.75 billion euros per year, which is the equivalent of 10% of the total value of beef output (Cunningham, 2003). Further, the loss of value of product for MBM exceeds €1.5 billion annually. Others have estimated the cost-effectiveness of national programs in preventing vCJD and the estimates range from €4.3 to €17.7 million per life saved (Benedictus et al., 2009). According to the EC TSE Roadmap the cost linked to the finding of the one positive case in 2002 in the healthy slaughter surveillance stream in the age group 30-35 months was 302 million euro.

Thus, as the BSE prevalence was lowered, the program was modified accordingly. For example, guidelines for changes to the European program to eradicate BSE are explained in the TSE Roadmap (European Community TSE Roadmap, 2005 and http://ec.europa.eu/food/food/biosafety/bse/roadmap_en.pdf). This roadmap adjusts for the decreasing prevalence of BSE in Europe and provides guidance for relaxing some of the existing legislation. See also the DEFRA website for recent changes to the UK surveillance program. From a global perspective, “The OIE [Organisation Internationale Des Epizooties, or World Animal Health Organization] through its experts and world network of Reference Laboratories and Collaborating Centers provides policy advice, strategy design and technical assistance for the control and eradication of BSE” (http://www.oie.int/eng/info_ev/en_BSEHome.htm). The EFSA, 2008 commented on the likely impact of changing the age of testing for healthy slaughter and “fallen” cattle. They also noted that testing fallen cattle between 24-30 months of age would not likely detect any BSE cases. Given the dramatic and continued decline in case numbers, people have begun to question the high expenditures on SRM management and the work of de Vos and Heres (2009) suggests that the risk of BSE transmission from feeding category 3 MBM is now very low.

2.2 Pathogenesis: The development of BSE within an infected animal

Younger cattle are thought to have an increased susceptibility to prion infection (Harman and Siva, 2009). Following exposure to, and infection by the BSE prion, the infection remains localized within Peyer’s patches in the ileal wall (it can be detected there after approximately 6 months) with very little spread via the lymphoid system. Most “within-animal” spread appears to be via the autonomic nerve system that innervates the gastrointestinal tract (Harman and Silva, 2009). (See Arnold et al, 2009 for further details on tissue infectivity at selected times post exposure.) Evidence indicates that cattle blood is not infected although a few bone marrow samples have been found to be infected (perhaps through cross-contamination (Harman and Silva, 2009). The ileum remains positive until approximately 18 months.

In controlled experiments, prions can be detected in the ileum 6 months after exposure. This infectivity appears to disappear until 32-38 months after exposure (Anil and Austin, 2003) (likely at the time when the disease is at or near the clinical stage). Prions are first detected in the central nervous system (CNS which includes the brain, spinal cord, dorsal
root ganglia and trigeminal ganglia) at 32-40 months post exposure. Furthermore, in another series of experiments the first clinical signs occurred at 35 months after exposure. Summarizing the experimental work it has been estimated that the mean incubation period (time from exposure to clinical signs) is 45 months with a range of 32 to 55 months. Only 0.02% of the cases in the UK (0.05% according to the Official Journal European Communities 23.3.2001) occurred before the cattle were 3 years old (Harman and Silva, 2009). It is also recognized that the incubation might be inversely related to dose of exposure; higher exposures lead to shorter incubation periods (Donnelly et al 1997). Furthermore, the level of prion infectivity in cattle increases in temporal proximity to the development of clinical signs (Arnold et al, 2009); however, this infectivity is difficult to detect until approximately 70% of the way through the incubation period. The exponential increase in infectivity is often summarized by saying the titre doubles every two months (Comer and Huntly, 2003). This feature has huge implications for the ability of tests to detect the presence of BSE prions. Most cases can only be detected by current postmortem tests within 3 months of the time they would develop clinical signs (Benedictus et al, 2009).

However, Anil and Austin (2003) point out “There must be serious doubts that there is any fixed relationship between the onsets of clinical signs and transmissibility in the central nervous system that allows the onset of transmissibility to be estimated from the subtraction of a finite period from the time of clinical onset. If there is such a relationship it would likely be much longer than 3 months.” They further assert “The nature of these early signs suggests that they are the result of functional changes in the central nervous system, presumably associated with the activity and presence of the transmissible agent, at around 40% through the incubation period.” and “We do not have the necessary information to construct a population distribution curve for the onset of BSE transmissibility in the CNS, but it seems probable that this begins substantially before 30 months and extends to overlap with that for the onset of clinical signs.” With respect to testing at slaughter, Anil and Austin comment that “If food safety is to be based on the age when transmissibility first becomes established, it would seem that this age needs to be appreciably less than 30 months. Some countries have adopted 24 months as the age beyond which all carcasses should be tested for evidence of BSE by immunological tests for PrP.” However, whereas some infectivity may be present before 30 months, the ability of current tests to detect that infectivity is close to zero. For example, only one of the confirmed cases in Japan was less than 30 months of age (a 21 month old steer; one other 24 month old steer test positive was deemed “atypical”). In the United Kingdom, of 180,000 cattle found to be positive for BSE, only 0.006% were 24 months of age or less (http://www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/cpv8104).

2.2 Canadian Experience

The first BSE case in Canada occurred in 1993 in a cow that was imported from the UK 6 years earlier. The first native born Canadian case of BSE was diagnosed in 2003. Although the actual source of the BSE epidemic in Canada is unknown, it is now believed that it likely arrived via one or more infected cattle out of group of 168 cattle imported from the UK between 1982 and 1990 (at least 10 of these cattle came from
farms that subsequently had cattle that developed BSE). To date, a total of 18 BSE cases have been identified in Canadian born cattle; two of these were defined as “atypical BSE” (see Section 2.4).

Table 2.1 contains a brief listing of the confirmed cases attributable to exposure (or arising in) in Canada, since 2003 (The imported 1993 case is excluded).

<table>
<thead>
<tr>
<th>Case</th>
<th>Case Date</th>
<th>Animal age (yr)/breed</th>
<th>Place of Birth</th>
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<tbody>
<tr>
<td>17</td>
<td>02/2010</td>
<td>6 Angus</td>
<td>Alberta</td>
</tr>
<tr>
<td>16</td>
<td>05/2009</td>
<td>6 Holstein</td>
<td>Alberta</td>
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<td>11/2008</td>
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<td>Fraser Valley BC</td>
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<tr>
<td>14</td>
<td>08/2008</td>
<td>6 GelbviehX</td>
<td>Northern AB</td>
</tr>
<tr>
<td>13</td>
<td>06/2008</td>
<td>5 Holstein</td>
<td>Fraser Valley BC</td>
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<td>12</td>
<td>02/2008</td>
<td>6 Holstein</td>
<td>Northern AB</td>
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<td>12/2007</td>
<td>14 Hereford</td>
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<td>Atypical BSE</td>
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<td>Fraser Valley BC</td>
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<td>6.5 Angus Bull</td>
<td>Northern AB</td>
</tr>
<tr>
<td>8</td>
<td>08/2006</td>
<td>8-10 CharolaisX</td>
<td>Officially “untraceable”</td>
</tr>
<tr>
<td>7</td>
<td>07/2006</td>
<td>4 Jersey</td>
<td>Northern AB</td>
</tr>
<tr>
<td>6</td>
<td>07/2006</td>
<td>16-17 CharolaisX</td>
<td>Manitoba Atypical BSE</td>
</tr>
<tr>
<td>5</td>
<td>04/2006</td>
<td>6 HolsteinX</td>
<td>Fraser Valley</td>
</tr>
<tr>
<td>4</td>
<td>01/2006</td>
<td>6 HolsteinX</td>
<td>North-central AB</td>
</tr>
<tr>
<td>3</td>
<td>01/2005</td>
<td>7 Charolais</td>
<td>Central AB</td>
</tr>
<tr>
<td>2</td>
<td>01/2005</td>
<td>8 Holstein</td>
<td>Northern Alberta</td>
</tr>
<tr>
<td>US</td>
<td>12/2003</td>
<td>6.5 cow</td>
<td>AB—case found in Washington, USA</td>
</tr>
<tr>
<td>1</td>
<td>05/2003</td>
<td>6-8 cow</td>
<td>Saskatchewan^</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Detected in Northern Alberta</td>
</tr>
</tbody>
</table>

Note: The cases were numbered to correspond to that of Dudas et al, 2010
^S. Czub pers comm
2.3 **Surveillance and Inspection**

The Role of Sampling in Surveillance

For practical reasons, it is often impossible to test every animal in the population of interest. Hence, many surveillance systems are aimed at testing a sample of animals. However, for sampling to be effective and efficient two conditions need to be met:

1) there needs to be a mechanism to obtain a formal random sample of the population of interest (eg the Canadian cattle population), otherwise the basis for believing that the animals selected represent this population in jeopardy

2) the disease of interest needs to be relatively frequent (say a 5% prevalence) otherwise the sample size needs include virtually all of the animals in the population.

Although the first condition could be met in Canada, the second (high prevalence) cannot. The prevalence of BSE in the Canadian cattle population is unknown, but it probably is on the order of 1 per million. Furthermore, even when the source of infection in a herd is a feed item to which many animals are exposed, only a few animals will go on to develop clinical signs. Hence even within exposed herds the maximum percentage of cattle testing positive in the UK was approximately 3%. So the only practical sampling and testing regime within an exposed herd is to test all animals; sampling will not achieve any savings. At the population level, this means that a relatively large proportion of the population needs to be tested to ensure that the disease will be detected if present (this is known as the “power” of the surveillance program).

Given that the first condition (above) is met, for disease surveillance, the number of animals required in a random sample of a population to provide sufficient power to detect disease, or to estimate prevalence within defined limits can be determined based on statistical sampling principles. A rule of thumb is that 100 investigations should be carried out on cattle with BSE-compatible signs for every $10^6$ cattle over 30 months old (Harman and Silva, 2009). Often, in order to achieve efficiencies, the sampling is targeted towards the higher risk animals to minimize the number of animals that are required to be sampled. Thus, in the case of BSE, the OIE has suggested weights be given to the different categories of high risk animals, and to routinely slaughtered animals (Table 2.2 below) in order to estimate the number of animals that should be tested. Based on the population distribution, the sum of the weights multiplied by the number of animals sampled per category needs to meet the criteria provided by OIE. The OIE also classifies the BSE status of each country using a set of published guidelines (OIE QUESTIONNAIRE FOR BSE-STATUS RECOGNITION 2008 and http://www.oie.int/downld/Doc_OIE/A_BSEquest.pdf, 2009).

The former discussion assumes active sampling where the target number of animals to be sampled is identified in advance and then the authorities actively select this number. In Canada, the target number of animals (or points) is known but the animals to be sampled are identified by farmers, veterinarians and others based on their belief that the animal is a BSE suspect or falls into a category that CFIA has declared should be sampled (eg dead
stock above 30 months on a farm). Once CFIA is notified of BSE suspects the necessary farm/ slaughter plant visits are conducted and an investigation commenced. Suspect animals are not allowed to enter a slaughter plant and suspects detected on ante-mortem inspection at a plant are held in isolation outside of the plant until the investigation is completed. The details of the investigation procedure are described in a CFIA manual (copies of which are available upon request).

Estimating the prevalence of BSE in the national herd is very difficult. Prattley et al, 2007 pointed out that each of the streams of cattle (healthy and 4Ds>30M-see below) has its own biases and this is complicated by the nature and extent of the surveillance program. Nonetheless they developed a program (BSurvE) which uses data on the age distribution of cases and the cattle population to provide both national overall and birth-cohort-specific estimates. Powell et al, 2008 later demonstrated that when BSE prevalence is low, the surveillance program often lacks power to detect changes in BSE prevalence even when the sampling fraction exceeds OIE suggested levels.

For its validity, passive surveillance needs complete reporting of suspect cases (Cazeau et al, 2004). Because the passive surveillance (of down, diseased, dying, or dead cows (4Ds) over 30 months of age with neurological signs) for BSE depends on producer compliance, the federal government provides financial support to producers reporting “eligible BSE suspect cases”, and to veterinarians and dead stock collectors who assist with the sampling. For example, beginning in 2004, the federal program reimbursed the producer/owner $75 and the attending veterinarian (up to $100) (http://www.inspection.gc.ca/english/for/pdf/c5372e.pdf). Both Alberta and British Columbia have increased the level of funding to encourage complete reporting of BSE suspects. In British Columbia, the top-up is $100 per eligible animal (to a specified number per year)(www.gov.bc.ca). In Alberta the surveillance system integrates with the Canadian system and includes a program to train and certify veterinarians to assist in the surveillance effort (www.agric.gov.ab.ca). The combined payment to the producer for eligible cattle is $225. See the Canadian and Alberta BSE Surveillance Program for further details (http://www1.agric.gov.ab.ca/general/progserv187).

As noted above, the current system for BSE surveillance in Canada uses “points” as designated by the OIE (details can be found at http://inspection.gc.ca/); this is summarized in Table 2.2 below. More points are assigned for testing the highest risk animals (i.e. 4 to 7 year old animals with nervous system symptoms). The fewest points are awarded for testing animals that are the least likely to develop the disease (i.e. young health animals tested at slaughter).

This approach is consistent with findings from the EU where both passive surveillance and active testing of all animals over 30 months of age at slaughter has been conducted for a number of years. It appears that about 14% of all BSE cases will be detected in the healthy slaughter category of cattle. Others have reported that their passive surveillance systems were relatively ineffective at finding BSE cases (Ducrot et al, 2008)
Table 2.2
OIE Point System for BSE Surveillance by Risk Category

<table>
<thead>
<tr>
<th>Age</th>
<th>Healthy Slaughter</th>
<th>Dead/Fallen stock</th>
<th>Emergency Slaughter</th>
<th>Clinical Suspect</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;1≤2 years</td>
<td>0.01</td>
<td>0.2</td>
<td>0.4</td>
<td>N/A</td>
</tr>
<tr>
<td>&gt;2≤4 years</td>
<td>0.1</td>
<td>0.2</td>
<td>0.4</td>
<td>260</td>
</tr>
<tr>
<td>&gt;4≤7 years</td>
<td>0.2</td>
<td>0.9</td>
<td>1.6</td>
<td>750</td>
</tr>
<tr>
<td>&gt;7≤9 years</td>
<td>0.1</td>
<td>0.4</td>
<td>0.7</td>
<td>220</td>
</tr>
<tr>
<td>&gt;9 years</td>
<td>0.0</td>
<td>0.1</td>
<td>0.2</td>
<td>45</td>
</tr>
</tbody>
</table>

Canada currently is classified by OIE as a “controlled risk” country based on the following criteria:
1. have a risk assessment demonstrating appropriate and effective management measures
2. meet Type A surveillance requirements1 (i.e. 300,000 points over 7 years)
3. meet Type B surveillance requirements2 after this (i.e. 150,000 points over 7 years)
4. have: a program to have industry participants report all cases with clinical signs
   - compulsory notification and investigation of all animals with clinical signs
   - examination of (brain) samples in an approved laboratory
5. ruminant meat and bone meal (MBM) may have been fed to ruminants in the past 8 years
6. identify all animals born in the same herd within a year of positive cases, control their movements, and completely destroy them at slaughter or death.

Table 2.3
The number of animals tested and positive for BSE by year in Alberta and Canada (Note two atypical cases excluded)

<table>
<thead>
<tr>
<th>Year</th>
<th>No. Tested in Alberta</th>
<th>Positive in Alberta</th>
<th>No. Tested in Canada</th>
<th>Positive in Canada</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>7,985</td>
<td>0</td>
<td>23,550</td>
<td>0</td>
</tr>
<tr>
<td>2005</td>
<td>21,938</td>
<td>2</td>
<td>57,768</td>
<td>2</td>
</tr>
<tr>
<td>2006</td>
<td>27,221</td>
<td>3</td>
<td>55,410</td>
<td>5</td>
</tr>
<tr>
<td>2007</td>
<td>30,111</td>
<td>2</td>
<td>58,174</td>
<td>3</td>
</tr>
<tr>
<td>2008</td>
<td>23,191</td>
<td>1</td>
<td>48,613</td>
<td>4</td>
</tr>
<tr>
<td>2009</td>
<td>15,3261</td>
<td>0</td>
<td>34,617</td>
<td>1</td>
</tr>
<tr>
<td>2010</td>
<td>Incomplete</td>
<td>1</td>
<td>Incomplete</td>
<td>1</td>
</tr>
</tbody>
</table>

1 Jan-June 30.
Sources:
http://www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/cpv12286
http://www1.agric.gov.ab.ca/general/progserv.nsf/all/pgmsrv187
http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/surv/surve.shtml#num
S. Czub pers comm.

1 Type A surveillance is designed to detect 1 case per 100,000 adult animals
2 Type B is designed to detect 1 case per 50,000 adult animals.
http://www.oie.int/eng/normes/mcode/en_chapitre_1.11.6.htm
2.4 Atypical strains of the BSE prion in cattle

Most cattle with BSE appear to have been infected with the one major strain of the BSE agent. However, retrospective analysis of the BSE cases in the UK, verified that a rare strain was present at least occasionally during the epizootic (Stack et al., 2009). In France, by 2007, of 645 confirmed cases of BSE, 7 were H-type and 6 were L-type. By 2008, approximately 30 cases of atypical BSE had been confirmed worldwide.

Thus, there are at least 3 strains of the BSE agent in cattle: the classical BSE strain of the UK epidemic and 2 atypical strains (designated as L-type and H-type [denoting characteristic light and heavy molecular prion banding patterns revealed via western blot analysis]) (Dudas et al., 2010). The H-type has a higher molecular weight but the same glycopattern as typical BSE prions; whereas the L-type has a lower molecular weight and a very different type of glycopattern. Characterization of the molecular signature via western blot analysis enables identification of the strain of BSE prion; the atypical L-type and H-type BSE prions can be distinguished from the classic form of BSE prion. The L-type strain has been experimentally transmitted to cattle and nonhuman primates, and is thought to be capable of causing disease in humans (Comoy et al., 2008). Both types can be transmitted to inbred mice and cattle (Buschmann et al., 2006).

In Europe, atypical L-type BSE (BASE) has been identified only in cattle that appeared healthy at slaughter, and most of those animals were older than the animals typically affected with the classic strain of BSE. In Canada, the two atypical cases (case #s 6 and 11: one of the H-type, and the other of the L-type) (Clawson et al., 2008; Dudas et al., 2010) were clinical BSE suspects (“diseased”) and sampled accordingly. To date, at least 1 case of H-type atypical BSE has been associated with a heritable mutation in the gene expressing the normal cellular prion protein (Nicholson et al., 2008). The susceptibility to BSE disease strains may be related to genetic differences among cattle. One haplotype was present in 90% of the atypical cases and 26% of healthy controls. Thus, by itself, this haplotype does not fully explain atypical BSE occurrence but rather it signals a “likely” genetic component to susceptibility to typical BSE. Both of the BSE cases ascertained in the US indigenous cattle were atypical cases (H-type). The L-type atypical BSE most closely resembles transmissible mink encephalopathy. Finding these “atypical” cases has become an element of quality control since it is anticipated that they are present at extremely low levels in virtually all countries. Japan detected 2 atypical cases during the 2001-2006 period. Failure to detect atypical cases suggests that the surveillance system needs enhancements.

2.5 Testing Methods and Validation Protocols

TAFS, 2009c in their Position Paper on Testing of Cattle for BSE – Purpose and Effectiveness make the point that “The main purpose of testing is to identify whether BSE exists in a country, and if so, the likely numbers of infected cattle.” This activity has proven very helpful in tracking the progress of eradication in a number of European countries that have a much higher prevalence of BSE than likely exist in
Canada, and historically, it has proved helpful in detecting weak links in the control procedures.

No validated live animal test for BSE currently exists. Accordingly, testing for BSE is currently performed using brain samples of dead animals. Brain samples are screened using rapid tests that perform with high diagnostic sensitivity and specificity to accurately and quickly detect a BSE positive sample (an infected brain roughly within 3 months of developing clinical disease) nearly 100% of the time. The two rapid tests validated in and CFIA approved for Canada are the Prionics® Check PrioStrip and Bio-Rad TeSeS® ELISA. Rapid tests can, in rare cases, react when a sample is not infected with BSE. These rapid-test responses are known as "inconclusive or initially reactive" results. Arnold et al., 2007 published on rapid-test sensitivity. EFSA [European Food Safety Authority] (last: EFSA Journal 2009; 7(12):1436) has determined and published the evaluation results on diagnostic sensitivity and specificity, and to some degree on the analytical sensitivity of rapid post and ante mortem tests.

All samples that yield inconclusive results using a rapid test are sent to the BSE Reference Laboratory with the CFIA in Lethbridge, Alberta for disease confirmation. This is done either by using the immunohistochemistry (IHC), or in the case of poor tissue quality by the Scrapie Associated Fibril (SAF) Immunoblot. Both are internationally recognized and OIE recommended confirmatory tests for BSE. (http://www.inspection.gc.ca/english/animal/health/disease/bse/bseesb/surv/sampe.shtml)

Many European countries developed a program of testing animals over 30 months of age, while some tested animals over 24 months of age. A few, such as Japan testing all cattle at slaughter, although the official rules now state that testing can be restricted to animals over 21 months of age. Countries where there is sound reason to believe that the prevalence of BSE is very low, have tended to focus testing on fallen or casualty stock. As TAF, 2009 states, “Testing of fallen stock and casualties is the most cost-effective approach of finding BSE infected animals in that fewer animals have to be tested for each positive detected.” As noted in the next section, the major control procedure to protect the human food chain is the removal of specified risk materials. Current post-mortem tests cost about 15-20 Euro, not including laboratory work and items such as the transport of samples etc. (Europa Food Safety). Since 2001 in England, it has cost over 214 million Euro. “This includes laboratory costs, the costs of Meat Hygiene Service controls in abattoirs and Rural Payments Agency expenditure on the collection, brainstem sampling and disposal of cattle that have died or been killed on farm or in transit (fallen cattle). The costs of testing cattle with clinical signs of BSE are excluded.” From the USA, estimates are that the costs of testing, including salaries of lab technicians, the cost of grinding up and delivering cattle brain samples for testing, and the tab would be $30 to $50 per animal.

With regard to prospective ante mortem tests that could be used to detect BSE, the de facto international standard is set by the EFSA (European Food Safety Authority) which took over from the SSC (standard Steering Committee) the EU regulated mandate for the scientific evaluation of rapid TSE tests. It is the EFSA opinion that the purpose is to
replace post-mortem tests for BSE with ante-mortem tests, thus creating the need of a comprehensive evaluation to meet all requirements for consumer protection. These criteria are the following: the performance of the ante mortem tests should not be statically inferior to that of currently approved post mortem tests (diagnostic sensitivity > 98.5%), 100% sensitivity for samples from clinically confirmed BSE cases, and the test performance should be capable of detecting infected animals earlier in the incubation period. The evaluation process follows established criteria laid out by EFSA which includes the submission of application dossiers following an EU call for expression of interest; an assessment of the application dossiers by a panel for 15 scientists external to the EFSA; a pre-evaluation assessment and report; a laboratory evaluation and report; and finally a field trial and report. At any stage, a test may be excluded from further assessment. The assessment of the application dossier targets the scientific basis of the potential test, the available experimental evidence, the practicability of the sampling and testing (robustness and “ease of transfer into the field”) and the stage of the development of the test. Is the review favourable, the test will be selected for the evaluation exercise. The established criteria laid out for the laboratory evaluation are focused on the diagnostic sensitivity of the test (to correctly recognize 54 samples of 53 confirmed BSE positive animals), on the diagnostic specificity (to correctly recognize 558 samples of 488 animals which are BSE negative, clinically suspect and with other diseases or infections) and on the analytical sensitivity (to correctly recognize 16 of BSE-challenged and unchallenged animals during early incubation). Should the laboratory evaluation of the ante mortem test meet the established performance criteria, the EFSA will approve the test for its use and publish the evaluation and the approval on its website. For Canada, once the test is approved by EFSA, the test will be subjected to a small scale “suitability testing” by the Canadian BSE Reference Laboratory as it is standard operating procedure for BSE tests. Should the national evaluation meet the (EFSA) predefined performance criteria, the BSE Reference Laboratory will recommend to the CFIA Office of Veterinary Biologics to approve the test for use in Canada.

To date, no ante mortem tests have been approved by EFSA. EU issued a call for expression of interest on an ante mortem BSE test in January, 2003. Six different tests were submitted by six companies, but only one was selected by the external panel for the full evaluation exercise. The “AquaSpec” rapid ante mortem BSE test was submitted by DiaSpec and Scil Diagnostics/ Germany (Phillip et al, 2006). The test aims to detect disease associated features in infrared spectroscopic patterns of bovine serum using a Fourier-transform infrared spectroscopy spectrum in middle infrared range (MIR) in an AquaSpec flow cell. Depending on the applied corrector, the test performance was ranging between ~ 88-89% for the diagnostic sensitivity and between ~ 64-78% for the diagnostic specificity. The candidate test did not meet the predefined criteria of the laboratory trial, the overall assessment was negative and the test could be recommended for approval.

Potential ante mortem tests for BSE are based on two different approaches. The first would be the disease-specific or direct tests which would detect the misfolded prion protein in blood, serum, urine or tears. Since there is no experimental evidence of the misfolded protein in BSE in any of these matrixes, this approach is basically abandoned.
The second approach is the use of surrogate markers or the indirect tests. These tests would use the detection of molecular changes or other parameters in blood, serum, urine or tears. In Canada, there are essentially four approaches to a live BSE test that are currently in development. It should be noted that all approaches are more or less in the development stage using high-end, complicated and expensive equipment, thus the development of a robust test platform which will allow an easy transfer “into the field” is not yet addressed:

1. Diagnostic mass sequencing in disease
2. Determination of abundantly expressed proteins in urine
3. Induction of PrP\textsuperscript{sc} specific antibody response to develop of BSE-specific vaccination
4. Non-invasive analysis of eye fluids

The work on identifying BSE-specific DNA sequences is occurring at the University of Calgary, the University of Göttingen, and by Chronix Biomedical. Experimental work has been done on cattle using this approach in Germany. In Canada, most of due diligence work has been done on Chronic Wasting Disease in experimentally-infected elk, and the results showed that this approach could identify CWD 6 months prior to clinical observation in most of the animals [1]. However, it is important to note that in contrast to BSE with its noted neurotropism, CWD infectivity is widespread throughout the body including almost all peripheral tissues, saliva, blood, urine, and feces. Little data are available regarding the diagnostic sensitivity and no data are available regarding the diagnostic specificity in BSE. Potentially, data seem to exist in Germany that could be used to support the application dossier for the EFSA validation. The group developing the test hopes to seek EU regulatory approval for the test in 12-24 months (August, 2011 or 2012) should there be another EFSA call for the expression of interest. The Canadian approval process will take another 9 – 12 months.

The detection of abundantly expressed proteins in the urine of infected cattle is another approach that could yield an ante mortem test for BSE. This work is occurring at the University of Manitoba (for example, Simon et al, 2008). To date, this approach has yielded variable results with regard to diagnostic sensitivity comparable to the above mentioned approach, and it has identified infected animals only shortly before the onset of clinical disease. Little data are available for the diagnostic specificity. To collect urine samples may also limit the practicality of the test.

Another approach targets the misfolded prion protein (PrP\textsuperscript{sc}) as a potential strategy for immunotherapy. This work is occurring at the Vaccine Infectious Disease Organization in Saskatchewan in conjunction with the University of British Columbia. The factors limiting this approach relate to the fact that the prion protein is host-specific and as such has no antigenic property. In a first step, optimization of epitope and formulation/delivery, the immunogenicity is enhanced while retaining the PrP\textsuperscript{sc}
specificity. This work is currently a research tool using Scrapie as model, and its prospects as an effective BSE test are long-term in nature. It is important to note that in contrast to BSE with its noted neurotropism, Scrapie infectivity is widespread throughout the body including the lymphoid system, blood and amnion fluid. No data are available regarding the diagnostic sensitivity and the diagnostic specificity in BSE.

A fourth alternative approach uses the analysis of eye fluids is at a preliminary stage and is mostly focused on detection and treatment of cataracts in human populations. Most of the animal work in this area has been done in Scrapie in sheep rather than BSE. Scrapie similar to CWD is characterized by a widespread, peripheral distribution of infectivity involving the lymphoid system, blood, and amnion fluid. It is at a preliminary, investigative stage. No data are available regarding the diagnostic sensitivity and the diagnostic specificity in BSE.

Before leaving the discussion of testing, it is important to point out that this study focuses on “voluntary” testing which is interpreted here as the voluntary membership in a program most likely focused on one or two major slaughter plants where slaughter cattle would be tested with a rapid test at slaughter, or in the future, where cattle would need to be live tested before entry to the slaughter facility. It is possible to envision the use of live tests in purebred cattle destined for live sale for breeding purposes where the seller would voluntarily agree to such testing as part of the sales negotiations. In any event, the usage of any live-animal test would need to be regulated and controlled by CFIA in the same manner as exists for the post mortem tests.

2.6 Control and Mitigation Procedures in Canada

Since the BSE epidemic began in the UK, in 1986, most of the mitigation responses were first implemented there, followed by their adoption in most of the other states in the European Union. The impact of these responses on the infectivity of human foods from cattle has been recently investigated (Adkin et al., 2010). Because of the growing UK epidemic, the importation of live cattle to Canada from the UK was banned in 1990 and from “non-BSE-free” European countries in 1991. The Canadian Food Inspection Agency (CFIA) instituted a national surveillance program for BSE in 1992, and in 1997 (following a report by the Spongiform Encephalopathy Advisory Committee (SEAC), entitled "The Zoonotic Potential of BSE"), a preemptive feed ban was instituted which prohibited the feeding of "certain" mammalian by-products to ruminants. Cattle feed had to be labeled accordingly and feed processors were required to increase their level of record keeping about sources of ration components. Canada also limited the import of all TSE susceptible animals and by-products at this time. In 2001, the Canadian cattle identification program was instituted to ensure traceability of cattle as an aid to disease control in general and BSE in particular. Under this program all cattle had to be identified with specified tags prior to leaving the farm of birth. In 2002, Canada’s risk of having indigenous BSE was assessed as "very low" and the potential for amplification and transmission of BSE was assessed as "negligible". Hence Canada was classified as "provisionally free". This categorization of risk was based on the existing
A Cost-Benefit Analysis of Voluntary BSE Testing of Cattle

OIE criteria which were subsequently published under the title of "Risk Analysis of Prion Diseases" in April 2003.

In reviewing the Canadian response to autochthonous BSE, following the first Canadian-born case in 2003, it is important to remember that all known facts pointed to a very low prevalence of BSE relative to Europe in general, and many magnitudes lower than the prevalence in the UK. Additionally, given the predominant feeding of “fat cattle” on grass in the UK, the age of cattle for the high quality meat trade was higher there than in Canada. Both of these issues likely shaped our initial and ongoing response to BSE. LeBlanc, 2008 has updated the chronology of BSE-related events and government initiatives following the first 2003 BSE case confirmed in Canadian cattle.

On of the early responses was that beginning in July 2003, all cattle carcasses destined for human consumption had to have potentially infected tissues removed at slaughter; these tissues were denoted as specified risk materials (SRM). Recently, it has been verified that “prevention of human exposure to BSE agent mainly relies on SRM removal policy.” (EFSA, 2008).

Other than cows, most cattle are slaughtered at between 18 and 22 months of age. Thus, under this program, for cattle (largely cows) over 30 months of age, the specified risk materials included: the distal ileum, skull (not the head meat), brain, trigeminal ganglia, eyes, tonsils, spinal cord, and dorsal root ganglia. Full-term foetuses were also included as specified risk materials. This process is reported to remove approximately 99% of possibly infected tissues from the carcass (see further discussion below).

The specified risk materials had to be stained and disposed of in a prescribed manner to prevent their inclusion in human food products and environmental contamination. The small intestine was removed as specified risk material in all ages of cattle. Recent studies based on extrapolation of dosage studies in mice, suggest that the doubling time for prions in the central nervous system (CNS) is 1.2-2 months (Comer and Huntley, 2003). “The titre in the thoracic dorsal root ganglia (DRG) is, on average, approximately 1 log unit less than in the CNS, and the cervical DRG have approximately 0.5 log less infectivity than thoracic dorsal root ganglia. The pattern of infectivity in the distal ileum is that of an initial increase up to 14-18 months post exposure, followed by a decrease, which is likely to be highly variable between animals” (Comer and Huntley, 2003). TAFS, 2009a noted that in animals less than 2 years of age, almost all of the infection would be confined to the small intestine. All specified risk material had to be identified, permanently stained and managed in a specified manner. The criteria to be used in this process are published as items 3.7 and 3.8 in Chapter 4, Annex N of http://www.inspection.gc.ca/english/fssa/meavia/man/ch4/annexne.shtml.

Another early response was that the National BSE Surveillance Program increased the number and types of animals/samples tested for BSE beginning in 2004. In January 2004, CFIA increased the testing of cattle to a target of 30,000 animals per year beginning in 2005 (23,000 cattle were tested in 2004). This increased testing was designed to help estimate the prevalence of BSE in Canada (by July 2008, over 230,000 animals were tested). Increased emphasis was placed on testing feeds to ensure they did not contain
mammalian protein and to minimize the possibility of cross contamination between feeds destined for cattle and other species. Testing of imported fish and poultry meal for specified risk materials was also initiated.

In 2007, the previous feed ban was enhanced prohibiting the inclusion of specified risk material in any animal feed, pet food, or fertiliser. Blood could still be used in ruminant feeds provided the animals were not killed with captive bolt guns (the latter can lead to carcass contamination through the spread of infected brain emboli).

Today, most Canadian slaughter houses, carcasses are split in half down the vertebral column. This carries an increased risk of contaminating the carcass, as studies have demonstrated that washing does not remove all contamination from splitting the spinal cord and that the procedure can spread contamination to adjacent carcasses via the saw (Lim et al, 2007). TAFS, 2009a present a thorough discussion of this issue.

### 2.7 Specific disease control measures in Canada established in response to BSE.

Initially, emphasis was placed on identifying the farm of birth of a confirmed case and from that point identifying all animals born within 12 months of the index case (all sharing the same environment and potential contaminated feed during their first year of life). Trace back and trace forward programs were instituted. In 2003, investigations were initiated to assess if spill-over of chronic wasting disease to cattle had occurred. Prior to 2001, there was no mandatory animal identification system in place and hence a quarantine program based on temporal and geographic proximity to the index case was instituted. Approximately 2700 cattle were identified and humanely destroyed as a result of the investigation. Following the 2nd case of indigenous BSE (this animal was identified in Washington state) 12 animals were identified and humanely destroyed.

Prior to 2006, because of the possible direct transmission from dam to offspring and the sharing of contaminated feedstuffs, provided records were available, the progeny from the index case in the 2 years prior to its occurrence were identified and culled. Since 2005, “Based on advances in science, the OIE (Terrestrial Animal Health Code 2006) no longer recommends regulatory action with respect to calves of BSE positive cows. The hypothesized increased risk to calves born within 24 months of the onset of clinical signs in dams with BSE is not supported by ongoing research and analysis of data. Therefore, the CFIA has amended its policy regarding such calves and will no longer require their destruction. However, the CFIA will trace calves born to a positive female in respect of current export certification requirements requested by importing countries.” (http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2006/7investe.shtml) Similarly, all cattle sharing the same environment during their 1st year of life, and all cattle born within 12 months of the index case in the same herd were culled. Usually, all herd mates of the index case were culled as well as members of its birth cohort that were traced to other herds (Bohning and Greiner, 2006, discuss their method for assessing freedom from BSE in cohorts of Danish cattle). However, other work suggests that the power to detect BSE in defined cohorts may be low (Powell et al, 2008)). Also, since the
carcass of the 1st index case had been processed into animal feeds, these feeds were potentially contaminated and were traced and in a few instances the receiving farms were quarantined. In addition, cattle epidemiologically linked to possible BSE exposure were identified, quarantined, and usually destroyed (for example a neighbouring farm that shared feed and/or feeding equipment). As noted elsewhere, following the cases identified in 2003 there was increased emphasis on cattle identification and on increased surveillance for BSE.

Ultimately, the identification of confirmed BSE cases included identifying and humanely destroying:

- All living calves born to an affected cow during the two years prior to the onset of clinical signs (this action was rescinded after July 1, 2006);
- All living members of the birth and feed cohort (cattle born on the farm of origin within the 12 months before and the 12 months after the birth of the affected animal or animals purchased and present on the farm during this period which were also in their first year of life); and
- Tracing the feed to which the animal may have been exposed early in its life.

The presence of direct transmission from the dam to her calf has been suspected for a number of years (Donnelly et al, 1997). In contrast to the statement above concerning the transmission of BSE to offspring of affected cattle, Braun et al, 2009 commented that the destruction of offspring of affected cows remains justified based on ongoing research investigating whether protease-resistant prion protein (PrPres) occurs in plasma samples of offspring of cows that developed BSE. In the Braun et al study, cattle in group A consisted of 181 offspring of cows that developed BSE and group B consisted of 240 healthy animals from a region in Switzerland where no cases of BSE occurred between 2001 and the end of 2006. All plasma samples were evaluated using Alicon PrioTrap, a potential ante mortem test for PrPres. The results showed that 29 (16.1%) of Group A had PrPres-positive plasma samples while 10 (4.2%) of Group B had PrPres-positive plasma samples (Braun et al, 2009). As the time between birth of the offspring and onset of BSE in the dam decreased the risk of PrPres in the plasma of the offspring increased. A recent report from Denmark further suggests that the width of the cohort culling category needs to increase with the age of the index case (Stockmarr, 2009)

In 2002, the European Union set up the European Food Safety Authority to provide scientific technical guidance about aspects of TSE control including the inclusion/exclusion of specific body tissues in human foods and products, what animals needed to be identified and destroyed following an index case of BSE in a herd, as well as to develop guidelines for the assessment of new post-mortem and ante-mortem tests. These reports are available at http://www.efsa.europa.eu/cs/Satellite.

### 2.8 BSE: The European Experience

As noted earlier, over 185,000 confirmed BSE cases occurred in the UK. Estimates of prevalence of BSE in healthy slaughter cattle during the peak of the epidemic vary by
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birth cohort ranging from a high of 2.5x10⁻³ in 1996/97 to a low of 3.8x10⁻⁴ in 1999/2000. The frequency of clinical suspects was lower by about an order of 10 (Adkin et al., 2010; Appendix data). In general the two major thrusts to protect human health were to control the epidemic of BSE in cattle, and, as more was learned about the nature of BSE transmission, to implement processes to protect the human food supply and minimize iatrogenic spread. See DEFRA (Department for Environment, Food and Rural Affairs), 2008 for a review of the surveillance activities in the UK.

In the UK, changes to the rendering process for ruminant carcasses that would not destroy prions was deemed to be a component cause of the BSE epidemic. Thus, the re-feeding of rendered meat and bone meal (MBM) among cattle was deemed to be the vehicle which spread the BSE prions. In 1988, in an attempt to halt the BSE epidemic, it became unlawful to feed ruminant derived protein to cattle. This was a key component in the control program; however, this was not deemed fully effective until 1996. Today, there is just one approved world standard rendering process for use on ruminant materials that may carry a transmissible spongiform encephalopathy (TSE) risk and this demands exposure of particles ≥50 mm diameter to 133°C, at a pressure of 3 bar, for 20 min (often referred to as “pressure cooking”) (Bradley et al., 2006).

In November 1989, in an attempt to prevent human exposure to BSE, the use of specified bovine offal (SBO) in human food was prohibited in the UK (defined as brain and spinal cord, spinal ganglia, retina, and terminal small intestine); this was largely based on what was known about scrapie in sheep and goats. It became fully effective in 1995 (Bradley et al., 2006) when the SBO ban was extended to protect the foods of all species of mammals and birds. In 1996 an over 30 months (OTM) rule was invoked which prohibited using the carcass of cattle over 30 months of age for human food; they were treated as specified risk material and destroyed (for details see Food Standards Authority, June, 2000). In 1998, it was believed that the vertebral column contained 2% of the BSE animal’s infectivity and the dorsal root ganglia (DRG) 3.8% (OJEC 23.3.2001). The recommendation was to remove the vertebral column in cattle > 30 months if prevalence was high, and in cattle > 12mth if prevalence was low. In the UK the head, except the tongue, the thymus, spleen and spinal cord from cattle > 6 months of age were denoted as SRM. In 2003, given that testing of cattle at slaughter was in place, the Food Safety Authority recommended an end to the over 30-month rule beginning January, 2005 for cattle born after August 1, 1996.

As more knowledge was gained about the pathogenesis of BSE, the SBO ban became the specified risk material (SRM) ban in Europe in 2001. Although head meat was initially included as an SRM, in 2006 its removal and use for human food was allowed. As well, there were restrictions on the manufacture and sale of mechanically recovered meat (MRM), particularly from the vertebral column. MRM poses a serious risk of transmission because it is difficult to remove all vestiges of spinal cord, dorsal root ganglia, and associated nerves from the material. MRMss were largely used in retail economy burgers, frozen and dried mince meat. European law prohibited trading of MRM from animals more than 30 months of age; now all trade in MRM is banned. Nonetheless despite the ban on the use of specified risk materials (the definition of which
has changed somewhat over the years), a number (albeit few) of breaches of the regulations occur. A low-level of infection has been noted in peripheral nerves of BSE-infected cattle. There is no evidence of infection in the lymphoreticular system of cattle other than the tonsil and ileum. The Internation Forum for Transmissible Animal Diseases and Food Safety has published a recent position paper on SRMs (TAFS, 2009b).

In 1996, SEAC recommended that cattle aged over 30 months had to be deboned in licensed plants and that obvious nervous and lymphatic tissue and the vertebral column (excluding tail vertebrae) be treated as specified bovine offal (SEAC Annual Report 1997-98). As this rule proved to be inoperative, the over thirty month (OTM rule) was invoked which prevented meat from cattle OTM entering the human food chain.

Until 2001 most of the BSE surveillance in the UK was based on passive clinical detection of suspect cases (i.e. on the deads, diseased, downers and dying categories of cattle). In the later 1990s a number of rapid tests were developed and used as part of the surveillance program. This development allowed active surveillance of apparently healthy cattle for BSE at slaughter and removal of their carcass from the human and animal food chains. The change from passive to active surveillance greatly improved the knowledge about the frequency and sources of BSE in a number of countries (Ducrot et al, 2003; Pawitan et al, 2004). In fact, a number of authors have stressed the need for data from both types of surveillance in order to gain knowledge about the epidemiology of BSE (Cazeau et al, 2004; Calavas et al, 2007). Nonetheless, testing of fallen stock and casualties is the most cost-effective approach of finding BSE infected animals in that fewer animals have to be tested for each positive detected (TAFS, 2009c).

In 2001 mandatory testing of animals over 30 months of age, at slaughter, was invoked throughout the European Union (FSA, Dec 2001). In addition, beginning in 2002, any cattle in the dead, dying, downer, and diseased categories over 24 months of age had to be tested (DEFRA paid compensation for positive testing cattle). If positive, the entire carcass was destroyed including all organs hides and blood from these cattle. Other measures, such as the removal of the vertebral column from carcasses more than 12 months of age were instituted. In January 2006, this requirement was relaxed and was only mandatory for animals 24 months of age and older (REF). Also, valuation of animals born after August 1, 1996 was reduced so that their carcasses were essentially valueless as of January 2009.

Burke in 2008 (DEFRA, 2008) summarized the history of the UK BSE control progam. He noted “Following an EU review of surveillance, the UK and other EU15 MSs expect to be able to revise their active BSE surveillance programmes from 1 January 2009, by raising the threshold above which all fallen stock, emergency slaughtered cattle and cattle showing clinical signs at ante-mortem inspection require testing from 24 to 48 months; and all healthy slaughtered cattle require testing from 30 to 48 months. Public health will continue to be protected by SRM removal, which has been shown to be the key public health measure, by ante-mortem inspection and by the ban on slaughtering cattle born or reared in the UK before 1 August 1996 for human consumption. Animal health will continue to be protected by feed controls. Under the new active surveillance programme,
the UK would test over 600,000 cattle per year compared to over 770,000 in 2007. Passive surveillance will continue.” Abattoirs have to pay for the testing of health slaughter cattle beginning in 2009 and farmers will have to pay for transport of suspect BSE cases; DEFRA pays for the actual testing of fallen stock.

EFSA, 2008 commented that “in case the age of BSE testing increases to 72 or 84 months of age for healthy slaughtered animals respectively less than four and six cases can be expected to be missed annually in the old 15 European Member States (EU15). Moreover, in case BSE testing would be stopped in healthy slaughtered cattle born after 31/12/2003, less than 6 BSE cases per birth cohort can be expected to be missed in EU15”. By 2009 the following rules existed:

- cattle < 30 months; no testing and no vertebral column removal, SRM removed
- cattle 30-48 months; no testing but vertebral column removed, SRM removed
- cattle > 48 months; testing and removal of vertebral column, SRM removal
- cattle born before 1996, not allowed in food chain.

Consideration was also given to reducing the level of inspection to better reflect the risks of specified practices such as SRM removal (RCVS Advisory Committee, 2009).

2.9 BSE: The Japanese Experience

It is instructive to compare the Canadian experience with that of Japan where the annual incidence of BSE was likely between 1.4-2.9/10^6 cattle (by the end of 2004, 12 cases had occurred, 7 in 2005 and 10 in 2006)(Sigiura and Murray, 2007). In Japan, BSE surveillance was initiated as early as 1996-1997 but widespread passive surveillance did not begin until 2001; in September, 2001 the first native-born case of BSE was detected in a 5 year old cow. An immediate ban on the importation and feeding of MBM and the importation of live cattle from affected countries was instituted (Banning the feeding of MBM was later shown---consistent with findings from other countries---to reduce the future level of BSE by about 100 fold (Sugiura et al, 2008)). In addition, BSE testing of all cattle at slaughter was instituted using a post-mortem (reported incorrectly as “ante mortem” in Yamanouchi and Yoshikawa, 2007) animal test (Bio-Rad-Elisa). This testing was relaxed in 2005 to include only cattle over 21 months of age; however, funding was made available to continue testing all slaughtered cattle, until 2008, to retain “consumer confidence”. All dead-on-farm cattle over 24 months of age were tested beginning in 2003. The SRM tissues (initially defined as CNS, distal ileum and eyes, later tonsil (2002) and vertebral column including dorsal root ganglia (2004)) were removed and incinerated. In 2003 the national cattle identification program was initiated. Yamanouchi and Yoshikawa noted that a spinal cord suction apparatus was used in most slaughter houses (125 of 154 factories). The dura matter of the cord is removed after splitting and the dressed carcass carefully washed (the authors say this should remove all visible contamination). However, some carcass contamination was noted despite careful washing; thus, testing is relied on to identify infected carcasses which are removed before further processing.
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Although none of the cases were known to have consumed MBM (10 were born between December 1995 and 8 April 1996 before the MBM ban), the possibility of cross-contamination by feeds destined for non-ruminants could not be ignored. Large quantities of MBM had been imported from Europe in 1999 and 2000 (Sugiura et al., 2008). Thus, by 2005 all feed plants had to have exclusive production lines, and testing at slaughter was changed to animals over 21 months of age. As of May, 2006, a total of 29 cases were confirmed; only 9 of these were detected by the passive system, 20 were found by testing at slaughter. Cattle testing positive at slaughter are prevented from entering the food chain (Sugiura et al., 2009a; Sugiura et al., 2009b; Tsutsui and Kasuga, 2006; Yamanouchi and Yoshikawa, 2007; Yoshikawa, 2008). Modeling suggested that only a small proportion of potentially infected cattle (5/155) actually entered the food supply (Yamamoto et al., 2008).

Interestingly, the authors noted two atypical cases, one a 23 month old steer (No atypicals were found in the 15 member EU states under 8 years of age; EFSA, 2008) and the other a 169 month old beef cow. The cases in the 21 and 23 month old cattle were never confirmed by mouse transmission (the youngest confirmed cases in the EU was 28 months (http://www.bseinfo.org/scieDetectionofCases.aspx). Fourteen cases (including the 2 atypicals) had been detected by 2007 (Sigiura and Murray, 2007); two of these were in steers, and the remainder in dairy cattle. Sigiura and Murray (2007) developed a model to estimate the frequency of BSE cases by birth cohort. Some of the key assumptions were that the MBM ban was perfectly effective after 2002 and that the rapid tests had a sensitivity and specificity of 1 (for cases in the last 6 months of their incubation period). They also assumed (based on the 1996 birth cohort) the relative number of cases by category of animal were clinical suspects 71.3, fallen stock 4.62, sick at slaughter 79.6 and healthy slaughter 1. Assuming the source of BSE was from MBM in 1995, the model predicted 54 cases and 419 infected animals by the end of 2004. No new cases were expected after 2008 (although 1 did occur). As will be apparent in this overview, modelling has played an important role in guiding directed action to prevent BSE and vCJD, and the principles of developing good models have been elaborated (Ferguson et al., 1997). Nonetheless, Ackerman and Johncheck, 2008, and Dahms, 2003 stress that many of the models contain untested (or untestable) assumptions and because of these potential “flaws”, we need to use the precautionary principle in making decisions about prevention and control.

2.10 Transmission of BSE to Humans

As can be imagined, a host of inter-related factors can affect the amount of infected tissue in a carcass that might be consumed by humans.

Tsutsui and Katsuga, 2005 assessed the role of alternative cattle testing strategies and SRM removal on the infective load of human food in Japan. Given the assumptions in their model, they found that testing all cattle at slaughter would find 20% of all infectivity in the cattle destined for food, this would be reduced slightly if testing were delayed to 20 or 24 months, and to 15% if testing was delayed to 30 months. The removal of SRMs was estimated to reduce the infective load by 95%; both testing and SRM removal reduced the infective load by 99.9%. They noted that bovine bioassay was much more sensitive than
mouse bioassay and reported that some cattle are spinal cord positive to bovine bioassay at 22 months of age (Wells et al, 2007).

Benedictus et al, 2009 modeled the likely effect of three control procedures on reducing the amount of BSE infectivity in the human food chain. The three strategies were

- Identifying and incinerating BSE cases
- Culling, testing and incinerating cohorts of cases
- Removal of SRM

The infective load of each organ was the product of its weight, its BSE titre and the proportion of the organ entering the food supply after a control procedure (such as SRM removal). Based on their model, SRM removal reduced infectivity by 93%, post-mortem testing by 83% and both combined by 99%. Cohort tracing and removal had only a small impact on reducing the infective load in the human food supply.

Another recent paper (Adkin et al, 2010) included many of the important factors affecting infectivity in developing a model of carcass contamination with BSE prions over the course of the UK BSE epidemic. Some of the factors included in the model are listed below:

- Whether or not an infected animal is slaughtered for human consumption (this depends on the age of the animal, whether or not was exposed to BSE prions, the exposure dosage (higher doses shorten the incubation period), and how long before clinical signs would have developed had the animal not have been slaughtered). In addition, if the animal was to develop some clinical signs from BSE, whether these signs would be sufficient to be noticed and the subsequent action taken by the producer, veterinarians and government authorities.

- In the European Union the OTM rule prevented the consumption of meat from these animals by humans. When this rule was relaxed in 2006 there was a potential increase in the level of contamination of human foods.

- The European Union also invoked the mandatory testing of animals when slaughtered if they were older than defined ages. The sensitivity of these tests can vary depending upon the time period prior to the potential development of clinical signs (end-stage of pathogenesis)(Arnold et al, 2007). The level of infectivity and hence the sensitivity of the test increases in temporal proximity to the occurrence of clinical signs. In 2009, the age for mandatory testing was increased to 48 months, from 30 months, and this may have slightly increased the risk of contamination of food products. The model estimates that about 391 infected carcasses are missed annually in the UK.

- The level of contamination of the carcass following captive bolt stunning (this includes potential leakage of brain material from the wound as well as the potential formation of emboli). The type of stunning and the use of “bungs” (in 2005) were changed to reduce this level of contamination.
Whether or not head meat was removed for human consumption (after 2006 it became legal in the European Union to consume head meat). Most head meat was removed on line and was not subject to contamination from the stunning process.

It appears that the spinal cord and brain become infected at the same time post exposure. Contamination of the carcass by spinal cord material (this includes incomplete removal, or no removal of spinal cord in selected ages of animals, as well as contamination as a result of carcass splitting). Close inspection of plants suggests that almost all visible contamination is removed by washing. Nonetheless, this appears to be an important component determining the infectivity of carcass meats (the model suggests that it can account for an average of 35% of all contamination). In 2008, it was necessary to remove the spinal cord only in animals over 30 months of age; previously, it was removed from animals more than 24 months of age.

The inclusion of tonsillar tissue in tongue meat (the model suggests that this could account for 28% of carcass infectivity).

Whether or not the dorsal root ganglia were removed (this depends on the deboning method (if used) or if the carcass meat was consumed as "bone-in" meat (e.g. a T-bone steak)). The model suggests that about 7% of the carcass infectivity comes from missing removal of the DRG.

The peripheral nervous system may contain more infectivity (up to 20%) but there is considerable uncertainty on this issue.

The level of infectivity depended on the time before clinical signs would appear if the animal had not been slaughtered (estimates of the infectivity are difficult to obtain but this component could account for 20% of carcass infectivity levels).

One means of describing the amount of infective material in the human food chain is to use the bovine ID_{50}. This is the dose of prion that would lead to BSE in 50% of the exposed cattle. Since 2006, the model employed predicted that about 20-25 bovine ID_{50}s were consumed in the UK (wide confidence intervals ranging from 1 to 91 ID_{50}s) (Adkins et al, 2010).

In addition to the actual cases of vCJD, a number of investigations have been conducted on the psycho-social impact of potential BSE transmission on humans, their behaviour and their choices of foods. McCallum et al, 2006 provide an annotated bibliography of this literature. Like much of the literature, we have not focused on this aspect of BSE; however, we do think that the following summary comments are important

“Broadly speaking, the treatment of social determinants of health in the BSE literature is weak. No articles addressing social status, social environments, physical environments, healthy child development or education and literacy were found. Very few articles relate to social support networks, which offer potential to be significant determinants of health
in times of crisis and uncertainty. Even research relating to employment and working conditions – areas that are directly affected by a disease such as BSE – is virtually nonexistent.

Where one might have expected to find research relating to changes in employment rates in the beef industry (from the farm to the grocery store), or to concerns relating to the health and safety of workers, or to farm income and the loss of livelihoods, or comparisons between family farms and ‘big barn’ operations, only three articles emerged in total, dealing with efficiencies and profitability in the cattle industry. Nonetheless, the creation of the Food Safety Authority was seen as a very positive step in rebuilding consumer confidence in the food system (Wales et al, 2006)

There is also surprisingly little mention of globalization in the current BSE literature. While there are numerous considerations of the means of transmission of the disease, these are rarely placed in the broader context of agribusiness and the globalization of food. Food politics are addressed in a very limited way, usually in relation to personal dietary choices. Indeed, there is even some discussion of the nutritional risks of eliminating beef from one’s diet, without broader analysis of alternative sources of protein.”

Tyshenko et al, 2008 edited a workshop summary designed to present a new integrated risk management framework for prion disease risks. Lemyre et al, 2009 reported on a survey of over 1500 Canadians “conducted from October to December 2007. The survey data reveal that Canadians do not perceive mad cow disease as a salient risk but consider it more of an economic, political, social, and foreign trade issue than a public health one. Canadians are somewhat prepared to pay a premium to have a safer food supply, but not to the same extent that they desire extra measures pertaining to BSE risk management.”

2.11 BSE and variant-Creutzfeldt Jacob Disease

During the initial phase of the BSE epidemic in the UK, it had been assumed that BSE, like scrapie, would not be transmitted to humans. However, as cases of BSE became identified in a variety of ruminant and non-ruminant species in zoos, and in 1990 a case of feline spongiform encephalopathy was reported in a domestic cat, speculation about transmission of BSE to humans increased. Shortly thereafter, in 1995, initial cases in humans were recognised in the UK and reported in The Lancet in 1996; these cases now are denoted as variant CJD (vCJD). Because the average age at onset of BSE in cattle is between 4 and 6 years of age, the entry of infected clinically healthy cattle into the human food chain likely would have occurred before the onset of the BSE epidemic in cattle and continued throughout the epidemic. It is now thought that humans were exposed to BSE beginning in the early 1980s following the withdrawal of hydrocarbon solvents in the rendering process. Cohen and Valleron (1999) stressed that predictions about the future number of vCJD cases would depend on knowledge of when the BSE epidemic actually began. Possible human health impacts of BSE were presented in an editorial of the Canadian Medical Journal in 2001. Anil and Austin, 2003 reviewed the BSE-related factors that impact on meat safety for FAO. By 2006, 160 vCJD cases had
been confirmed in the UK and 28 elsewhere (Collee et al, 2006). Currently over 200 vCJD cases have been confirmed worldwide, but mainly in the UK. Three cases were confirmed in the U.S. (Notari et al, 2010).

Today, based on biological and molecular strain typing, the BSE agent and the agent of variant CJD are known to be identical. Epidemiological links between the patterns of BSE and vCJD further support the causal link between the two syndromes. The incubation period for vCJD is unknown but has been estimated to be approximately 10 years or more. These estimates are based on the confirmed clinical cases of vCJD. Following secondary transmission of vCJD via blood transfusion, the incubation period is shorter and estimated to be between 6.5 and 8 years. Similar to the situation in cattle, there is epidemiological evidence that young people have a higher risk of becoming infected if exposed to BSE than older people with those aged 10-20 years having the highest risk (Ghani et al 2003b). Some of this age-related risk might relate to the increased consumption of products containing mechanically recovered meat by younger people in addition to their increased susceptibility to prion infections (Boelle et al, 2004).

In addition to differential exposure, across age categories, there is evidence that humans have a genetic component to the expression of vCJD. All humans encode glycoprotein as a normal constituent of cell membranes and this is denoted as PRNP or PRPc. The abnormal form of this is denoted as PRPsc because of the initial assumed link of vCJD with scrapie. At codon 129 of the gene that codes for normal prion protein, individuals may have 2 methionine alleles (MM), 2 valine alleles (VV), or one of each (MV). All but 1 of the vCJD cases that have been investigated to date are homozygous for methionine (ie the MM alleles) (Collee et al, 2006). It is believed that the MM allele increases susceptibility to vCJD; however it is possible that it actually predisposes to a shorter incubation period whereas the other alleles (VV or MV) may encode for relative resistance or support a longer incubation period. It is even possible that they may code for a different clinical form of the neuropathy. In comparison, cattle are homozygous for methionine at codon 129 and thus it is believed that all cattle are uniformly susceptible to BSE.

The change from normal prion protein (PRNP) to miss-folded PRP is post-translational and results in the conversion of an alpha helix rich protein to a beta sheet form of protein. The abnormal protein is partially protease resistant and this forms the basis of many diagnostic tests.

Once the vCJD epidemic began, there was concern over how large the epidemic would become. Using the data on confirmed cases in the UK up to 2001, Valleron et al (2001) predicted that the total number of cases would be 205 (upper limit of the 95% CI: 403) based on the following assumptions- the risk of developing the disease in susceptible exposed subjects decreases exponentially with age after age 15, that all infections occurred between 1980 and 1989, and that the distribution of the incubation period is lognormal. Shortly thereafter, based on modeling the existing 121 vCJD cases up to 2003, it was estimated that an additional 40 cases would occur (and if the subclinical infection found in human appendix was considered this might rise to 100 additional
cases). The upper 95% limits of these predictions were 540 and 2,600 respectively (Ghani et al, 2003).

The future frequency and pattern of variant CJD is uncertain but at present many scientists believe that the greatest period of risk for the human population in UK is over (Bradley et al, 2006; Collee et al, 2006; Adkin et al, 2009). Nonetheless, the risk of transmission of variant CJD by blood transfusion has lead to restrictions on donors of blood, organs and other tissues. The risk of iatrogenic spread of the disease has required greatly increased vigilance in the cleaning and sterilization of dental, ocular and other surgical equipment (Collee et al, 2006).

Recent surveys of human appendix have indicated that a small percentage of people are infected by the abnormal protein. This suggests that a number of preclinical or subclinical cases of vCJD exist. This has stimulated much research on the development of tests that can detect small amounts of abnormal prion protein in live subjects.

2.12 Testing beef cattle less than 24 months of age

From the perspective of preventing BSE, the ban on feeding ruminant protein to ruminants and other animals is key. History has shown that such a ban has been imperfect; however, history has also shown that this is the major way of preventing the transmission of prions to cattle. Canada has had such a ban and this will continue for the foreseeable future.

Although cattle of all ages are susceptible to oral exposure by prions, younger animals (less than 1 year of age) are at a higher risk of becoming infected if exposed. Thus ensuring that products such as calf starters and calf supplements are free of BSE prions is particularly crucial to preventing future cases.

It is also known, that the incubation period prior to developing clinical BSE (and thus prior to developing high levels of infectivity in the central nervous system) is dependent on the dosage of exposure. Higher exposure levels lead to shorter incubation periods. However, even with high doses in experimental situations few cattle developed detectable levels of prions before 28 to 32 months of age. Under field conditions the youngest animals with confirmed BSE in the European Union were 28 months of age. Although 2 younger cases have been reported in Japan, it was not possible to transmit BSE to mice using their tissues.

At this point in time, the only feasible large-scale testing program for cattle, outside of continuing to monitor cattle in the 4D categories, is to use a post-mortem test at slaughter. These rapid tests have a very high specificity (give very few false positives) and provided the animal is in the last stages of its incubation period they also have a very high sensitivity (that is, they will test positive when the animal is moderately heavily infected).

Given that cattle for the high quality beef meat market in Canada are largely between 18 to 22 months of age, and given that the current tests only identify animals in the last
stages of the incubation period, the proportion of these cattle that would test positively will be essentially 0. Thus, testing cattle of this age is no additional public health advantage for the consumers of the meat products. “If their brains were tested at slaughter they would invariably be negative” (TAFS, 2009a). Whether or not such testing should be performed purely for market access is another question. Certainly, other governments have recognized that the testing of animals less than 30 months, and now in the UK less than 48 months is a very expensive process that provides little additional benefit to the consumer in terms of product safety. However, if an importing country tests its own young cattle, then provided the economics justify it, testing could be performed purely for market access. Questions related to the testing of older animals (>30 months of age) is beyond the scope of this study. The SRM removal program used in Canada, while imperfect, offers very high levels of protection to consumers of meat products and should be continued for the foreseeable future.

2.13 Observations

From the broad discussion above, the following key points emerge:

- The pathogenesis of BSE is such that cattle are most susceptible to infection at an early age. In infected cattle, prions are initially confined to the ileum. At the age of approximately 18 months, prions begin to move and can be detected in the central nervous system at 32-40 months.
- Prions appear to have an incubation period of 32-55 months; only a very small proportion (<1%) have been observed to have an incubation period of less than 36 months. The incubation period of the prion is inversely proportional to the dosage of infected material.
- The above makes the SRM feed ban quite critical. The feed ban is charged with reducing the dose of infective material in the feed system to essentially zero. In the absence of the feed ban and a higher level of infective material in the system, the prion incubation period would decrease resulting in more, younger positive cases.
- Because of the low level of infectivity due to the feed ban, it is exceedingly unlikely that BSE testing of slaughter cattle would result find a positive case. More likely, its value lies in the perception of the people that want tested product. Given the low prevalence of BSE believed to be in the Canadian herd, the infective material dose limitations due to the SRM/feed ban, and the biology of the prion with respect to age, testing under thirty month (UTM) animals, and especially animals under 24 or under 21 months can be expect to result in literally zero positive cases.
- In Europe, testing all animals has generated more positive BSE cases. However, this must be placed in context. Europe (especially the UK) is believed to have a much higher incidence of BSE in the herd than Canada. Secondly, in many (most) cases slaughter cattle are grass fed so they reach market weight at a much higher age compared with Canadian, and on that basis alone are more prone to test positive for BSE.
- Countries that have previously implemented universal testing are generally attempting to scale back this effort.
To date, attempts to develop an approved live test for BSE have failed. There are currently four distinct approaches that could result in a live BSE test. Most of these appear to be long-term considerations, as issues of practicality of use with livestock and/or accuracy limit their efficacy. The proponents of a genomics-search based test that could be used to detect BSE expect to submit their test for regulatory approval within two years, although it is unclear when the test would be submitted for regulatory approval in Canada. This test observed CWD cases six months pre-clinical; it is unclear what implication this has in observing positive cases of at younger ages in its potential use in BSE testing.

The implication is that, given the scope of Canadian SRM removal and the age at which fed cattle are slaughtered, post mortem BSE testing is extraordinarily unlikely to identify positive animals or indicate progress toward BSE eradication. Its value is essentially determined by the preferences of customers for, and value assigned to, tested product. The ante mortem test has uncertain prospects, as only one of the approaches appears to be close to commercial reality, and practically speaking this could easily take five years for the Canadian market. It is similarly unclear whether live BSE tests in development could detect positive BSE cases in younger cattle than the existing post mortem tests.
3. Economic Body of Knowledge on BSE and vCJD

The economic literature on BSE has extensive breadth and depth. To focus the discussion, in the sections below we review literature that relates to the economics of testing and valuation of beef relative to BSE, and the literature setting forth the economic framework for the introduction of new agricultural products.

3.1 Economic Literature relevant to BSE Testing

Lippert (2002) evaluated different BSE testing scenarios, acknowledging that testing can prevent damage but that it also can be costly. The following control scenarios were considered: 100 percent testing, no testing, random sampling with positive results and random sampling with negative results. The factors considered were the social damage associated with an undiscovered case; control intensity (i.e. if all cattle over 24 months would be tested, control intensity is 100%); test costs (in Germany test costs were approx. Euro 35/test in 2002); indirect sanctions (producer loss that goes above monetary fines) and compliance costs to reach the standard.

Based on an economic model and empirical testing data from Germany, Lippert concluded that essentially two scenarios could help to achieve the goal of BSE free beef. First, 100 percent control or second, the acceptance of a small probability of having BSE cases by implementing a low sampling intensity. “Healthy” cattle should not be tested under 24 months or 30 months of age.

Coffey et al (2005) considered BSE testing as a policy response to BSE in the US. The estimated cost of testing was $15-20/head, exclusive of the fixed costs associated with constructing an analytical lab in a packing plant. To consider the benefits of testing, scenarios were considered that related testing a given proportion of US cattle tested to the prospective proportion of 2003 Japanese and South Korean markets regained as a result, and the implied increase in net revenue per head (after the variable cost of the test). Their results showed the following. In order to justify testing 100% of cattle, recovery of a minimum of 50% of export markets was necessary. Conversely, testing 10% of cattle had a positive return provided that 10% or more of 2003 market volume could be recaptured. The authors also suggested that testing by a single small firm would be of little benefit to producers as it would have an insignificant impact on cattle prices; it could however be of significant benefit to the firm testing, and if testing were successful in increasing market access others would be inclined to test as well, thereby increasing prices.

Cox et al (2005) conducted a risk analysis of potential US policy responses to BSE in Canada using a value of information framework. The study considered a range of import conditions for Canadian cattle imported by the US, including BSE testing. A framework was developed in which policy decision rules were identified, the consequences of the
decisions were identified, and probabilities were assigned to the consequences. The results provided an optimal policy decision rule and optimal actions.

A decision tree was developed that considered import tracking of Canadian cattle in the US as well as BSE testing of cattle imported from Canada, and BSE testing of all cattle. Estimates of costs, revenues, and nested probabilities were used to estimate the net benefits of alternative decision tree nodes. The assumed cost of tracking Canadian cattle in the US was $US 10/head, and the BSE testing cost was $US 30/head. The consequences of alternatives were based on nested probabilities obtained from apparent BSE prevalence in the Canadian herd based on a binomial distribution.

The results showed the following. In the case of a US BSE case of unknown origin and/or a case known to be of US origin, the cost was $US 12.3 billion/year. In the case of BSE in the US not known to be of Canadian origin, if BSE testing occurred and no new cases were found the cost decreased to $US 6.1 billion/year. A new BSE case in Canada provided a gain to the US of $US 1.4 billion/year. A new US case of BSE known to be of Canadian origin, with the ability to identify Canadian cattle in the US gave a loss to $US 2.7 billion. The optimal decision rule was to use limited sampling of all cattle (surveillance) and to track Canadian origin cattle. However, the results assumed that markets lost due to BSE remained lost indefinitely; the value of tracking and testing could dwarf other effects if it could help regain market access.

Steiner and Yang (2007) employed survey methods to estimate willingness to pay for BSE-tested beef and beef free of genetically modified feed in Alberta and Montana. The study used “choice experiments” and a random utility model to explore consumer preferences. The results were estimated using logit regression methods. The results showed that Alberta and Montana preferences for tested product were not different, and that consumers generally preferred the BSE-tested attribute to the GM-free attribute.

McCluskey et al (2005) investigated willingness to pay for BSE tested beef in Japan. The survey was completed in December, 2001 following Japan’s first case of BSE in September, 2001. Consumer data were surveyed from a grocery store in Nagano, Japan. A sample of 381 respondents that consumed beef were surveyed using choice experiments relating food safety, environmental quality, and price attributes. The survey questions were elicited using dichotomous choice contingent value methods, with parameters estimated using a logit model. The results showed that 66% of the people sampled were willing to pay a premium for BSE tested beef. The key determinants supporting a willingness to pay were food safety attitudes, whether the respondent was female, and whether they had reduced their beef consumption since the Japanese BSE case.

Tonsor et al (2009) investigated preferences and valuation for food safety attributes in beef in the US, Canada, Mexico, and Japan. The study was not focused specifically on BSE testing, but rather on differences in broader food safety attitudes. Choice experiments were conducted in a survey to analyze consumer attitudes toward beef steaks. The survey captured a broad range of socio-demographic information as well as attitudes toward differing levels of food safety attributes, at varying price levels. The
data were analyzed to estimate willingness to pay for food safety attributes using a random parameters logit approach. The results showed statistically significant willingness to pay for food safety attributes in Canada, Japan, and Mexico. Moderate increases in food safety were valued less than assured tenderness in the product. However, at higher levels of food safety attributes, Japanese consumers were more willing to pay more for the food safety attributes than assured tenderness. Moreover, when moderate and higher levels of food safety enhancement were numerically scored (as “40% enhancement” vs. 80% enhancement), Japanese and Mexican consumers implied that they were willing to pay well over twice the premium for 80% enhanced compared with 40% enhanced. The estimated market for an 80% enhancement in beef safety was estimated to be much larger than for a 40% enhancement; even at a premium of $US 5.00/lb, the results imply that 63% of Japanese consumers and 57% of Mexican consumer would purchase the 80% food safety enhanced product. The authors concluded that the value of investing in additional food safety measures rests heavily on consumer preferences for safety in target markets.

3.2 BSE Testing and Market Externalities

As discussed above, given the SRM feed ban and the low prevalence of BSE in the Canadian cattle herd, testing of slaughter cattle for BSE creates little actionable information from the perspective of controlling or reducing BSE risk. However, if there are consumer preferences supporting a demand for tested product then a benefit from testing exists; conversely, these come with costs of implementation and the prospect that introduction of tested product depresses the broader market.

An economic framework has been developed to consider just this situation. Initially developed to consider the effect of the introduction of new grain varieties, it provides the logic to assess the costs and benefits of approving a new product that is a substitute for an existing product, creates additional costs in handling, but has a (prospective) higher benefit.

Ulrich et al (1987) considered the impact of Canadian registration of lower quality wheat varieties. They developed an economic model to evaluate the benefits of registering HY320, a medium-hard wheat variety, which was of lower quality than hard red spring wheat (HRSW) varieties that were previously registered. In their analysis of HY320 registration, the authors initially assumed that only HRSW varieties are available. After the licensing of HY320, some farmers adopt it, which reduces the acreage of HRSW. Assuming that Canada is a price taker in HRS and medium-hard wheats, this means that profitability must increase on the acreage sown to HY320, and remain at least constant on the acreage remaining in existing HRSW. In the following crop year, the increases in profits experienced in the first year of registration induce more acreage planted into both types of wheat.

The authors then considered the impact if Canada was a sufficiently large supplier of HRSW to impact world HRSW prices. With the registration of HY320, the acreage initially pulled from HRSW to HY320 resulted in a decrease in Canadian HRSW supply,
and an increase in HRSW prices. In the following crop year, this results in even more acreage coming into wheat production. Ultimately, as a result of the approval of the HY320 variety, total wheat acreage in both varieties increases, and total profitability in both varieties increases. Ulrich *et al* found that, under the assumption that Canadian HRSW acreage has no effect on HRSW prices, the registration of HY320 would have increased the farm gate value of wheat sales 5-10%, or $200-400 million in the period 1982-83.

Furtan *et al.* (2002) examined the optimal time to introduce a technology given uncertainty in future revenues, production and consumption externalities, and decisions that are irreversible. The authors use real option theory to determine the value of waiting for new information in the licensing and adoption of an irreversible technology. The focus is primarily on Canada and its decision of whether to approve GM wheat, and two types of externalities created by the licensing of GM wheat are considered. The first externality is the environmental externality caused by the spread of the new variety into non-GM crop fields, imposing additional herbicide costs on non-adopters. The second externality is the market externality created that results in a potential loss of returns due to the lack of segregation system. Some consumers are concerned about purchasing GM foods. These concerns have been expressed in the form of consumer demand for more regulation, demand for product labeling, and/or an outright ban on the production and importation of GM varieties. With a lack of segregation, the introduction of GM wheat will create a ‘lemon’ market for all wheat.

The study uses the real option value approach to determine the optimal time to license GM wheat. In the case of GM wheat, the real option value is the relevant measure of social desirability because of the uncertainty over future costs and benefits of GM wheat, and because the introduction of the variety is irreversible. Deciding to make an irreversible investment eliminates the option to wait for more information.

In terms of market externalities, the decision to license GM wheat creates an irreversible market cost, which is determined by estimating the reduction in the pooled producer price of Canadian wheat. Assuming no segregation system, the price discount will impact both adopters and non-adopters of GM wheat. According to the authors, industry experts anticipated that GM wheat will be priced on the world market at a $.05 - $.35 per bushel discount to non-GM varieties (this assumes a number of countries will not import GM wheat and that Canada is the first and only country to license the new wheat variety).

The authors estimate the impacts on producer surplus, profits to biotech firms, and consumers’ surplus of the adoption of GM wheat under several cases. In the first case, they assume that it is not feasible to segregate GM and non-GM wheat and that 26% of producers do not adopt GM wheat. As a result, non-adopting producers are made worse off (compared with before GM wheat was introduced) because they are receiving a lower market price and incurring additional herbicide costs. Adopting producers benefit from the yield increase and lower production cost, but in aggregate are worse off financially due to the lower market price. The end result is some farmers produce the GM product who would otherwise produce non-GM wheat because of the lack of market segregation.
In the second case, the authors assume a costless segregation system. As a result, market externalities will be eliminated. Non-adopters of GM technology will not incur the market price decline. As well, segregation impacts the producers’ willingness to pay for the new variety because producers have a choice between the new technology at a lower wheat price and the traditional technology at the higher market price. Costless segregation removes the ‘lemon’ characteristics of GM wheat. However, the environmental costs of cross pollination with non-GM varieties remains.

The authors then calculate optimal threshold values for each of the cases mentioned above. The authors conclude that in all cases without segregation, Canadian wheat producers are better off waiting to license the new technology.

Furtan, Gray, and Holzman (2003) consider the sequence of adopting GM crop varieties worldwide as a market externality problem. They propose that, contrary to received innovation theory, the advantage from being the first innovator may not be achieved if there is a market externality (consumer resistance) associated with the approval decision. In their analysis, the authors assume that the United States and Canada do not have the ability to affordably distinguish/segregate GM and non-GM wheat. Therefore, if the US and Canada approve GM wheat without a segregation system, importing countries will assume that all wheat in the two countries contains some GM wheat. The resulting lack of market information may nullify any first mover advantage from approving the new wheat variety.

The authors develop a model of strategic behaviour, with complete and perfect information, based on whether the two players (Canada and the United States) approve the new wheat variety. The model determines the trade and welfare impacts of approval or non-approval by the two players. The resulting solution is dependent on which market participants are considered in the government’s objectives. If the government only considers changes in producer welfare, then it is optimal for both countries not to approve GM wheat. If the change in total welfare of the biotech firms and consumers are included, it is optimal for the US to approve and for Canada not to approve GM wheat.

In the case of GM wheat, there is no first mover advantage for wheat producers because of consumer resistance to the product. Without a segregation system, the market for the higher valued non-GM wheat is destroyed because of the lack of information. By ignoring consumer response, the approval process for GM crops in both the United States and Canada may result in a sub-optimal approval decision. The inclusion of market information in the approval process will create a challenge for government because of the trade off between the biotech firm and wheat producer welfare.

Constantine et al (1994) considered the impact of a regulation in California that allowed only a single variety of cotton to be grown. The California One-Variety Cotton Law (OVL) has regulated cotton varieties in the San Joaquin Valley since 1925. From 1925 to 1978, cotton producers were permitted to grow only one variety of cotton – Acala cotton – from only one type of seed produced by a single seed breeder, and then sold by a single
distribution agency. The OVL was motivated by the belief that textile mills would be willing to pay a price premium for cotton originating from a one-variety district. The premium was anticipated because the OVL would provide a guarantee of cotton quality, maintain quality over time, and lower grading and processing costs at the mills. In 1978, private companies were permitted to develop Acala varieties. These new, privately bred Acala varieties were adopted rapidly by growers throughout the San Joaquin Valley. Non-Acala cotton varieties are still prohibited.

In their analysis, Constantine et al developed a model of access to alternative varieties in the context of market externalities that is quite similar to that used by Ulrich et al. They proceed under the assumption that non-Acala cotton varieties are priced in broader commodity markets, while Acala cotton prices are determined through the interaction of the California supply with demand. In addition, they assume that a premium can be maintained for Acala cotton because the uniform quality under the OVL reduces processors’ costs of handling and grading. If access to non-Acala varieties of cotton were allowed, the acreage planted to Acala cotton would decrease and plantings of non-Acala cotton would increase, as some farmers plant new varieties in expectation of higher yields and higher profitability.

For producers that continue to grow Acala cotton, this produces offsetting price effects. First, the reduction in the supply of Acala cotton will tend to increase its price. However, the mixing of Acala and non-Acala varieties would weaken or destroy the premium for Acala varieties, thereby reducing the price of Acala cotton. Which effect is dominant is left as an empirical question. The price of non-Acala cotton would be unaffected, because its price is determined in the broader market. Thus, it is conceivable that the quality premium associated with Acala cotton is sufficiently large that the reduction in price of Acala cotton on farmers continuing to grow it dominates the increased profits of farmers growing the non-Acala varieties. This potential net loss, if it were to occur, is a form of market externality resulting from an introduction of a new variety that weakens the premium for a substitute product.

Thus, the agricultural economic research has dealt with situations of new product introduction with prospective benefits, but that could have adverse market and cost implications in seed genetics. Authors have sought to determine the marketing costs and benefits of releasing new seed varieties. The essential criteria used to evaluate the merit of releasing a new product are:

- What are the benefits of the new product approval (increased sales, profits)?
- Will the introduction of the new product affect market level supply and demand balance?
- To what extent are there direct costs and diseconomies in grading and inspection associated with the new product?
3.3 Observations

The literature on BSE testing suggests the following. First, in the US and Canada, consumers appear to have only a weak inclination to pay for BSE testing or other enhancements in beef safety. This is particularly in relation to certain other countries, notably Japan. Secondly, BSE testing is not seen as a panacea in the literature. It is not the only way of enhancing safety in the system as there are other approaches such as tracking and tracing of cattle, and ensuring SRM removal. As illustrated by Coffey et al, it is also not a market access opener by itself, but by increasing the sales of producers/firms wishing to test, it could make market access discussions easier.

The market externality literature relates to the BSE testing question as follows. Allowing a tested product creates a prospective benefit in terms of a subset of consumers willing to pay a premium for the product and/or some consumers not currently willing to purchase beef being willing to do so. This comes at the additional cost in terms of handling tested product, and the impact on product demand.

Thus, the essential economic basis upon which to evaluate testing is the following:

1. What benefit can be expected from testing due to increased market access and/or price premiums, relative to
2. Adverse market impacts resulting from testing, such as lower prices or decreased market access for non-tested product, and
3. The direct cost of implementing testing.
4. Prospective Demand Interest in BSE-tested Product

This section of the report summarizes the beef packing sector’s opinions and perspectives on voluntary testing for BSE in cattle. Packing company officials from 12 of the 23 federally inspected plants in Canada were contacted. Questionnaires were sent out to participants in advance and followed up with phone calls (see Appendix B). Written or verbal responses were received from eight of these firms. Of the eight firms, Cargill and XL Foods were included along with smaller firms from across the country. Interviews and surveys were also conducted with the Canadian Meat Council and the Canadian Beef Export Federation. These were supplemented with relevant secondary information.

The purpose of the interviews and surveys was to provide packing sector insights into the issues, challenges and opportunities associated with voluntary testing. The main focus of the questions and responses related to marketing, and apparent customer interest in BSE-tested product. This section provides the overall viewpoint or general consensus of those interviewed.

4.1 Testing Awareness and General View Point

As a starting point it is noted that individual packers and the industry have kept informed on the concept and methods of BSE testing. There was a high level of awareness of testing methods, costs, and efficacy.

The industry is aware that the Canadian Food Inspection Agency has been opposed to the testing for BSE for marketing purposes because it has no scientific merit. Respondents indicated that they think that the CFIA does not believe that the use of CFIA resources for surveillance purposes should be diverted to testing which does not achieve any additional food safety or public trust outcome within Canada. CFIA has undertaken discussions broadly with industry and there has not been an industry consensus to support the Government of Canada moving away from that position.

There is also a very high level of awareness of the issues associated with testing. A prevailing view is that the issue of BSE testing is best handled by country governments in accordance with OIE standards for purposes of disease surveillance, not as an implied food safety measure. The industry is supportive of government decisions in North America that individual animal testing for apparently healthy cattle at harvest is not scientifically valid. Respondents generally believe that current BSE firewalls that are in place are recognized by international animal and human health authorities as the most effective combination of measures to prevent potential human exposure to the BSE agent.

The industry participants also generally endorse the Canadian Meat Council (CMC) position that testing for BSE and getting a negative result is not a guarantee that the infectious prion proteins are not present in the animal. The CMC asserts that many studies have been completed and Health Canada and the Canadian Food Inspection Agency have set out rules and processes for removal of the specified risk materials; the tissues where the prions are most likely to be found. The CMC believes that removal of
these specified risk materials, such as brain and spinal cord, make eating beef safe for human consumption. Testing offers no additional guarantee of food safety.

Most of the industry respondents asserted that testing healthy animals, especially those under 30 months of age for marketing purposes, holds no scientific merit. They note that Canada has been using science as the basis for all its policy decisions on this and all other animal diseases; voluntary testing of BSE for marketing purposes would undermine Canada’s domestic and international credibility.

4.2 Beef Packer Customer Perspectives

Beef packer customers are defined as domestic retailers or foodservice buyers as well as international buyers. Canadian packers report that BSE is not an issue or concern to customers in either domestic or international markets. BSE is not a topic that customers inquire about in anyway, including safety or marketing. Domestic or international customers have not expressed concern about product safety due to BSE.

Any issues or concerns relating to BSE from international customers tend to evolve around lack of access. That is, customers in the US decry regulatory barriers and potential customers overseas express the desire to purchase Canadian product but are unable to do so due to government access restrictions. The concerns revolve around not being able to access more product from Canada due to their government restrictions.

Further to the fact that BSE is not a topic of the trade, it logically follows that the issue of testing for BSE is also not an issue. Domestic or international customers generally do not discuss or request BSE testing or BSE tested product.

The important exception to that generalization is that packers do note that at least one Japanese customer expressed interest in Canadian companies testing for BSE. This customer was interested in increasing their ability to access product from Canada as well as differentiating itself in the market. The discussion in that regard also centered on the fact that testing would increase available volumes thus resulting in lower pricing or reduced premiums. In fact increased access and reduced cost is the motivating factor.

In general interviewees felt that BSE and BSE testing is not a commercial or trade issue between buyers and sellers. Individual firms on both the buy and sell side view these issues as government to government issues related to access.

4.3 Potential Benefits of BSE Testing

The industry participants noted that the potential benefit of BSE testing is the possible increase in customers willing to purchase or access Canadian beef. This is particularly the case for Japanese customers. The argument put forward is that if Canada or Canadian firms could test then age would not matter (currently the Japanese require fed cattle to be less than 21 months of age to enter the Japanese market). This would allow Japanese and other customers access and thereby increase year round business. This would not only
increase the customer base but there could be an argument put forward that testing could reduce or eliminate related SRM and segregation costs.

The potential benefit of testing may include premiums for the product but there is significant doubt in that regard. The industry is asserting that premiums would or should at least equal the added costs associated with testing. The main benefit though is not centered on premiums but on providing the Canadian industry a competitive advantage over the industry in the United States.

Generally the Canadian industry sees the potential to increase access, particularly to Japan as very hypothetical and uncertain. The industry is very skeptical of potential benefits, a prevailing view point is that customers expect that product is safe to eat, and generally speaking do not differentiate on more safe vs. less safe.

4.4 Concerns Regarding BSE Testing

Industry respondents were very concerned that the start of any non-scientifically justified testing will send the wrong message to consumers and would only serve to raise concerns especially in domestic markets. Once started, BSE testing at slaughter would become difficult to stop. European regulators have had a hard time rolling back BSE testing on healthy animals despite clear knowledge that it adds no value to product safety or to national surveillance information. Testing for BSE will send a message to the public that the solution to any future animal disease outbreak or food safety concern is to test animals or product. A strongly held and representative view is that resources directed to meaningless testing mean that resources are diverted from where they are actually needed.

The industry broadly felt that testing healthy animals (of any age) would have a perverse effect of raising concern where none exists, would lead to negative marketing against any firm choosing not to test, and would build new, unsustainable costs into the beef processing complex.

Further to that point, industry respondents pointed to the Canadian Meat Council estimates that testing for BSE for marketing purposes would effectively slow down Canada’s processing capacity. Should all the animals in Canada have to be tested for BSE it would likely slow down slaughter capacity by 40%. This would defeat the purposes of testing for marketing purposes as any increase in market prices would be more than offset by reduced production.

A summary point of one smaller packer is fairly representative of overall industry views:

*Based on the current standards, it would be very difficult to quantify the benefit of BSE tested meat and or any premiums that would result as we have not seen any market indicators demonstrating demand for this product. Should the industry adopt a standard for testing, then there is real concern over the negative impact on both domestic and international perceptions of non tested product. Furthermore, without a premium guarantee, the repercussions of the added costs*
of testing would have serious competitive economic disadvantages on the currently strained, heavily regulated international and domestic markets.

The overall consensus seems to be that although BSE exists, it is being controlled. In this sense it will cease to be an issue unless the current system fails.

Another concern of smaller firms is that testing would be a way for large companies to take away market share from smaller packers who cannot afford to install, manage and service a technologically dependent process.

4.5 Future of Testing

The overall view of the industry is that the issue of testing will gradually disappear as the control measures continue to take effect. BSE is a non-issue domestically. As such, testing for domestic consumption would be a waste. With regard to international sales, the issue is access rules imposed by governments. The BSE issue and thus testing is a government to government issue dealing with non-tariff trade barriers.

4.6 Supplementary Information

In addition to the beef processor interviews, secondary data was obtained from broader industry sources, the Canadian Beef Export Federation (CBEF), past Alberta/Canadian beef trade initiatives with Japan were reviewed, and related discussions and interviews with individuals involved in the Japanese import trade were conducted. Interviews with South Korean customers were not sought out due to the ongoing trade case Canada has with South Korea in beef.

A copy of a letter sent by Japan Organic Foods (JOF) Corporation of Chiba, Japan to Rancher’s Beef in Balzac, Alberta dated June 20, 2005 was obtained (Appendix C). The letter confirms the interest in JOF in obtaining BSE-tested product from Rancher’s Beef at that time. It also describes the interest that JOF received in pre-sales promotion from some of its customers in using Ranchers Beef items if the BSE test certificate were attached. The letter indicates that JOF’s Korean affiliate had a similar interest in BSE-tested product from Canada. The letter concludes that JOF itself had an interest in purchasing 5-6 container loads of product per week, and that BSE testing was a critical element of the prospective sale. Ocean-going containers carry in the range of 20 tonnes, so at a weekly purchase of 5 containers for 50 weeks/year, the prospective volume amounts to 5000 tonnes/year. This compares with 2009 exports to Japan of just over 10,000 tonnes per week; thus, if fully realized, this magnitude of order would increase Japanese market share by 50% (on a prospective basis). With total Canadian beef exports ranging around 500,000 tonnes, this single order would amount to about 1% of total beef exports.

A presentation was made at the Western Stockgrowers’ Association Annual Meeting in August, 2006 by Tatsuo Iwama, the Executive Director of the Japan Meat Traders Association. This trade association represents about 80% of total beef imports into
Japan. In his presentation, Mr. Iwama was candid in his support for BSE testing of beef in Canada. He stated that by testing, he felt that a larger volume of Canadian product could be made available to his members.

CBEF’s *International Markets: Environmental Scan* (December, 2010) states that “Japan must increase the age limit for its “voluntary BSE testing” from U21M [under 21 months of age] to U30M [under 30 months of age] prior to Canadian importing beef derived from O20M-U30M cattle without BSE testing. Japan has indicated that a review of its domestic BSE testing regime will not be completed until at least the spring of 2011”. The apparent implication is that the only prospect of obtaining market access beyond 21 months of age before the spring of 2011 is to test cattle for BSE (Ted Haney, President, CBEF- personal communication).

In 2006 CBEF conducted market research in Japan and elsewhere in Asia. In the study, retailer and foodservice respondents were asked to rank product attributes. The Asian component included a section on retail and food service demand drivers - those product or service attributes that positively contribute to increased purchases of beef products. The most highly valued attribute, as rated by retail and food service industry leaders in Japan, was BSE Testing.

Summary information was reviewed from meetings conducted in Japan by an ALMA subcommittee in the fall of 2009. The group met with a range of stakeholders in the Japanese meat trade to discuss beef market access issues. The notes from these discussions revealed the following.

- There appeared to be a broad awareness on behalf of the Japanese of SRM handling in Canada vs. the US, and a view that the US system was subject to errors and gaps, with an acknowledgement that Canada had a superior system with value that could lead to preferential access for Canada.
- Age verification was felt to be an important driver of market share in Japan. One interviewee presented private data showing that since Canadian age-verified product has become more widely available, the Canadian share of the Japanese beef market has grown more rapidly than US share. In addition, Canadian product was seen as more successful in recovering its pre-BSE market compared with the US. The data supporting these assertions is private; in order to independently validate it, public data on Canadian and US exports of beef and veal to Japan since 2000 were obtained and are presented in Table 4.1 below. The data in the table are broadly supportive of the assertions made regarding the recent role of age verified product and market retention post-BSE. In 2008, compared with the previous year, the proportional export growth was essentially the same for Canada and the US. Japanese export growth in 2009 was very different with Canadian volume up 76% vs. 17% for the US, in a market with a weaker US dollar that essentially made Canadian product more expensive. The data in the table also validate the assertion that Canada has been more successful in retaining its pre-BSE market share than the US. Compared with 2000-02 average export volumes, in 2009 Canada had retention of about 38% of historic volume, while the US had 26%.
Interest was expressed in a tested product by Japanese meat stakeholders. One importer among the four large meat import traders requested testing repeatedly in discussion. The significance of this, it was suggested, could be attested to by the fact that the Japanese government still funds testing for cattle over 20 months of age, and that the prefectures fund testing of cattle under 20 months.

Table 4.1 Canadian and US Exports to Japan, Tonnes

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<th>Year</th>
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<th>US</th>
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<td>2007-08 Growth</td>
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<td>54.9%</td>
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<td>2008-09 Growth</td>
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<td>17.4%</td>
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<tr>
<td>2009 vs 2000-02 Average</td>
<td>37.8%</td>
<td>25.8%</td>
</tr>
</tbody>
</table>

Source: AAFC Red Meat Section, and US Department of Commerce, U.S. Census Bureau, Foreign Trade Statistics

A Japanese meat trade executive who has played a central role in the North American meat trade with Japan for many years was interviewed to obtain his sense of Japanese perceptions of Canadian beef and of the prospect for a BSE tested product. The discussion revealed the following.

- The Japanese beef market suffered following the US BSE case and the associated import restrictions - beef prices increased markedly, and some consumers turned against beef based on price. Also, the market became dominated by Australian product, the vast majority of which is grass-fed, which further turned some consumers against beef.
- As a consequence of the above, there has been relatively little in terms of new initiatives by the major beef importers in Japan, and little in terms of leadership by the meat import trade. In fact, the importers are waiting for “a good package” of product and attributes to be presented to them, if this were to occur then they will move on it.
- With regard to offering an imported BSE-tested product in Japan, it was felt that at a market level in Japan, leading with a negative product attribute was probably unwise for the mass market, and runs the risk of actually doing damage if new tests are developed that uncover more positives. With that acknowledged, Canada needs a point of differentiation because, given its size, it will only ever be a niche player in the Japanese market. Canadian product will be a niche regardless of
BSE testing, but by testing Canada could better exploit and grow its niche. There is room for products with “proven to be healthy” attributes associated with them, and BSE testing is consistent with this, along with radio-frequency identification (RFID), and age verification. To be successful, BSE-tested Canadian product would need to be targeted and promoted, but this should be done carefully using a “soft” approach. The key economic driver behind testing would be the enlargement of market share in a high revenue return market, rather than a price premium. It was easy for him to visualize how a major retailer would adopt a Canadian marketing program based on tested product from animals that can be identified. The economic model therefore would be expansion of the niche in a high return market.

- There is a sense of resentment in Korea and Taiwan\(^3\) regarding the agreement they have with the US on market access in beef. There is a feeling in both countries that they were in effect pushed into accepting US product that lacks attributes preferred by some. This creates a niche opportunity for Canada to provide a targeted niche product that caters to distrust and resentment toward US beef in these countries. Moreover, Canada needs to consider its strategy if the US changes direction and opts for access under 30 months of age. Because it is inherently a small niche player, UTM access into Japan for all countries is not necessarily in Canada’s best interest and will require Canada to further differentiate.

### 4.7 Observations

In drawing observations on anticipated benefits, it must be acknowledged that the discussion is inherently hypothetical. The hypothetical questions of if we tested and if we had tested product to sell, are anecdotal- there is no published data, only information that can be offered by people close to the market, so it cannot be independently verified. Secondly, it would appear that some respondents lacked complete knowledge of the workings of a BSE test- for example, a BSE test is in no way a substitute for SRM protocols or age verification. This acknowledged, we observe the following.

It is apparent from the results that Canadian processors are not seeing regular requests for BSE-tested product. At the same time, Japanese importers have directly requested it in several venues, and past market research suggests it is an important beef attribute in Japan. A senior meat trader knowledgeable with the Japanese market did not see BSE testing as a viable mass marketing strategy, but rather saw it as a niche strategy and observed that Canada is inherently a niche supplier in Japan; he believed there was potential for BSE testing to anchor and grow this niche in Japan, and potentially also in Korea and Taiwan. Discussions in Japan in late 2009 suggested that the Japanese meat trade was well attuned to Canadian SRM controls, cattle identification and traceability, and age verification in addition to a BSE test. The data are supportive of assertions made by the Japanese that the availability of credible age verified product has improved

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\(^3\) For example, a petition drive has been initiated to renegotiate the US beef market access agreement with Taiwan [http://focustaiwan.tw/ShowNews/WebNews_Detail.aspx?ID=201007160023<Type=aSOC](http://focustaiwan.tw/ShowNews/WebNews_Detail.aspx?ID=201007160023&Type=aSOC)
Canadian beef sales relative to the US. Thus, it is evident that these attributes can provide improved export access in some markets.

Any interest that processors had in BSE testing was driven by market access. This was confirmed by the Japanese meat trading executive; if successful BSE testing could lead to increased market access in a highly valued market rather than a price premium *per se*. There appeared to be some confusion on behalf of processors as to what form prospective enhanced access might take—some felt this was a government-to-government issue, others indicated that they thought testing could supersede age verification or SRM removal. In other cases, it seemed that processors saw testing as a competitive advantage to gain market share from the US.

Overall, processors were cautious and somewhat skeptical of the merits of a BSE test. They see risks associated with criteria that they view as not based on science. There was also a sense among processors that testing could drag down capacity utilization and drive restructuring of meat processing toward fewer larger processors better equipped to do testing. Some also felt that by opening the door to testing it would essentially be driven into the marketplace as a standard operating procedure and that their costs would not be compensated.

Conversely, information from meat traders familiar with the Japanese market is supportive of customer interest in a tested product. It is also apparent that to capitalize on it will require marketing effort and development as the Japanese meat trade is unlikely to take the lead. The boost in Canadian sales claimed by the Japanese as being due to Canadian age verification, which can be inferred from data, is supportive of interest in a portfolio of attributes of which a BSE test could be one. There was also a sense of latent competitive advantage relative to the US in Japan, Korea and Taiwan through BSE testing.

Table 4.2 Summary- Findings on Prospective Demand for BSE Testing

<table>
<thead>
<tr>
<th>Source</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canadian processors, cattle feeders</td>
<td>Not generally being asked about testing, cautious regarding testing</td>
</tr>
<tr>
<td>Letter from Japanese importer to Rancher’s Beef</td>
<td>Expresses commitment to purchase tested beef</td>
</tr>
<tr>
<td>Presentation by Japan Meat Traders Association</td>
<td>BSE testing could result in larger volumes of beef imported into Japan</td>
</tr>
<tr>
<td>CBEF</td>
<td>Only way to increase access to Japanese market at this time is to test for BSE; BSE testing was the key beef attribute sought in a 2006 CBEF importer survey</td>
</tr>
<tr>
<td>ALMA Mission to Japan, 2009</td>
<td>Awareness in Japan of Canadian SRM protocols, perception of value around age verification, direct request for testing from one importer</td>
</tr>
<tr>
<td>Japanese meat trade executive</td>
<td>Canadian product inherently a niche; BSE testing could cultivate the niche, but testing is not a strategy for the mass market</td>
</tr>
</tbody>
</table>
5. Costs Associated with BSE Testing

This section develops the context within which to understand the operations/engineering costs associated with post mortem and ante mortem testing of BSE in animals under thirty months of age, and provides estimates of BSE testing costs.

5.1 Overview of Existing Beef Plant Operations

Under existing protocols, the dressing process in most medium and large cattle slaughter establishments involves the following:

1. First, each animal is moved into a knocking box for stunning
2. The animal is stunned
3. The animal is shackled and elevated and CCIA ear tag recorded
4. The animal is bled and blood goes into a holding tank for shipment to rendering (including some wash water)
5. Dentition is assessed in plants processing fed cattle and any cattle over thirty months (OTM) of age are marked for special treatment during processing to ensure no cross contamination (this process may occur after the head has been removed in some plants)
6. The hide is pulled
7. The head is removed and placed on a rack to allow matching of carcass and viscera through the dressing process
8. The viscera is removed and edible organ meats (“fancy meats”) are harvested; viscera is dropped on to a conveyor table/belt and moves by conveyor to a point where matching to head and carcass is no longer required and drops through the floor into a holding area or directly into a truck; conveyors/augers then move the inedible material into a transport vehicle to go to rendering; (segregation of the specified risk material (SRM) must occur during the dressing process and go into a holding area/tank separate from other inedible rendering)
9. Dentition is verified by CFIA inspectors
10. Carcass trimming to meet CFIA inspection criteria is completed, followed by carcass weighing, washing/pasteurization and cooling
11. For carcasses determined to be 30 months of age or older, the vertebral column (containing the dorsal root ganglia) is removed during the fabrication/boning process, usually 24 to 48 hours following processing.

5.2 Engineering/Operations Changes in Beef Plant Under a Post Mortem BSE Test

If a plant were to test for BSE on a post mortem basis, some changes to plant engineering operations and rendering can be anticipated. These are the following

1. As generalized in the livestock product flow diagram in Figure 5.1, other than at the testing location in the plant the animal and subsequently the carcass would flow normally without any cost or change in flow until the actual head was severed and the internal organs removed.
Figure 5.1 Product Flows in Beef/Pork Processing Streams

Source: FAO
2. The head would be severed as normal and then the brain material for the test would be harvested before the head moves to the SRM trailer. The brain material would be collected for testing; this would be performed by the same person performing the head harvest function. The issues at this location will be dictated by the CFIA rules for collection and protocols for ensuring sample segregation and sample integrity. The anticipated maximum added cost here would be two full-time equivalents collecting and moving samples to the on-site lab. There is a strong likelihood the internal quality and food safety roles would be able to divert their energies to ensure adhering to the required CFIA protocols; the added functions would likely just be added to the internal quality and food safety role.

3. The head would be moved to mobile rack storage. The head would hung in sequence with kill and identified carcass number and held until test results were back. An A-frame rack on wheels with three or four hanging levels for the heads on each side of the rack would be used. The rack height and length would be determined by the ability of plant staff to raise and lower the head to the hanging racks. Heads are heavy and not that easy to handle even after being yielded. The racks would then be wheeled off the evisceration floor to appropriate storage space. There would be an additional person required to cover the floor responsibilities and movement of racks. There would be an added CFIA inspector added to ensure flow, traceability, and accuracy. I would suggest this added inspector would be able to cover lab and the floor protocols. If the tests are all compliant then once confirmed the heads would be wheeled to a chute or conveyor and sent to SRM facilities. Heads associated with animals that were not clearly negative from the quick test would be used by CFIA for further analysis at the Lethbridge Laboratory.

4. Once the edible fancy meats and viscera are harvested the next change would take place in the carcass and yielded product flow. Likely the “fancy meats and viscera” would be pooled in the harvest and cooling, then tracked and pooled again through the packaging and cold storage process. Packing plants would be hard pressed to spend capital specific to building additional capacity to accommodate a low incident program. Additional stainless tubs and add on electronic tracking to pre-existing systems would make the most sense for the pooled materials. Additional bins can handle up to 500 lbs of material. Each bin can accommodate the fancy meats and viscera of 22 animals, with an approximate cost of $475/bin with a service life of 5 years. When this is amortized over the volumes of a plant and the useful life of the bin, the cost would appear to be minimal.

5. Accommodation for cooling is minimal because the pooling does not create increased space demands outside of the incremental stainless bins.

6. The tracking of the pooled materials represents minimal incremental costs as well because the in-plant system will already exist and this protocol will only be an additional “yield” to monitor. The addition to the software of a field and an additional handheld device will suffice. Carcasses are already tracked and monitored and this will not require any additional protocols with a positive test result.
7. There would be no other requirements to change the regular flow of by products and SRM materials until the regular byproducts arrive at the rendering facility.

8. Because the majority of Canadian beef processing plants use external rendering facilities, there would be a challenge in segregating materials by plant, with the identity of materials lost in the trailer before arriving at the rendering facility. The byproducts would be mixed once at the rendering facilities and even plant identity will become increasingly difficult once the products are in the system. This would occur prior to knowing the results of BSE tests at the plant.

To mitigate this risk a time stamp procedure would be used to connect a positive test with delivery of inedible materials to rendering; indeed, this type of procedure is generally in use today. Because of international rules regarding fats derived from the byproducts there will be no interventions required even with a positive test. The meat and bone meal derived from the byproducts will need to be segregated because of the imbalance in timing of test results and the processing of the rendering materials. BSE test results would be back within 24 hours and the rendering materials will be in the rendering process system within 8-12 hours of collection. In order to keep finished meal materials separate and eliminate the potential contamination by materials from a positive test, “flat storage” would be employed. A simple elevator discharge spout would empty into an empty “undetermined materials” into a trailer for the 24 hour “hold period”, pending the results of the carcass test. Once the carcasses are cleared for BSE tests at the packing plant, the protein meals at the rendering plant would be released and delivered to the feed system.

Materials affected by a positive test would be handled as follows. As per international agreement the fats are not an issue regarding BSE and would be sold into the standard customer base. With regard to protein meal, the material that had been processed and of issue would be collected and transported to a licensed landfill or incinerator. Any product that had been stored with the at issue materials would also be destroyed within a few meters below and all of the product stored on top. The actual cookers would need to be flushed with a predetermined amount of raw material to be cooked and flush the system. Discussions with CFIA confirmed that there is no established protocols for flushing in this instance; the extent of flushing that occurred would be based on the liability perceptions of the rendering firm. Once the flush was complete, which would include new fats (they act as a slurry facilitator and make the material flow more easily) the materials would be collected and again sent to licensed landfill or incinerator for destruction. The contingent cost would consist of the economic value of the affected materials (original and flush volumes), destruction of same, and the operating costs of the rendering of the flush materials.

5.3 **Costs Associated with a Voluntary Post Mortem Test**

The costs associated with post mortem testing relate to (1) direct costs of sample collection, transport to laboratory, test kit and laboratory analysis, and (2) costs of required changes in engineering/operations in the plant. These are discussed below.
Cost of Collection and Testing

The cost of the BSE quick test kits themselves was estimated by Cox et al (2005) at $US 30/head. It is unclear what is included in this estimate (test kit, transport to a test laboratory, laboratory analysis), the implied volume of testing assumed, and the assumption of the anticipated number of positive cases. Coffey et al (2005) estimated the variable cost of testing at $US 15-20/head; this excludes the cost of a suitable laboratory in a packing plant.

Information on the costs of BSE testing were obtained from manufacturer quotes given to the former Rancher’s Beef plant in Alberta (Appendix C). Three quotes were obtained; one was a Bio-Rad test, a second was an Enfer test from Abbott Laboratories, the other a Prionics test. The total cost (variable and fixed cost) quoted for the Bio-Rad test, on the basis of 1000 head/day slaughter, was $18.35-$19.42/head. The Enfer-Abbot test cost was estimated at $16.90/head, based on 1000 head/day. The Prionics quote was $28.42/head, based on 1000 head/day.

In the Rancher’s Beef budget plans, the actual anticipated cost of testing at its location in Alberta on a daily slaughter of 800 head/day was $32.57/head. This assumes the following:

- Test kit and consumables- $25.00/head
- Laboratory labour costs - $.89/head
  - Assumes a laboratory manager at $35/hour, laboratory technicians at $25/hour
  - Manager at 2.5 hours/day, technicians at 25 hours/day
- Other variable costs- $1.46/head
  - Waste and electricity at $.46/head
  - Labour for sample extraction and transfer to on-site lab $1.00/head
- Fixed costs- $5.22/head
  - Assumes on-site container lab, instrumentation, equipment
  - Total fixed costs of $1.044 million, depreciated over 1 year

The current experience of the Alberta government in enhanced BSE surveillance using a quick test is that the total costs of test kits, sample collection, sample transport to a Level 3 laboratory and automated analysis are $70-$90/head.

Given the above, the direct costs of post mortem testing relate to relatively minor changes in in-plant operations, and redundancies in rendering facilities. For the purposes of this analysis, it is assumed that the total cost of the test (sample collection, delivery to on-site lab, test kit, analysis) would be about $40/head. This estimate is much lower than current practice in surveillance, but somewhat higher than estimates in the literature, actual quotes, and budgeted total cost values based on actual quotes from an Alberta processor. It should thus be conservative.
Costs of Engineering/Operations Changes in Plants

Given the anticipated changes observed in section 5.2 above, the following costs are evident:

- To properly segregate and ensure protocols are properly followed in handling harvested heads and in the fancy meat yield and cooling area, it is assumed that two labourers is required at $17/hour for an 8 hour day. This amounts to $272/1000 head or $0.27/head.

- Racks for hanging heads would handle 22 heads, or 45 racks/1000 head. The racks costs about $750 each, so the cost for 1000 head/day plant is $33,750. Segregation bins for fancy meats would handle 22 head/bin or 45 bins/100 head. The stainless steel bins cost about $500 each, so for a daily kill of 1000 head the capital cost would be $22,500. The total cost of racks and bins are thus $56,250.

  Both the racks and the bins would be fully amortized over a 3 year period.

  Assuming 1000 head/day kill at 5 days/week and 50 weeks of processing per year, a volume of 750,000 head would be covered over the 3 year life of the segregation containers. The cost per head is thus $0.07/head.

- There are other costs that will need to be incurred but they are the “sleeve losses” of time, yield and quality. All three would be very tough to quantify and justify because each plant will be different; the fact remains that these costs exist.

- There would be additional costs associated with an additional inspector in the plant, as well as one-time inspection/certification and periodic inspection of laboratory facilities.

- Thus, the total quantifiable cost at the slaughter plant would be about $40.35/head assuming 1000 head daily volume.

At the rendering facility level, the following costs are evident:

- The 1000 head/day slaughter volume will produce 70,000 to 100,000 lbs of meat and bone meal (MBM). In order to hold the finished MBM pending BSE test results, the best method would be to load the tonnage into finished product trailers. Approximately 3 trailers dedicated to hold the material pending the test results. Once cleared the materials could be delivered directly or held in the trailers until demand pulled it (always very short term because price always fixes overage in this sector).

- Each trailer would cost $110,000 and would last 15 years. Trailers would be fully amortized over the 15 years, or the equivalent of 3,750,000 head. Thus, the cost per head is 3*$110,000/3,750,000, or $0.088/head.

- It is likely that 1/2 of a full-time equivalent person would be needed to ensure tracking and movement of the trailers. This would be inclusive of the labor component if indeed there was a positive test result and the materials needed to be pulled to a CFIA designated SRM destruction site. Assuming a wage of $23/hr, this amounts to $184/2, or $92/1000 head or $0.092/ head.
Thus, total costs in rendering are $0.18/head.

The quantifiable combined slaughter plant and rendering total cost is about $40.53/head. The vast majority of this cost is the direct cost of the test itself; the anticipated costs due to changes in plant engineering/operations are minor.

5.4 Costs Associated with a Prospective Ante Mortem Test

The notion of an ante mortem test differs sharply from the post mortem test. The ante mortem test would occur at the farm prior to shipment to a slaughter facility. In assessing the nature and likely cost of an ante mortem test, some assumptions are necessary. First, it is assumed that the availability of an approved ante mortem test would have no impact on Canada’s protocols regarding SRM treatment and the existing feed ban; these would remain in place, and costs in beef plants associated with SRM would remain unchanged. This is an important assumption because the costs in the beef slaughter/rendering/feed manufacturing chain associated with SRM handling, destruction, and the feed ban are significant. Thus, there are no changes in costs at slaughter or rendering using the ante mortem test.

Secondly, it is assumed that a veterinarian would administer the test, and not the producer. This is a critical assumption as it increases the cost of the test, and because it preserves the integrity of BSE reporting. This latter point relates to the following- if a veterinarian is responsible for the conducting the test, since BSE is a reportable disease under section 5 (1,2) of the Health of Animals Act and under section 1 and 2 of the Reportable Diseases Regulations in Canada, there is a guarantee in place that positive cases will be reported. It also allows for better regulatory control over the distribution of test kits.

Under these assumptions, the cost of ante mortem test is limited to the cost of the test kit administered on-farm by a veterinarian, and the cost of analyzing the test. Based on discussions with one of the key researchers at the University of Calgary involved in developing an ante mortem test, the expectation is that the test kit would cost about $5/head, including analysis of the samples. The cost of a veterinary visit is based on schedule mobile fee and an hourly rate. The scheduled mobile fee is assumed at $50. The guideline set by the Ontario Veterinary Medical Association for hourly rates is $180/hour. The productivity of the veterinarian in conducting the test depends on the facilities available on the farm, but it is assumed that a producer would have a mechanized squeeze and appropriate confinement facilities such that a blood sampling procedure could reasonably occur at a rate of 3 minutes per head, or 20 head per hour. Thus, the sample collection cost would be about $9 per head, plus a charge that is inversely proportional to volume to cover the mobile fee. If it is assumed that BSE testing would typically exceed 50 head per veterinary visit, this amounts to $1/head, to give a total veterinary cost of $10/head. Thus, the anticipated total cost of the ante mortem test is about $15/head.
5.5 Observations

The results above suggest that BSE testing under a voluntary test expected to be relatively low cost. With regard to the post mortem test, the anticipated cost is just over $40/head, comprised almost entirely of the cost of the test kit and sample analysis, as adjustments in slaughter plant and rendering operations are relatively minor. For the prospective ante mortem test, the expected cost is $15/head with the dominant proportion of the cost associated with veterinary oversight of sample collection.

In both cases, caveats should be observed as the cost estimates relate to hypothetical situations. Mass use of post mortem testing kits beyond surveillance has not occurred in Canada as yet, so the reduction in unit cost can only be speculative. With regard to the ante mortem test, while the assumptions are transparent, the fact that it is prospective lends a speculative nature to the estimates.

To put the cost of testing in context, it can be related to the cost per pound of beef cuts. According to Canfax, the average Alberta steer carcass weight in 2010 was about 852 lbs; thus, the basic cost of post mortem testing is $40.53/852 lbs, or just under $.05/lb. For the ante mortem test, the cost would be $15/852 lbs, or just under $.02/lb. In reality, this cost would be unlikely to be allocated on a uniform basis over the cuts and primals from the carcass— the allocation of costs will be driven by marketing. Figure 5.2 below presents the range in cut yield from the carcass; the cuts and primals also vary significantly in value. The implication is that highly prime cuts such as the sirloin, loin, and ribs might readily carry well over 5¢/lb in post mortem testing cost, where lesser valued cuts such as the chuck may not be able to support a markup of 5¢/lb. Moreover, export markets like Japan prefer a subset of the cuts; an incentive would exist to allocate testing costs to these cuts.

The analysis done by Rancher’s Beef regarding BSE testing contemplated precisely this. In arriving at the conclusion that a net margin of about $75/head existed from BSE testing, Rancher’s considered the proportion of the various cuts that were more demanded in Japan, and the premium that could be obtained over the domestic market for the various cuts. This allocation of carcass value and testing cost made the prospect of BSE testing viable.
Figure 5.2
Beef Carcass Breakdown %

Source: Canfax
6. Prospective Benefits of a BSE Test

To gauge Canadian consumer reaction to BSE testing, BSE tested beef, and valuation of BSE tested beef consumer, consumer research was conducted on a sample of 1000 Canadian consumers. The detail of the survey instrument and analysis is contained in Appendix A. This section summarizes the results of the analysis.

6.1 Respondents Attitudes Toward Beef

Ipsos Reid’s Canadian online consumer panel was used as the sample frame. The target sample size was 1,000 English-speaking Canadians. Respondents were asked to rate the importance of seven different attributes they might consider when purchasing beef. The rating was undertaken by asking respondents to assign a total of 100 points to the seven attributes, with more points assigned to more important attributes and fewer points to attributes of lesser importance. Table 6.1 shows the ordinal ranking of these attributes, as well as the mean score for each. The three highest ranked products, across the entire sample, were freshness, price and region or country of origin. Interestingly, attributes most often associated with taste/sensory aspects (i.e. fat cover and marbling) ranked in the bottom three. They were also asked about perceptions of the safety of beef relative to other meats, with the results showing a positive impression of safety attributed associated with beef (see Appendix A).

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Mean score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freshness</td>
<td>28.19</td>
</tr>
<tr>
<td>Price</td>
<td>20.78</td>
</tr>
<tr>
<td>Region or country of origin</td>
<td>12.04</td>
</tr>
<tr>
<td>Colour</td>
<td>11.70</td>
</tr>
<tr>
<td>External fat cover (fat which can be trimmed before preparation)</td>
<td>9.57</td>
</tr>
<tr>
<td>Premium brand (such as Certified Angus Beef)</td>
<td>9.44</td>
</tr>
<tr>
<td>Marbling</td>
<td>8.28</td>
</tr>
</tbody>
</table>

6.2 Knowledge and Perceptions of BSE & Testing for BSE

Figure 6.1 shows respondent’s self-declared familiarity with BSE. While 14 per cent of respondents indicate they are very familiar with BSE, the majority (62 per cent) indicated they were somewhat familiar with BSE and only three percent said they were not at all familiar.
After subjects were asked to rate their familiarity with BSE, they were provided with a brief information paragraph related to BSE:

_Bovine spongiform encephalopathy (BSE), or mad cow disease, is a nervous system disease of cattle. Scientific research from around the world indicates that BSE is concentrated in specific nervous system tissues, and as such these tissues are treated as hazardous and removed from the food system. Any animals found to be positive for BSE are immediately destroyed and completely removed from the food system. As such, common cuts of beef (such as roast, steaks, and ground beef) are considered safe by the Canadian Food Inspection Agency, and international agencies such as the World Organization for Animal Health. Because of this, BSE poses an extremely low risk to human health. While Canada maintains a BSE surveillance program for Canadian cattle, it does not require mandatory testing of all cattle for BSE because there is no scientific basis for doing so._

This passage was developed based on publically available information on the websites of: Health Canada; Agriculture and Agri-Food Canada; the Canadian Food Inspection Agency; and the World Organization for Animal Health. Subjects were then asked the following question:

_Suppose you were shopping for a cut of beef (such as steak or a roast) in the retail store where you typically buy beef and you notice that some packages of beef have a label saying “Tested for BSE”, while other packages of beef do not_
A Cost-Benefit Analysis of Voluntary BSE Testing of Cattle

have the “Tested for BSE” label. How likely would you be to purchase a cut of beef (such as steak or a roast) that has the “Tested for BSE” label?

Based on the pattern of responses to this question, three groups of different sizes were identified:

1. Those with a low intention to purchase beef that has been labeled as being tested for BSE; this group accounts for about nine per cent of the sample.
2. An intermediate group with a moderate intention to purchase product labeled as tested for BSE; this group accounts for 56 per cent of the sample.
3. Those with a high intention to purchase beef that has been labeled as being tested for BSE; this group accounts for 35 per cent of the sample.

The ranking beef product attributes in Table 6.1 was rerun after the BSE information paragraph above was presented to test the significance of BSE testing as an attribute. In this instance, however, the ranking criteria included a “Tested for BSE” option. The ranking of the beef attributes, and the associated “importance scores” are shown in Table 6.2, along with the mean scores and ranking from the original constant sum exercise with seven attributes. Introduction of the “Tested for BSE” attribute does not change the ordinal ranking of attributes considerably, but it reduced the importance of many. “Freshness” and “Price” continue to be the top two ranked attributes, followed by “Tested for BSE”. The ordinal ranking of most of the remaining attributes shifted down one position, while the importance of “Premium brand” and “External fat cover” switched.

Table 6.2 Ranking of attributes by average importance score (including “Tested for BSE) (n=1,008).

<table>
<thead>
<tr>
<th></th>
<th>Mean score</th>
<th>Original score</th>
<th>Original rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freshness</td>
<td>22.63</td>
<td>28.19</td>
<td>1</td>
</tr>
<tr>
<td>Price</td>
<td>19.18</td>
<td>20.78</td>
<td>2</td>
</tr>
<tr>
<td>Tested for BSE</td>
<td>14.19</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Region or country of origin</td>
<td>11.04</td>
<td>12.04</td>
<td>3</td>
</tr>
<tr>
<td>Colour</td>
<td>10.22</td>
<td>11.7</td>
<td>4</td>
</tr>
<tr>
<td>Premium brand (such as Certified Angus Beef)</td>
<td>7.84</td>
<td>9.44</td>
<td>6</td>
</tr>
<tr>
<td>External fat cover (fat which can be trimmed before preparation)</td>
<td>7.70</td>
<td>9.57</td>
<td>5</td>
</tr>
<tr>
<td>Marbling</td>
<td>7.21</td>
<td>8.28</td>
<td>7</td>
</tr>
</tbody>
</table>

Next, consumers were asked the following question:

Now suppose you hear a newscast where it is stated that all Canadian beef which is exported for consumption in other countries is tested for BSE (and has to be tested for BSE before it can be exported), but that beef which is sold in Canada is not tested for BSE. Compared to your current perception of the safety of Canadian beef, how would your perception of the safety of the following two beef products change after hearing the newscast?
Respondents were then asked to indicate their perceived safety of Canadian beef tested for BSE that is exported to other countries and Canadian beef not tested for BSE that is for sale in Canada. A five-point response scale (1= less safe than before; 5=safer than before) was used. Figure 6.2 shows the response frequency to these questions. Three points stand out from Figure 6.2:

- The bulk of respondents perceive that both types of beef have the same level of safety; nearly 70 per cent of subjects indicated a perception that Canadian beef that is not tested for BSE that is for sale in Canada has about the same level of safety as tested export product, while 60 per cent of respondents indicated a perception that Canadian beef that is tested for BSE and is exported to other countries has about the same level of safety as non-tested product.
- There is a smaller segment (36 per cent) that feels Canadian beef that has been tested for BSE and exported is safer than non-tested. Lastly, there is a small segment (24 per cent) that believes Canadian beef for sale in Canada (which has not been tested) is less safe compared with beef that is tested and exported.

Figure 6.2 Frequency of perception of Canadian beef that is tested and exported or not tested but for sale in the Canadian market (n=1,008)

---

Survey question “Suppose you are shopping for a cut of beef (such as steak or a roast) in the retail store where you typically buy beef and you notice that some packages of beef have a label saying “Tested for BSE”, while other packages of beef do not have the “Tested for BSE” label. Based on your existing perception of the safety of Canadian beef, what is your perception of the safety of (1) the package of beef with no “Tested for BSE” label and (2)The package of beef with a “Tested for BSE” label.
One question to ask is the extent to which perceptions of safety illustrated in Figure 6.2 overlap; in other words, are perceptions regarding safety consistent. To explore this issue, Table 6.3 shows cross tabulations (stated as a per cent of the sample) between responses to the question concerning perceptions of safety of Canadian beef tested for BSE that is exported to other countries and Canadian beef not tested for BSE that is for sale in Canada. About 51 per cent of respondents indicated that beef for sale in Canada and beef that is exported have about the same level of safety as before (this cell is in bold in Table 6.3).

The intersection of those indicating a perception that Canadian beef that is not tested for BSE and sold in Canada has about the same level of safety (i.e. a response option of 3 on the five-point scale) AND that Canadian beef that is tested for BSE and exported is safer (i.e. a response option of 4 or 5 on the five-point scale) equaled 18.2 per cent of respondents (these cells are in italics in Table 6.3). Thus, the number perceiving that untested beef in Canada as no less safe and perceiving that tested exports are safer or no less safe is almost 70% (51% + 18.2%). The intersection of those indicating a perception that Canadian beef that is not tested for BSE and sold in Canada is less safe (i.e. a response option of 1 or 2 on the five-point scale) AND that Canadian beef that is tested for BSE and exported is safer (i.e. a response option of 4 or 5 on the five-point scale) equalled 13.4 per cent of respondents (these cells are shaded in Table 6.3).

On balance, these results suggest that about 70% the sample believes both types of beef are at least as safe as before testing, while a smaller segment believes the exported beef is safer, but beef sold in Canada is less safe. While the latter segment is not large (it represents about 13 per cent of respondents), it does suggest potentially harmful impacts on the domestic market if testing for BSE as a condition of export were to become a requirement.

Table 6.3. Cross tabulation of perception of safety of Canadian beef that is tested and exported or not tested but for sale in the Canadian market

<table>
<thead>
<tr>
<th>Canadian beef tested for BSE that is exported to other countries is...</th>
<th>Canadian beef not tested for BSE that is for sale in Canada is...</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 (Less safe than before)</td>
</tr>
<tr>
<td>1 (Less safe than before)</td>
<td>1.2%</td>
</tr>
<tr>
<td>2</td>
<td>0.6%</td>
</tr>
<tr>
<td>3 (About the same level of safety as before)</td>
<td>3.6%</td>
</tr>
<tr>
<td>4</td>
<td>1.3%</td>
</tr>
<tr>
<td>5 (Safer than before)</td>
<td>5.3%</td>
</tr>
</tbody>
</table>
6.3 Demand and Willingness to Pay for BSE Tested Product

To understand better the impact of testing for BSE on Canadian consumer demand for beef, and to measure willingness to pay for beef that has been tested, two contingent valuation experiments were undertaken. Respondents were asked if they would “…be willing to purchase the cut of beef [such as a steak or a roast] that has the label “Tested for BSE” when it is offered at a price that is given percentage more expensive than the same cut of beef that does not have the “Tested for BSE” label?” Premiums of 10% to 50% were considered and randomly assigned.

Figure 6.3 shows the proportion of respondents who indicated they would purchase the labeled cut of beef at the assigned price premium (relative to the overall sample size). As one might expect, the proportion of respondents who said they would purchase the cut of beef that has been tested for BSE fell as the percentage premium increased. Overall, 16 per cent of respondents indicated they would purchase beef that had been tested for BSE, at the given percentage premium. These responses were then analyzed statistically to estimate willingness to pay.

Figure 6.3 Proportion of respondents who indicated they would purchase the cut of beef at the assigned price premium (n=1,008)

Secondly, a statistical analysis of the predictors of purchasing BSE tested product was conducted; based on coefficient estimates the willingness to pay a premium was
calculated. The details of this procedure are contained in Appendix A. Table 6.3 shows the estimates of the mean WTP premium for tested product, standard errors and 95 per cent confidence intervals for consumers identified as high intention to purchase and low/medium intention to purchase. Using the model estimated with all respondents, the estimated mean WTP reflects a 43 per cent premium for BSE-tested product. The estimated WTP for respondents with a high intention to purchase was 52 per cent, with a 95 per cent confidence interval ranging from 13 to 92 per cent. The estimates for all respondents and high intention to purchase respondents are statistically significant; the results for low/medium intention to purchase consumers were not statistically significant.

Table 6.3 Summary of WTP estimates

<table>
<thead>
<tr>
<th></th>
<th>All respondents</th>
<th>High intention to purchase</th>
<th>Low or medium intention to purchase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean WTP</td>
<td>43.14%</td>
<td>51.99%</td>
<td>27.85%</td>
</tr>
<tr>
<td>Standard error</td>
<td>13.04%</td>
<td>20.24%</td>
<td>15.31%</td>
</tr>
<tr>
<td>95% confidence interval</td>
<td>(17.57%, 68.70%)</td>
<td>(12.33%, 91.66%)</td>
<td>(-2.16%, 57.87%)</td>
</tr>
</tbody>
</table>

6.4 Observations

The results from this analysis suggest the following. The consumer sample indicated a broad positive perception of the safety of Canadian beef, and of Canadian beef relative to other meats. As a whole, the sample had a good degree of familiarity with BSE. Freshness and price were ranked as the two most important factors respondents consider when purchasing beef, regardless of whether tested product was available.

Secondly, most respondents indicated some willingness to purchase a beef product that had been tested for BSE, while some (35 per cent) were more positively disposed toward purchasing a tested product. Also, the introduction of a beef product with a “Tested for BSE” label did have a negative effect on the perception of safety of the beef that does not have a “Tested for BSE” label. However, there remained a clear tradeoff between BSE testing and other product attributes (notably freshness and price). Thus, BSE testing was not perceived as “trumping” other aspects of a beef product; it is viewed as a part of a portfolio of characteristics that make up the product.

At the same time, labeling of beef products that had been tested for BSE did appear to influence more broadly held perceptions regarding the safety of Canadian beef. The baseline perception held by the lion’s share of respondents (95 per cent) was that Canadian beef is safe or very safe. However, when respondents were presented with the hypothetical choice of a tested product, the tested product received significantly higher marks for safe or very safe (97 per cent) compared to the product that had not been tested (75 per cent). The presence of a “Tested for BSE” label may thus have a negative effect on the perception of safety of the beef product that does not have a “Tested for BSE” label. To the extent that perceptions of safety influence actual consumption choices, these results suggest that some consumers (about 20 per cent) may alter their purchase
decisions away from beef that does not have a “Tested for BSE” label. Conversely, attitudes seemed to differ in the scenario in which exported product was tested, but domestic product was not tested for BSE. In this case, most respondents saw no difference in safety, and only 13 per cent saw untested domestic product as less safe than tested exports.

There is some evidence of willingness to pay for a beef product that has been tested for BSE. Price premiums for respondents indicating a high intention to purchase a tested product were on the order of 50 per cent, with an average premium of 43 percent for the sample as a whole. Nevertheless, the proportion of respondents who were predicted to purchase a tested beef product is small, and ranges from 21 per cent for the high purchase intention respondents to eight per cent for the low/medium intention respondents.

Thus, while respondents appear willing to pay for beef that has been tested for BSE, the latent market for such products appears small, and caution in marketing a tested product would be well advised.
7. Policy and Regulatory Implications of Voluntary BSE Testing

For reasons that are evident below, BSE testing raises a number of policy and regulatory issues. What Canada can do is framed by Canadian law as interpreted by Canadian regulatory officials. This section reviews Canadian domestic law, compares it to the United States’ legal system as recently interpreted in the Creekstone Farm case and then the export trade implications are reviewed. Because of the wide degree of administrative discretion enjoyed by the CFIA officials, the current CFIA position is then set out briefly before conclusions and recommendations are provided.

7.1 The Canadian Domestic Law

Veterinary Diagnostic Test Approval

A “veterinary biologic” is defined in the Health of Animals Act to include a substance “that is manufactured, sold or represented for use in restoring, correcting or modifying organic functions in animals or for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or symptoms thereof, in animals”.

Therefore a “substance” that is used for diagnosing the animal disease of BSE is a veterinary biologic. Pursuant to this definition and the regulatory authority granted by subsection 64(1) (s) of the Health of Animals Act, the CFIA has developed a detailed regulatory regime for veterinary biologics that prevents their sale or use without pre-market approval by the CFIA. This approval system is administered by the Veterinary Biologics group at the CFIA who have issued detailed Guidelines relative to their sale and use, including the labeling of Veterinary Biologics.


The result is that any test that is going to be used to support the “BSE Tested” claim would have to be reviewed and approved by the CFIA. Clearly this involves complex issues that relate to proving the “efficacy” of the test to support the claim as well as non-science considerations that will be discussed below.

Meat Label Approval

The other issue is whether the meat from the animal that was tested can have on its label reference to “BSE-Tested”. Obviously, if no reference can be made to this fact, there is little or no commercial benefit to doing it.

There are tens of thousands of food products in our grocery markets. The labels for all of these cannot be “misleading or likely to give a false impression” (section 5(1) Food and Drugs Act). Depending on the nature of the product, there are hundreds of rules relating to what must be on the label and what cannot be on the label. The Canadian Agricultural
Products Act, for example, sets out hundreds of “standards of identity” and other rules to ensure that the package label accurately reflects what is inside. Almost all pre-packaged products require detailed nutritional facts information and the rules of setting these are strictly prescribed. The Guide to Food Labelling has hundreds of pages of guidance to ensure that the food label complies with all labeling laws. The vast majority of these products and their labels do not require pre-market approval. Enforcement is triggered by post market complaint by consumers or competitors or by routine surveillance by the CFIA.

Meat labels are one of the few exceptions. Under the Meat Inspection Act and Regulations, all meat labels must have pre-market approval. All meat labels must be submitted for pre-market approval to the Label Registration Unit (LRU) of the CFIA. In that sense, then, the CFIA has much more control over the meat label than for other labels where they can only push for post-market coming into compliance by setting out the basis for the alleged infraction.

It is this power in the Meat Inspection Act for pre-market approval of the meat label that the CFIA could use to prevent the “BSE-Tested” claim and the sale of the meat. The only real basis for denying approval of the label would be the broad prohibitions under the Food and Drugs Act and the Meat Inspection Act that the label is “misleading”. The argument would be that this is essentially a claim for “superiority”, that by virtue of the words used we are explicitly or, at least, implicitly implying that our meat is safer than the meat in the counter beside it. Indeed, we are implying some superiority, that is the whole point.

It is important to note that it is not a matter of whether the statement is true. For example, to say that a can of green beans is “GMO free” may be true but still misleading because there are no GM green beans. Mind you, we do allow “production claims” that may give a false impression and “organic” is the best example. It implies superiority even when there is no science to support that it is safer, more nutritious, tastier or more sustainable. So, whether a production claim needs “scientific” proof of efficacy is a policy matter.

The closest example to “BSE-Tested” is the claim that the meat has come from an animal “raised without hormones, raised without antibiotics.” Pressure from the meat industry that did not want such claims meant that the CFIA spent many months requiring the initial applicant to develop a comprehensive protocol with the requirement for affidavit evidence and routine third party audits before the LRU would approve the meat label production claim.

The “raised without hormones, raised without antibiotics” claim is instructive for another reason. During the many months that the first applicant in Canada was subjected to such a thorough pre-market approval by the CFIA, provincial producers and processors were widely labeling their products as “organic” and “hormone free” because provincial
facilities are not subject to federal law. (Meat from provincial facilities cannot cross provincial or international boundaries).

Moreover, the “raised without hormones, raised without antibiotics” case also demonstrates how political “BSE-Tested” is likely to be. The rest of the industry that does not chose to do the testing and cannot make the claim will lobby hard against it as they will correctly perceive a competitive market disadvantage. This is relevant to this project because there is so much regulatory discretion and because pre-market approval is necessary.

7.2 The US Law: The Creekstone Farm Case
A high profile case in the United States has dealt directly with similar issues as are now raised by this study in Canada. The following is a brief summary of the facts and law in this case presented, in part, to consider the good deal of misinformation surrounding the case and to elucidate the significant differences and similarities that exist with the Canadian situation.

The Facts
Creekstone Farms Premium Beef, LLC (Creekstone) raises and slaughters for sale Black Angus cattle. In December 2003, many countries began to ban or severely limit importation of US beef because BSE had been found in one cow in Washington State. To counter the fears of beef importers as well as domestic consumers, Creekstone developed a plan to test for BSE each of the approximately 300,000 cattle it slaughters each year. The United States Department of Agriculture (USDA), however, asserting authority under the Virus-Serum-Toxin Act (VSTA) denied Creekstone’s request to purchase or use a BSE test kit. Creekstone challenged the USDA’s action in district court, alleging that two of USDA’s regulations are ultra vires under VSTA and that, even assuming the regulations are valid, they do not authorize USDA’s restriction on the sale/use of the BSE test kit.

The Law
Enacted in 1913 following reports that farmers were sold ineffective anti-hog cholera serum, VSTA makes it “unlawful … to prepare, sell, barter or exchange … or to ship or deliver for shipment … any worthless, contaminated, dangerous, or harmful virus, serum, toxin or analogous product … intended for use in the treatment of domestic animals.” To this end VSTA requires that there be a licence from USDA for domestic use and it provides that it is illegal to import any virus, serum, toxin or analogous product without a permit from USDA. Moreover, VSTA grants broad regulatory-making powers to USDA to carry out the objectives of the Act.
The USDA promulgated several regulations. One regulation gave the USDA’s Animal and Plant Health Inspection Service (APHIS) the power to place restrictions on use and another provides that “no biological product shall be brought into the United States unless a permit has been issued for such product.” Biological products are defined to be “all viruses, serum, toxins … or analogous products … which are intended for use in the treatment of animals and which act primarily through the direct stimulation, supplementation, enhancement or modulation of the immune system or immune response.” And “treatment” is defined as the “prevention, diagnosis, management or cure of diseases of animals”.

At the district court, Creekstone argued that USDA did not have the authority to restrict the “use” of the product, nor did the product fall under the definition of treatment. The USDA responded that “allowing a company to use a BSE test in a private marketing program is inconsistent with the USDA’s mandate to ensure effective, scientifically sound testing for significant animal diseases and maintain domestic and international confidence in US cattle and beef products”. The position of the USDA’s Centre for Veterinary Biologics is that all BSE test kits (including the rapid test kit Bio-Rad) could only be used in USDA-approved labs, under the direct supervision and control of the USDA.

The district court took a narrow definition of the “treatment” provision and held that because BSE testing is not used for treatment, USDA lacked authority. The court reasoned that because there is no known cure for BSE and because testing can be done only post-mortem, rapid BSE test kits are not used for treatment.

In a long, rambling, and fulsome judgment, by way of a 2-1 decision, the United States Court of Appeal Circuit Judge Karen Le Craft Henderson overturned the district court decision giving a broader interpretation to “treatment”, considering that the statute defines treatment to include “diagnosis”. The court concluded that even though USDA admitted that it “did not consider the testing of bovines at slaughter to be scientifically justified or meaningful in the context of either human or animal health”, it nevertheless played an important role in disease surveillance which was necessary to monitor the success of risk mitigation measures. The court concluded that USDA had the full power to regulate the use of rapid BSE test kits and to restrict its distribution and sale as was done in this case.

The case caused quite a controversy in the United States. The original district court decision, for example, was applauded by the Consumer’s Union who lobbied USDA to not appeal it. The American Meat Institute (AMI) sided with USDA in the initial court case even though Creekstone was a member of AMI.

The American law as interpreted by this case is, therefore, roughly the same as in Canada. Unless USDA or CFIA approve the test for private use, it cannot be used. Moreover, as in the United States, pre-market approval of the label/claim is required. In both cases and in both countries, there is a high degree of regulatory discretion.
The American situation also suggests that the issue will be a highly charged political one in Canada as well. Science and private economic advantage may not be enough to overcome the political issues that will arise if the meat packing industry in Canada takes the same position as their American colleagues. This, of course, also involves trade issues which will be discussed in the section that follows.

7.3 Export Trade Implications: OIE and Equivalency

No person shall export a meat product out of Canada or convey it from one province to another unless it meets all the requirements and conditions of the Meat Inspection Act (MIA), that are set out in the detailed Regulations and the even more detailed Meat Hygiene Manual of Procedure. These conditions are very extensive with hundreds of pages of rules including the requirement that all meat for export must be accompanied by a certificate from a CFIA inspector authorizing the export of that meat product (s. 7 and 8 of MIA). The effect of various sections of the MIA Regulations (especially, sections 121 and 122) means that unless Canada has an Equivalency Agreement with an importing country, no Export Certificate will be given by the CFIA.

Therefore, before any country could import Canadian beef as “BSE-Tested”, the CFIA would have had to negotiate an Agreement with the importing country. Again, therefore, unless the CFIA is a full and willing partner with the private beef exporter, no exports of that beef can occur.

The international trade in beef products is also regulated by the WTO, NAFTA and the standards adopted by the world’s oldest international standard-setting body, the Office International des Epizooties (OIE). Briefly, the combination of these rules provides that there must be some scientific basis for an importing country to refuse to import Canadian beef but it is only the state, i.e., the Canadian government, that is a party to these organizations, and that can assert rights under these international law arrangements. Again, therefore, a Canadian meat packer that wants to export “BSE-Tested” product to another country would require the voluntary and active partnership of the CFIA.

As in other issues reviewed above, the current CFIA thinking on the subject of exporting “BSE-Tested” is a key consideration in assessing the policy and regulatory implications of voluntary BSE testing. We now turn to a review of the current thinking.

7.4 Current CFIA Perspective

We have seen that any scheme to introduce private BSE testing would be fundamentally affected by how the CFIA would react to an approach for their active cooperation and approval.

Approval For The Test

As we have seen, approval for private testing would have to be approved by the CFIA office of Veterinary Biologics. Senior CFIA officials at meetings on May 11, 2010, made
it clear that approval would not be readily forthcoming: they had scientific, policy and political concerns.

From a scientific point of view, like their USDA counterparts, CFIA was clear that from their perspective BSE testing never made scientific sense. It was only done to regain consumer confidence. Government testing is done as a surveillance methodology to understand epidemiological trends and to assess the efficacy of disease control measures. Expensive BSE testing of animals less than 30 months, (UTM) the age for most exports, is not efficacious. Almost repeating exactly the USDA position, CFIA officials said that allowing a company to use a BSE test in a positive marketing program is inconsistent with the CFIA’s mandate to ensure effective, scientifically sound testing for significant animal diseases and to maintain domestic and international confidence in Canadian cattle and beef products.

The senior CFIA officials had several policy objections to providing BSE testing. For example, it would create serious implementation issues: if one company tested and had a positive, that company may have hold and test processes in place but other companies that don’t test with animals from the same lot or farm would not have hold and test procedures requiring complicated tracing and recalls. Moreover, there would be pressure by operators that did testing to not have to pay for traditional inspection.

The CFIA also expressed political concerns with allowing private testing. Officials, for example, cited their fear that Canadian BSE testing would be “spun” by South Korea in the current Canadian case against that country before the WTO as a demonstration that Canada was worried about the safety of its meat. Officials also cited that the current legal case from RCALF would use the fact that Canada is even studying the question as proof that Canada has continuing concerns about the safety of its meat. To conclude, CFIA approval for the test would not be readily forthcoming.

Label Registration Unit Approval for Meat Label

Senior CFIA technical and policy officials and their Legal Services representatives from the Department of Justice were categorical: no approval for “BSE-Tested” on a domestic meat label will ever be granted as this is clearly an implied claim that would be misleading and contrary to section 5(1) of the Food and Drugs Act. Such a claim would be intended by the vendor to give the false impression that this meat is safer than meat not tested and guaranteed free of BSE. It is quite clear that there is no reasonable prospect of selling BSE-tested meat in Canada for the foreseeable future.

Exporting BSE-Tested Meats

In addition to serious concerns about the negative impact of even doing this study for Canada’s trading situation, it was clear that CFIA Senior officials have no intention at
this time of trying to assist a private operator to export BSE-tested meat abroad. They were quite dismissive of the whole idea of testing for several reasons:

- All countries who have done testing to regain consumer confidence are now trying to get out of it. Even Japan is cutting back the scope of its testing and the EU is trying to get out of it.
- No country is asking for it. To quote the senior CFIA international trade negotiator: “Testing has never come up from any Asian country. Our product is now seen as safe because of our SRM Measures and the feed ban and nobody thinks that BSE testing would enhance the safety of Canadian meat.” Regarding the much discussed potential to export to Japan, CFIA officials stressed that Japan is not asking for testing and would not want to because they would have to continue testing themselves and they want to stop.
- It is not possible for Canada to sustain a policy that provides a product to other countries that it is not providing to Canadians.

To conclude, it is quite clear that current thinking of the CFIA at this time is that:

- There is no demand and no market internationally for BSE-Tested meat;
- Even this study has potentially negative impacts on Canada’s international position;
- It is not in Canada’s interest to even explore at this stage whether other countries would be interested in buying BSE-Tested meat; and
- The BSE test has no application to the age group of animals that are exported.

(UTM)

### 7.5 Alberta Government Perspective

Discussions occurred with senior members of the Alberta government officials to get their sense of the advantages and disadvantages opinions of a voluntary BSE test. These discussions revealed the following. Government is broadly pleased with its efforts and the results of proactive initiatives on BSE, notably its efforts in funding enhanced BSE surveillance, training staff, and providing industry resources. With regard to the more narrow issue of BSE testing, the Alberta government appears to take a more conservative and risk averse view. There are concerns that allowing testing would be at variance with the science basis that government has consistently advocated, and that testing for BSE could create a precedent to test for a range of diseases. Concerns were also expressed that testing could be costly and that it could confuse consumers, particularly if it were done only for certain export markets.

### 7.6 Observations

This section shows that CFIA has extensive approval authority in regards to a BSE test, as well as extensive discretion regarding how that authority is used. Current CFIA think
is not supportive to a test; it is quite conservative in nature. They observe no market demand for a tested product, no science basis for it in UTM cattle, and note that some countries that test are attempting to stop doing so. Thus, CFIA approval for the test would not be readily forthcoming. Any proponents of a voluntary BSE test should expect resistance from CFIA in approvals of the test and/or product marketed based upon it. The opinions of the Alberta government are consistent with the CFIA regarding the merits of BSE testing.
8. Strategic Context and Competitive Dynamics of a BSE Test

Any discussion of impacts of BSE testing in Canada must consider how testing would affect Canada’s strategic position in global beef trade. This discussion must consider not only Canada’s major global beef competitors, but also how testing might impact access to target markets. Much of this discussion is by nature speculative based upon observed positions and reactions various countries have taken thus far. Nonetheless, presenting the thought process is worthwhile.

8.1 Canada’s Competitors and their BSE/Animal Health Protocols

Canada’s major global competitors are illustrated in Figure 8.1. Though there exists debate about which of the seven leading export countries compete directly with Canada for particular export market destinations, there is nonetheless substitutability of beef among source countries by importers. During the BSE discoveries in Canada and the US in 2003, notable gains in export market shares were enjoyed by Brazil and New Zealand. Brazil went from the world’s fourth largest exporter with 8% market share to the world’s leader with greater than 25% market share by 2005. The US lost considerable share following discovery of BSE in 2003 going from 17% in 2003 to only 3% market share in 2004. Canada had about 10% market share prior to BSE discovery and has struggled to regain and maintain that share being at about 6-7% share since 2006.

8.1.1 OIE BSE Risk Status Comparisons

The World Organization for Animal Health (OIE) has established standards by which they rank BSE risk status of their 176 member countries. OIE has three BSE risk status categories of 1) negligible risk, 2) controlled risk, and 3) undetermined risk status. Most of Canada’s major export competitors enjoy the preferred negligible BSE risk status with the OIE. Table 8.1 summarizes countries having negligible and controlled BSE status of OIE members as of June 2010. Countries listed in bold font are the seven leading world beef exporters. Brazil has controlled BSE risk status with Canada and the US. The remaining four leading export countries enjoy negligible risk status. The US recently applied for, but in 2010, was denied upgrading from controlled to negligible risk status.

Brazil’s controlled, as opposed to negligible, risk status has not prevented it from becoming and maintaining its leading world export market share. Of course, Brazil has had a different target market with mostly grass fed beef than has Canada with its predominant grain fed beef target market. However, Canada’s most direct grain fed beef export competitor, the US, has regained global market access faster than Canada (Figure 8.1) despite not having a change in BSE risk status. So, how much OIE BSE risk status itself impacts export market access is unclear.
Figure 8.1
Market Shares of Seven Leading World Beef Exporters, 2000-2010 (Forecast)

Source: Foreign Ag Service, USDA
Table 8.1. BSE Status of OIE Members, June 2010

<table>
<thead>
<tr>
<th>Members Recognized as Negligible BSE Risk</th>
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<tr>
<td>Argentina</td>
<td>India</td>
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<td>Singapore</td>
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<td>Iceland</td>
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<table>
<thead>
<tr>
<th>Members Recognised as Controlled BSE Risk</th>
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<tr>
<td>Austria</td>
<td>Greece</td>
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<td>France</td>
<td>Malta</td>
<td>United States of America</td>
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Germany

Source: World Organisation for Animal Health (OIE)
http://www.oie.int/eng/Status/BSE/en_BSE_free.htm

8.1.2 BSE Testing

None of Canada’s major export competitors currently routinely test all, or a large population of animals targeted for a specific market, for BSE. The only BSE testing done by major exporters is surveillance testing. Testing has occurred extensively in Europe where the extent of BSE infection has been much greater. Japan mandates BSE testing for cattle over 20 months of age; for cattle under 20 months of age, prefectures can fund BSE testing (and most do). When Japan began BSE testing in 2001 the product was labeled as tested; for the last several years, labeling as tested for BSE has not occurred. Other Asian beef markets such as Taiwan and South Korea test based on surveillance.

The US has had three confirmed cases of BSE, the first which was from a cow imported from Canada and the next two which were in US-born animals. The first case was December 2003, followed by a second case in June 2005, and a last case in March 2006. The rest of the major export country competitors (Argentina, Australia, Brazil, and New Zealand) have not had a case of BSE discovered in their bovine herd. With 17 cases of BSE discovered in cattle in Canada, 12 of which were born after the implementation of the 1997 feed ban including a discovery as recent as in 2010, Canada has had more cases
discovered than any other major export competitor. No cases have been observed in cattle born since the enhanced feed ban in 2007; however, inferences about the impact of this feed ban will have to wait 3-4 more years.

If Canada did begin full testing either the entire population of cattle or some segment of the slaughter cattle population destined for a specific market for BSE, major competing export countries are not likely to follow suit with similar testing regiments. That is, Canada would likely be the only major beef export country with a routine BSE testing protocol for exported beef. The reasons for this assertion is that the US has taken a position that they will not test for BSE beyond normal disease surveillance. The US is not likely to diverge from this position and other major exporters not having the disease present have no incentive to test, even if Canada does.

A substantial unknown going forward is whether and when other major exporting countries might discover bovines in their respective herds infected with BSE. Particular concern in other major export countries rests with potential for discovery of atypical strains of BSE that may occur spontaneously as opposed to the typical disease strain transmitted through known vectors. Atypical BSE is treated the same way as classical BSE by the World Association for Animal Health (OIE) in their BSE status classification. Likely, discovery of a BSE case, whether classical or atypical, in a major exporting country that has not had the disease would result in substantial economic trade impacts on that country. In such an instance, BSE testing would undoubtedly be considered among the options of mitigation strategies in such a country if it were apparent that it would re-open closed export markets. The point is, adoption of BSE testing protocols in other major export countries is unlikely, even if Canada did adopt a testing regime, without discovery of BSE in that country. Even then, adoption of such a strategy is difficult to forecast because there are clearly direct costs and indirect negative externalities associated with testing. Furthermore, the US who has had BSE and suffered associated export market losses, has taken a strong position against testing and they do not appear likely to waiver from that position.

8.1.3 Animal ID and Tracking

One of the things the Canadian cattle industry has as a comparative advantage to some of its international competitors is a mandatory animal identification program. Among the values of an advanced animal identification and tracking system are the ability to rapidly contain and mitigate animal disease and potentially food safety related concerns. In their Terrestrial Animal Health Code 2009, the OIE explicitly recognizes:

“Animal identification and animal traceability are tools for addressing animal health (including zoonoses) and food safety issues. These tools may significantly improve the effectiveness of activities such as: the management of disease outbreaks and food safety incidents, vaccination programmes, herd/flock husbandry, zoning/compartmentalisation, surveillance, early response and notification systems, animal movement controls, inspection, certification, fair
practices in trade and the utilisation of veterinary drugs, feed and pesticides at farm level.”

“There is a strong relationship between animal identification and the traceability of animals and products of animal origin.”
http://www.oie.int/eng/normes/mcode/en_chapitre_1.4.1.htm

With Canada’s current animal identification system and plans for a mandatory national traceability system including animal movement tracking by 2011 (Henuset, 2010), Canada has a much more formalized and advanced animal identification and forthcoming tracking system than the US. The US recently abandoned its voluntary National Animal Identification System (NAIS) which had very low producer participation rates. Going forward, in the US, only cattle that cross state lines will be subject to identification requirements. The protocols for US cattle ID are still being developed by individual states and are not yet established. Either way, the US does not currently have, nor is it currently planning to develop, national animal identification or animal movement tracking programs.

Australia’s animal traceability system is more advanced than Canada’s at this time, if for no other reason than they have a head start on Canada (Tonsor and Schroeder, 2006). Australia has in place a mandatory animal ID program, the National Livestock Identification System (NLIS) that was introduced in 1999. The current system tracks animal movements, even across properties of the same owner. As such, the system currently in place is an animal movement tracking system akin to what Canada is launching next year. New Zealand is at a similar animal ID and tracking phase as Canada with their new National Animal Identification and Tracing (NAIT) system set to be in place in mid 2011. New Zealand’s system will be a complete ID and movement tracking of animals from birth to post-mortem inspection at slaughter.

The status of animal identification and tracking is important to establish because it likely has more impact on export market access than does BSE testing. Animal traceability is more important than BSE testing because traceability addresses ability to conduct surveillance for, rapidly identify and control, and better manage all animal health (including zoonoses) or food safety concerns. In contrast, BSE testing is very narrowly focused and does not address general food safety. Furthermore, the dynamic aspect of Canada’s plan to enhance its animal traceability system may well impact potential value of BSE testing. With more advanced animal traceability, arguably BSE testing could realize reduced market value.

8.1.4 Import Country Considerations

In section 4 above, the issue of potentially expanding exports through BSE testing was discussed, with focus on Japan. Another noteworthy consideration is whether Japan is likely to preclude access of Canadian beef to Japanese markets under the guise that any imported product must meet the same standards of BSE testing in controlled risk
countries as Japan’s own domestic testing policy. To date this has not occurred and there is no basis for doing so under OIE standards, but if it did, potential benefits from BSE testing for that specific market become more apparent.

8.1.5 Existing Access in Key Markets

A related element to the above is existing market access in markets that could serve as targets for a BSE-tested product. These are summarized in Table 8.2 below. Australia and New Zealand have no non-tariff limits to Asian markets, but mostly supply a grass-fed product. In some of the target markets, Argentina and Brazil are faced with access limits driven by Foot and Mouth Disease (FMD). The US has access for product <30 months of age in Taiwan and South Korea, but no access into China.

Table 8.2 also presents the nature of testing and markets in the key import country markets of Japan, South Korea, China, and Taiwan. Japan, South Korea and Taiwan are controlled-risk status for BSE; the BSE status of China is unknown. Japan has a federal mandate to test all cattle over 20 months; individual prefectures can fund testing of cattle 20 months and under (almost all do). South Korea and Taiwan do surveillance monitoring of BSE. Japan and South Korea have cattle identification systems (MAF Biosecurity New Zealand, 2009).
## Table 8.2 BSE Status, Protocols, Production Systems, and Market Access in Major Beef Exporting and Importing Countries

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<td>Mostly grass-fed</td>
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<td>All beef &lt;21 mo</td>
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<td>Testing all &gt;20 months mandatory; ≤ 20 months by prefecture</td>
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* Resolution No. 18, OIE 78th General Session, May 2010
8.2 **Canadian Cattle and Beef Segment Situation**

This section of the report provides an overview of the trends and financial status of the cattle industry in Canada. The purpose of the section is to provide perspective on the overall condition and prospects for the industry.

### 8.2.1 Inventories and Production

Figure 8.2 shows the inventory of the Canadian beef cow herd over the past 15 years from 1996 through 2010.

![Figure 8.2: Canadian Beef Cows Inventory](image)

The following are important points from the graph:

- The herd peaked in 2005 at 5.3 million head.
- The 2003-2006 increase was due to BSE-induced border closure resulting in no cow exports to the United States.
- Beef cow numbers in 2010 declined by 4% compared to 2009 and by 15% compared to the peak year. The declining cow numbers in Canada are due to a variety of factors including diminished profitability, drought and demographics. The decline also reflects the above noted BSE-related inflation of the numbers. Prior to the border opening to cows in November 2007, Canadian ranchers kept cattle on the farm that normally would have been marketed. With the border opening, these numbers have been rapidly culled.
- The western herd comprises 85-90% of the Canadian total. Alberta is the largest province and accounts for 40%.
- The trend in inventory levels of steers, heifers and calves mirrors that of the cow herd.
Alberta has two thirds of the Canadian cattle on feed total. Ontario is second largest at 14%.

Figure 8.3 shows the trend in annual federally inspected cattle slaughter in Canada over the past ten years from 2000 through 2009.
As can be seen, the overall trend in cattle slaughter has been relatively stable between 3 to 3.5 million per year. The exceptions were the BSE years of 2003 through 2005. Slaughter was dramatically reduced in 2003 due to lack of markets while slaughter surged in 2004-2005 as packers increased capacity and were able to access the US market for beef.

Figure 8.4 shows the number of live cattle exported to the United States from Canada for 2000 to 2009. The immediate point of note of course was the reduction in volumes during the BSE years of 2003 through 2007 when the border was finally opened to over thirty month old cattle.
The other point of note is the reduction in volumes during 2009, mostly due to the US imposition of Country of Origin Labeling (COOL). COOL has a detrimental impact on US demand for Canadian livestock.

Figure 8.5 shows the annual beef supply and demand situation for Canada from 1980 through the end of 2009.

- Over the past four years, beef exports, not including live animals, comprised about 35-40% of total production while imports comprised 15%.
- Consumption (which includes imports) represents about 78% of total production.

The key points from the graph include the following:
- Consumption has been very stable.
- Exports rose dramatically during the mid-90’s to the BSE crisis in 2003. Exports have not recovered to pre-BSE levels. Exports are a very large proportion (35-40%) of beef production.
- The dramatic increase in exports coincides with the increased production over the same time period. The increased production was due to increased slaughter capacity with the entry of Cargill Foods to the Canadian market in 1989 and the increased capacity at Lakeside over the same time.

The underlying message derived from the trends in production and inventories is that post BSE, the industry appears to have settled into a period of stability.

8.2.2 Pricing and Financial Situation

Cattle prices have been mostly steady to lower during the post BSE years of 2007 through 2009. The steady to lower prices have coincided with the rapid appreciation of
the exchange rate during the 2003 through 2010 years. This appreciation has helped to pressure cattle prices in Canada lower. Figure 8.6 shows fed cattle prices in Alberta and the exchange rate on an annual basis from 2000 through 2009. The figure shows the steady to lower prices in addition to the appreciating exchange rate over the recent years.

Figure 8.6

In addition to the exchange rate impact on pricing, the industry has also faced the surge in feed costs, driven by the surging demand for grain in the ethanol industry. Figure 8.7 shows monthly Lethbridge barley prices from 2000 through mid-2010.

Figure 8.7
The soaring prices of 2007 and 2008 have eased but the average prices of 2009 and 2010 are still over 17% higher than the average of 2002 to 2006.

The rising grain costs and stable or declining cattle costs have had a predictable impact on the financial situation facing the industry.

Moreover, the cost of grain in western Canada relative to the US impacts the ability of Canadian feedlots to compete for feeder cattle. Since the early years of the last decade, the effective feed price spread between Alberta and the US High Plains has become more erratic, and the trend has been toward an increase in the price spread. This is shown below in Figure 8.8. This trend in the price spread is then reflected on Alberta feeder cattle export in Figure 8.9. While there are other factors than just the feed price spread that impact feeder cattle exports, a positive relationship is observed between the feed price spread and feeder cattle exports.

**Figure 8.8 Alberta Barley- Omaha Corn Price Spread, Standardized for 7% Protein Differential**
According to an analysis by Canfax, cow calf operators in western Canada have been in a loss position for the three years from 2007 through 2009. Those losses followed two years of profits after losses from 2002 through 2004. As a generalization it appears that western ranchers have been enduring a period of financial stress for much of the past eight years.

With regard to cattle feeders, again Canfax analysis can be used to determine the overall financial situation. In that regard, Canfax data suggests that cattle feeders were in a loss position from 2006 through 2009. The greatest financial stress for the industry occurred during the period of the rapid increase in grain prices during 2007 and 2008. During 2010, the industry has experienced a profitable first half of the year.

8.2.3 Herd Size and Prospects in the Coming Decade

The direction of the Canadian herd and production over the next five to ten years is dependent on profitability of ranchers, feeders and packers. With regard to the longer term, most of that profit potential is dependent upon domestic and international demand.
Most economic research into beef demand shows that income is one of the most, or the most important factor that drives demand. In that regard, economic forecasts are varied of course, but this current economic recovery seems shaky at best. Furthermore, in the United States, the jobless rate remains very high and consumers are wary for their jobs and are still watching their dollars. The US index of consumer confidence has been rising a little but it remains very low relative to prior to the recession. While Canadian unemployment and economy are stronger than in the US, overall North American conditions do not appear conducive to strong beef demand for the foreseeable future. It is doubtful that a stronger economy is going to drive strong beef demand during the first half of this decade.

In addition, most consumer surveys over the past year have said that consumers in North America are not going to shed their cost saving ways when the recession is over. They will remain cautious spenders.

The other strong component that drives beef demand is consumer perceptions. This broad driver can include preferences and taste as well as issues such as health and convenience. These factors can override income as they did during the late 1980’s and 1990’s. During that period, while the economy was growing, sometimes rapidly, beef demand was declining, sometimes rapidly. In that regard, there are reasons for concern. Negative health reports on beef of varying degrees of credibility continue to be published and widely quoted. They bring out health concerns that consumers continually hear. In addition, an aging population in North America tends to suggest that consumption per capita will wane. The ethnic mix going forward is also not likely to include a larger population of heavy beef eaters. Finally, there is little reason to suggest that consumers are going to be more familiar with factors such as beef preparation and usage. All in all, when considering income and preferences in the future it is prudent to think that domestic North American demand is likely to be steady at the very best.

International demand has the potential to be the strongest driver of the industry in this decade. As lesser developed countries urbanize and see their incomes grow, their preferences turn towards proteins. Looking to the future it is likely that lesser developed countries, as well as China, Russia and those in Southeast Asia will continue to see economic growth, sometimes strong. The Food and Agricultural Policy Research Institute sees global beef exports increasing at a rate of 3% each year for the next ten. That is the same rate of growth during the previous decade. In other words, it can be expected that global markets will provide some of the growth in demand that the North American industry needs.

Further to that, the issue of export market access for Canadian and US beef becomes even more apparent. BSE related restrictions as well as tariff and non-tariff barriers are significant challenges that the industry and government must tackle.

With the importance of exports noted, it also needs to be noted that only about 10% of North American beef production is exported. Even if that increases to 20% over the next decade, domestic demand remains the most important.
The next question then becomes what direction will Canadian production take in the coming decade. With regard to the ranchers, growth depends upon when prices improve profitability enough for producers to start retaining heifers and how fast they rebuild the cow herd. If we are only looking at modest recovery in demand over the next couple of years growth will be slower. That compares to the fast response that would have been caused by a sharp rebound in the economy, consumer demand and beef prices.

The other issue is that even with positive returns, how soon will beef producers start increasing the herd? Canadian producers have had a significant drain on their equity over the last 7 years that they will be looking to rebuild. In addition, availability of credit and individual producer finances will play a role in expansion decisions. In addition, in the US, even with positive returns prior to 2008, producers still culled their herds. There are clearly other factors involved in herd growth or contraction other than profits, at least in the US.

Based on demand expectations discussed above, the logical expectation is that the herd will stabilize in the next few years but continue to ease lower for the rest of the decade. If it does begin to grow again, it will be at a very slow pace. That growth or stabilization may start as early as next year, but again, it will not be the growth that the industry became familiar with during the 1990’s.

In the cattle feeding sector, the issue of tighter feeder supplies and grain prices are as always paramount. The feeding sector suffers from over capacity. The over capacity situation can be addressed by keeping most or all feeders in Canada. That of course comes at a cost in terms of a very strong, perhaps unsustainable basis. As herd numbers continue to decline and especially during any possible rebuilding, the supply situation will become increasingly difficult.

This means most importantly that feeders must have competitive feed supplies. By competitive, it means mostly a negative feeding basis. With regard to feed costs, the western advantage seen in the 90’s has become much more precarious. It is likely to become more variable in the next decade as Canada continues to peruse its ethanol policies. While it is true that the US market sets the overall price level on grains, it is the basis that matters most to a livestock feeding region. Canada’s aggressive ethanol policies relative to the US will eventually erase or at least shorten the time periods in which Canada has feeding advantages. In addition, the ongoing lag in prairie barley yields relative to US corn yield gains is going to work against Canada.

The feeder and grain basis issue points to the fact that there is likely to be a noticeable rationalization in feedlot capacity in Canada. The fact that the industry has bled equity for the past few years only makes that more certain.

At the packer level in the west, there is likely going to continue to be enough cattle to keep the big two sustained for the next decade. Despite the best intentions and hopes of cattle feeders, there are not enough cattle for another major packer. In the east, the
situation in Ontario is going to be precarious. Ontario gets about a quarter of its fed cattle supplies from Quebec. Even with the modest proposed changes to the ASRA program there, it should tighten Quebec numbers. Furthermore, Ontario is more hard hit on ethanol than the west. That in turn will hurt the feeding industry accordingly. Assuming Cargill decides to stay in Ontario that will put added pressure on smaller packers in the province.

8.2.4 Summary

The bottom line for the Canadian cattle and beef industry in the coming decade is that it will likely see overall inventory numbers stabilize in the next few years but continue to ease lower for the rest of the decade. If it does begin to grow again, it will be at a very slow pace relative to what the industry had become familiar with prior to BSE. The cattle feeding sector will likely endure a period of consolidation into even larger hands as supplies continue to tighten and capacity challenges force rationalization. The packing sector will see relative stability as the two large packers face tighter but still adequate supplies.

8.3 Observations

The above suggests the following. First, Canada is among the smallest of the significant beef exporting countries. Canada currently sits with about 6-7% export market share while larger exporters have a much larger presence; Brazil has about 25% market share, Australia 18%, and the US about 12%. In Asian markets such as Japan, Canada’s effective competitors are Australia and New Zealand supplying mostly a grass-fed product, and the US supplying a grain-fed product. South American competitors are faced with access issues relating to FMD.

Among the major exporters, none currently test for BSE beyond surveillance measures. Australia and New Zealand have livestock identification systems in place, but the other major exporters do not. It is not expected that the other major exporters will begin testing for BSE apart from surveillance because they are either negligible risk for BSE- a status which they would risk losing if testing uncovered a positive case- or lack a livestock identification system to manage the process which would take several years to implement.

Thus, it is unlikely that a BSE-tested Canadian product would be met by reciprocal BSE testing from competitors in the Asian markets explored above. Rather, as a grain-fed product with some preferable attributes compared with grass-fed, if testing Canadian product could improve market access, it is reasonable to expect that market share could be increased, particularly at the expense of grass-fed product5. It is not evident that competitors have an obvious competitive response to Canadian testing.

5 In the CBEF Beef Quality Perceptions Audit (2006) US and Canadian product (grain fed) was rated above Australian product (mostly grass-fed) and well above New Zealand (grass-fed) product in taste, texture, and tenderness. The audit further showed that beef with a corn or barley finish was preferred to a grass-finish, regardless of country of origin.
9. Conclusions

The purpose of this study was to evaluate the costs and benefits of voluntary testing of cattle for BSE. To that end, the following were undertaken:

- The veterinary epidemiology literature on BSE was reviewed
- Selected agricultural economics literature on BSE was reviewed
- A survey of industry participants was conducted to evaluate demand for a BSE-tested product
- The cost of implementing BSE testing using post mortem and ante mortem testing procedures was estimated
- Consumer research was conducted in Canada to evaluate the demand for BSE-tested product
- The policy and regulatory context for a BSE test was reviewed
- An overview of the strategic context for a BSE test was developed

9.1 Results

The results showed the following. First, given the scope of Canadian SRM removal and the age at which fed cattle are slaughtered, post mortem BSE testing is extraordinarily unlikely to identify positive animals or indicate progress toward BSE eradication. Its value is essentially determined by the preferences of customers for, and value assigned to, tested product. The ante mortem test has uncertain prospects, as only one of the approaches appears to be close to commercial reality, and practically speaking this could easily take five years to reach the Canadian market. It is similarly unclear whether live BSE tests in development could detect positive BSE cases in younger cattle than the existing post mortem tests.

Secondly, the agricultural economics literature suggests that the US and Canada are less inclined to pay for BSE testing in comparison with certain other countries like Japan. BSE testing is not seen as a panacea in the literature— it is not a market access opener by itself, and it is not the only way of enhancing safety in the system as there are other approaches such as tracking and tracing.

Third, Canadian processors and exporters are not broadly seeing requests for BSE-tested product. Nonetheless, a major Japanese importer has directly requested it, and a senior meat trader knowledgeable with the Japanese market saw BSE testing as a potentially effective strategy to exploit Canada’s niche in Asian markets. An Alberta processing plant no longer in operation had documented requests from Japanese customers for tested product, and had budgeted a $75/head margin from testing. Thus, while Canadian processors and exporters were somewhat ambivalent, information from meat traders familiar with the Japanese market was supportive of customer interest in a tested product, but indicated that it will require marketing effort and development as importers are unlikely to take the lead.
Fourth, BSE testing under a voluntary test expected to be relatively low cost. With regard to the post mortem test, the anticipated cost is just over $40/head, or about 5¢/lb carcass weight, comprised almost entirely of the direct cost of implementing the test; adjustments in slaughter plant and rendering engineering/operations are relatively minor. For the prospective ante mortem test, the expected cost is $15/head with the dominant proportion of the cost associated with veterinary oversight of sample collection.

Fifth, Canadian consumers indicated some willingness to purchase a beef product that had been tested for BSE, but BSE testing is not viewed as “trumping” other aspects of a beef product; there remained a clear tradeoff between BSE testing and other product attributes, notably freshness and price. Labeling of beef products that had been tested for BSE did appear to confuse some perceptions regarding the safety of Canadian beef, as about 20% of consumers appeared to have a less positive perception regarding the safety of Canadian beef when product labeled tested was available. Conversely when exported product was tested but domestic product was not, only about 13% perceived untested domestic product as less safe than tested exports. Price premiums for tested product observed were up to 50%.

Sixth, CFIA has extensive approval authority in regards to a BSE test, as well as extensive discretion regarding how that authority is used. Current CFIA thinking is not supportive to a test; it is quite conservative in nature. Any proponents of a voluntary BSE test should expect resistance from CFIA in approvals of the test and/or product marketed based upon it. The Alberta government appears also to have a fairly conservative view on the merits of BSE testing.

Finally, Canada is among the smallest of the significant beef exporting countries. Among the major exporters, none currently test for BSE beyond surveillance measures. Australia and New Zealand have livestock identification systems in place, but the other major exporters do not. It is not expected that the other major exporters will begin testing for BSE apart from surveillance because they are either negligible risk for BSE, or lack a livestock identification system to manage the process. In most Asian markets, Canada’s effective competitors are Australia and New Zealand supplying grass-fed product, and the US supplying grain-fed product; South American competitors are faced with access issues relating to FMD. Meanwhile, the Canadian cow herd is in structural decline, but the Canadian cattle slaughter has remained relatively constant. This has occurred as the segments of the cattle industry have been reeling from losses due to a structurally stronger Canadian currency and feed costs that are structurally higher than that in the US.
9.2 **Synthesis**

The basic economic criteria that apply in determining the allowance of a BSE test are:

1. What benefit might be expected from BSE testing?
2. What adverse market impacts might result from BSE testing?
3. What are the costs of implementing BSE testing?

**Prospective Benefits**

With regard to the first criterion, the economic results observed in this study are supportive of a latent export market for tested product. The evidence supporting this is somewhat anecdotal by nature, but includes written testament by would-be Japanese buyers to an Alberta processor, as well as presentations and appeals made by Japanese meat importers.

This market potential would be as a niche, and the nature of these markets is such that the potential that may exist for tested product will need to be developed proactively; it is unlikely to be motivated nor developed by importers themselves. Thus, a latent market benefit to a BSE-tested product is envisioned.

More work is required to understand the nature and potential size of benefits associated with BSE testing in assisting market access, because it is a prospective benefit. However for the purposes of context, prior to the BSE case in 2003, Canada exported almost 23,971 tonnes of beef to Japan in 2002, compared with 10,689 tonnes in 2009 (CBEF). The value of Canadian beef exports to Japan in 2009 was $59.2 million, or about $5534/tonne. Thus, at current unit values, if BSE testing could create increased exports to Japan that restored 2002 levels, the implied increase in export sales value would be about $73.6 million. Alternatively, drawing from the 2005 Rancher’s Beef analysis in Appendix C, the anticipated benefit based on price differential by beef cut across a range of cuts selectively marketed to the US amounts to about $109/head.

**Potential Adverse Impacts**

A range of considerations arise in terms of potential adverse market impacts:

- Testing works against Canada’s position that trade rules be science-based

As discussed above, BSE testing is counter to Canada’s position that trade rules be based on science. The implication of this issue depends somewhat on approach. If it is viewed as marketing based on customer preference rather than abandoning a scientific perspective, it is unclear that this is a significant issue nor that it sets an ominous precedent. Prior examples include a willingness on behalf of Canada to adopt hormone-free protocols for beef exported to the EU, and a willingness to segregate certain GM-free grains.

- Consumers perceive non-tested product as unsafe
Consumer perceptions of hypothetical scenarios regarding BSE testing were analyzed in this study, and it was observed that a core committed subset of Canadians perceived beef as less safe if it was not tested in the presence of other product that is tested; this is consistent with previous studies suggesting that Canadians and Americans demonstrate little interest in tested product. The presence of a BSE tested export product would not appear to significantly cannibalize the domestic market for non-tested product, as 70% of respondents perceived untested beef in Canada as no less safe and perceived that tested exports are either safer or no less safe; only 13% perceived non-tested product available in Canada as less safe and tested exports to be safer.

However, the risk of potential domestic consumer pushback of allowing testing for export marketing purposes suggests caution and would require close monitoring and excellent communications, as it begs some questions: why only test for export? Why not test beef over thirty months of age? There is the possibility that major customers might lead consumers by requesting BSE testing in their supply chain before their customers do.

- No premiums associated with BSE testing

The detailed analysis done by Rancher’s Beef suggests that, for a range of cuts preferred in Japan, prices are higher than in Canada. The Japanese market is known to be a good market which is underserved by grain-fed beef. At this point, beef is not labeled as tested but labeling was common until about 2007; it is unclear whether a Canadian BSE tested product could or would be labeled. The anticipation here is that Canadian tested beef could be well positioned to take market share from grass-fed beef in the Japanese market. According to the USDA Foreign Agricultural Service, Japanese beef consumption in 2010 was about 1.2 million metric tonnes; with Canadian exports to Japan currently at about 10,000 tonnes, even if Canadian exports sharply increased it should not be expected to materially affect prices in Japan.

- CFIA is not supportive of testing

CFIA has taken a very conservative position relative to testing, and Canadian proponents of voluntary BSE testing would need to engage the CFIA on this. It is ultimately the responsibility of a regulator to protect the public interest; up to this point CFIA has viewed this as minimizing the prospect of positive cases and promoting the benefits of Canada’s enhanced feed ban.

If it is indeed the case that testing could create significant benefit at low risk and low cost, this analysis should be presented to CFIA and advocated as being in the public interest; at a minimum, it must be acknowledged by the CFIA that the current situation itself constitutes risk in terms of lost market opportunity and associated revenue impacts.
A Cost-Benefit Analysis of Voluntary BSE Testing of Cattle

- Trade risks

The principal risk associated with voluntary testing from a trade perspective is that it results in more positive cases being observed. This risk is understood to be very low in UTM cattle. However, if this occurred it would diminish Canada’s reputation and prolong its “controlled risk” status. At the same time, there is a trade risk associated with not testing, as the prospect of enhanced market access to the Japanese market, and perhaps other export markets, is currently uncertain - BSE testing presents the prospect of facilitating enhanced access.

Costs of Testing

The costs associated with implementing a BSE test are relatively low. Based on assumptions regarding the decrease in costs of testing kits as the scale of testing expands and on required changes in plant operations, the post mortem test is expected to cost just over $40/head. A prospective ante mortem test is expected to cost about $15/head based on the expectations of one of the test developers and assumptions regarding the costs of a veterinarian to collect the samples at the farm.

Thus, the basic economic criteria for approval of a new product cited above place some context around the question of allowing a voluntary test. The most tangible is the testing cost of $40/head. The benefits are prospective; Ranchers Beef contemplated a benefit of over $100/head, and given the size of the Japanese market there appears significant room for growth. The least certain element is the prospect of allowing testing to adversely impact demand; the Canadian consumer results suggest little risk, but it is acknowledged that this is a complex element, and would need to be handled carefully.

On balance, the economic criteria would appear to be satisfied for voluntary testing for BSE. However, to be fully understood, this must be placed in the strategic context faced by the Canadian cattle and beef industry.

9.3 Strategic Considerations

The findings above show that, for beef from fed cattle that provides the source of export product, a BSE test presents very little chance of finding positive BSE cases using current technology. At the typical age of slaughter cattle in Canada and given Canada’s SRM rules and enhanced feed ban, a BSE test is extraordinarily unlikely to find a positive. Thus, a science basis for using such a test is lacking and it can only be of benefit in terms of marketing. Moreover, formal market access agreements between governments have not included BSE testing as an element of market access. Its potential value thus lies as a commercial proposition that could act as a private marketing tool to enhance the benefit of formal market access agreements, with the prospect that positive results in the commercial trade could improve the prospect of future increases in formal market access rules.
Secondly, Canada’s interest in beef trade is somewhat unique among major beef exporting countries. Compared with the US, Canada is much more dependent upon beef exports so its motivation to obtain market access is more urgent. At the same time, in the context of any of the export markets in which a high degree of BSE awareness exists, Canada is a niche supplier given its available volume. Canada’s beef is grain-fed, which differs from most of its major competitors that are grass-fed, with the exception of the US. Other countries also either lack a cattle identification system, or are very unlikely to adopt BSE testing of their own because they currently have negligible risk status for BSE and would not want to risk losing that status.

Canada’s beef industry is around 1/10th the size of the US, so Canada’s export volume is much lower than the US even though exports are much more important to Canada on a relative basis. Canada also offers some attributes that are distinctly different than the US which can have value in markets where BSE awareness is high (expanded SRM definition, enhanced feed ban, livestock identification). Producing these attributes in Canadian beef comes at a cost compared with the US, so compared with the US, Canada is at some cost disadvantage relating to these attributes as well as to feed.

Third, the primary market for a BSE-tested product is Asian, with the focus of analysis here on Japan. Consumer research in Canada reveals awareness of BSE and willingness to purchase tested product, but taste and freshness consistently rates as a higher priority among consumers than BSE testing. It is not evident that tested product would weaken or destroy demand for non-tested beef in Asian export markets as beef markets currently exist with a mix of domestic tested product and imported non-tested product; product is no longer labeled as tested in Japan. There are risks to domestic beef demand associated with testing of exports, but these appear manageable as only about 13% of respondents perceived untested domestic product as less safe, and tested exports as more safe.

With regard to regulatory approval, the greatest barriers exist in domestic marketing. CFIA must approve both a BSE test and a label on the domestic meat product, and the current view of CFIA is not supportive of approval of either. With regard to Asian export product, the requirement of pre-market label approval CFIA is not an issue; the regulatory issue is approval and use of the test.

In order for implementation of a voluntary test to occur, CFIA would need to approve the test and its use in export product; the latter component would require an equivalency agreement with the importing country. For a *post mortem* testing regime, the equivalency agreement would not seem onerous if CFIA were supportive as (a) Canada has already approved a test, (b) some export markets, notably Japan, already test, and (c) the *de facto* international validity standard is an established European standard. With regard to an *ante mortem* test a similar process would apply– the apparent standard is European, and both CFIA and the importing country agency would need to be satisfied that a prospective test met this standard, and then draft an equivalency agreement permitting the test. A potential irritant in this process is that some of the target markets that have employed a mandatory BSE test have signaled that they wish to abandon mandatory
testing, at least at specific age groups. If this were the case these countries might choose not to recognize the validity of a Canadian test and not sign an equivalency agreement.

Finally, the implicit assumption is that a prospective ante mortem test, and/or future post mortem tests, would have equivalent sensitivity and specificity to the existing test. However, future tests may use different mechanisms and modes of action and be capable of detection at younger ages; this is currently unclear. However, in the future, it is conceivable that a BSE test for slaughter age animals might be capable of identifying infected individuals. The risk of detecting a positive would thus fall solely on the integrity of Canada’s preventative measures—SRM removal/disposal, enhanced feed ban, etc. Given the observation of a classical BSE case discovered in February, 2010 this prospect should be approached with caution. Conversely, if Canada were to be subject to future BSE cases, having systems geared to the use of an internationally recognized ante mortem test for BSE would expedite the drive for market re-entry and sustain consumer confidence.

9.4 Conclusions

The results of this study are consistent with an economic benefit from allowing a voluntary test for BSE, with requisite caution. The target market for the tested product is Asian (with a focus here on Japan), it is by nature a market niche, and its development will require initiative and effort on behalf of Canadian beef marketers; importers are unlikely to provide the initiative even though some have directly asked for it. As with the roll out of any new product, due diligence is required and, as such, more formal market research is warranted in Asian target markets prior to proceeding. The basis for doing so appears well founded.

Under post mortem testing technology, the costs of implementing testing appear surprisingly low, contingent on a low prevalence of positive cases. It is also evident that the presence of a BSE tested product would not cannibalize the market for non-tested product.

Ante mortem testing presents less certain prospects. While it is expected to be less costly to implement, future ante mortem test might have a greater ability to identify positive cases at a younger age, running the risk of identifying positive cases in slaughter age cattle. As such, rather than reducing the dependence on Canada’s SRM controls and feed ban, use of a future ante mortem test could rely more heavily upon its integrity. At this point, it is unclear whether an ante mortem test would identify positives at younger ages than the post mortem test, and it appears that a workable ante mortem test is still years away. Conversely, it must be acknowledged that if Canada were to be subject to new cases of BSE in the future, an ante mortem test could serve as a powerful marketing tool.
References


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A Cost-Benefit Analysis of Voluntary BSE Testing of Cattle


A Cost-Benefit Analysis of Voluntary BSE Testing of Cattle


Schwermer H, de Koeijer A, Brulisauer F, Heim D. Comparison of the historic recycling risk for BSE in three european countries by calculating the basic reproduction ratio R0. Risk Anal. 2007;27:1169-1178.


Appendix A

This appendix provides the detailed analysis of Canadian consumer reaction to BSE testing, BSE tested beef, and valuation of BSE tested beef using data from a nationally representative consumer survey (n~1,000). This survey data includes responses to questions that elicit consumer attitudes, perceptions and beliefs towards beef in general, and Canadian beef in particular, and beef consumption behaviours (to help identify different segments of the market). The sections that follow include: a description of the survey proper and its development; a descriptive summary of socio-economic and demographic aspects of the respondents; a summary of responses to key questions; discussion of results of a discrete choice experiment and calculation of consumer willingness to pay (WTP) for beef that has been tested for BSE.

1. Development and Implementation of the Consumer Survey

Broadly speaking, the survey built on a previously published paper by McClusky et al. (2005) that explored Japanese consumers’ WTP for beef that has been tested for BSE. Our survey proper was developed by several members of the research team, with assistance of personnel from Ipsos Reid LP, a professional marketing research company hired to assist with survey development and implementation. The survey contained five sections containing questions related to: screening for eligibility; household beef consumption; food safety; consumer awareness and perceptions of BSE; contingent valuation/WTP; and respondent socio-economic and demographic characteristics (a copy of the survey is included in Appendix A).

Ipsos Reid’s Canadian online consumer panel was used as the sample frame. The target sample size was 1,000 English-speaking Canadians. The decision to exclude French-speaking Canadians was made in light of resource constraints and the time needed to back translate the survey. Because we focused only on English-speaking residents of Canada, and potential difficulty in obtaining responses from English-speakers in Quebec, we did not include Quebec in the sample frame. As well, northern regions of Canada (i.e. Yukon, Northwest Territories, and Nunavut) were excluded. Nevertheless, the sample was stratified by province, with provincial quotas based on each province’s share of the population of Canadians in the eligible provinces.

Screening questions were included to select subjects who met our eligibility requirements. Eligible subjects were required to: be 18 years of age or older; be a resident of British Columbia, Alberta, Saskatchewan, Manitoba, Ontario or Atlantic Canada; not employed on TV/radio/press/newspaper/magazine, ad agency/public relations or marketing research/marketing; be the primary grocer shopper in the home (or shares this responsibility); and have consumed beef sometime in the last six weeks.

The invitation to potential respondents was emailed to members of the Ipsos panel on 12 May 2010. All the provincial cell quotas were filled by 18 May 2010. In total, 1,008 complete responses were submitted.
Analysis and Results

Table 1 shows the mean and standard deviation of demographic and socio-economic questions. Because the target population was those who are the primary grocery shopper for the home (or those who share in this responsibility), it is difficult to find comparable statistics for the population. However, we can compare our sample to the overall Canadian population. To this end, the last column of Table 6.1 shows mean values of various demographic and socio-economic variables drawn from the 2006 Census of Canada.

Table 1 Mean and standard deviation of demographic and socio-economic information from the surveyed sample of Canadian residents (n=1,008).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean</th>
<th>Std. Dev.</th>
<th>Canada^a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>13.19%</td>
<td>33.86%</td>
<td>49%</td>
</tr>
<tr>
<td>Age (in years)</td>
<td>49.75</td>
<td>14.55</td>
<td>39.5^b</td>
</tr>
<tr>
<td>Children in the home</td>
<td>33.43%</td>
<td>47.20%</td>
<td>Not available</td>
</tr>
</tbody>
</table>

Highest level of education attained by respondent:

<table>
<thead>
<tr>
<th>Level</th>
<th>Mean</th>
<th>Std. Dev.</th>
<th>Canada</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesshigh (less than high school)</td>
<td>6.55%</td>
<td>24.75%</td>
<td>23.76%</td>
</tr>
<tr>
<td>Highschl (high school diploma)</td>
<td>46.43%</td>
<td>49.90%</td>
<td>25.54%</td>
</tr>
<tr>
<td>College (college diploma)</td>
<td>34.72%</td>
<td>47.63%</td>
<td>32.56%</td>
</tr>
<tr>
<td>Univdgre (undergrad degree)</td>
<td>10.02%</td>
<td>30.04%</td>
<td>11.62%</td>
</tr>
<tr>
<td>Postgrad (post-grad degree)</td>
<td>2.28%</td>
<td>14.94%</td>
<td>6.52%</td>
</tr>
</tbody>
</table>

Household income in 2009:

<table>
<thead>
<tr>
<th>Income Level</th>
<th>Mean</th>
<th>Std. Dev.</th>
<th>Canada</th>
</tr>
</thead>
<tbody>
<tr>
<td>incu25 (under $25,000)</td>
<td>17.56%</td>
<td>38.07%</td>
<td>20.33%</td>
</tr>
<tr>
<td>inc2549 ($25,000-$49,999)</td>
<td>26.69%</td>
<td>44.25%</td>
<td>21.51%</td>
</tr>
<tr>
<td>inc4570 ($45,000-$69,999)</td>
<td>23.02%</td>
<td>42.11%</td>
<td>21.50%</td>
</tr>
<tr>
<td>inc7099 ($70,000-$99,999)</td>
<td>18.06%</td>
<td>38.48%</td>
<td>17.30%</td>
</tr>
<tr>
<td>inc100p ($100,000 or higher)</td>
<td>14.68%</td>
<td>35.41%</td>
<td>19.36%</td>
</tr>
</tbody>
</table>

Province of residence:

<table>
<thead>
<tr>
<th>Province of Residence</th>
<th>Mean</th>
<th>Std. Dev.</th>
<th>Canada</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atlantic Canada</td>
<td>9.42%</td>
<td>29.23%</td>
<td>9.53%</td>
</tr>
<tr>
<td>Ontario</td>
<td>51.09%</td>
<td>50.01%</td>
<td>50.74%</td>
</tr>
<tr>
<td>Man/Sask.</td>
<td>9.03%</td>
<td>28.67%</td>
<td>8.83%</td>
</tr>
<tr>
<td>Alberta</td>
<td>13.49%</td>
<td>34.18%</td>
<td>13.73%</td>
</tr>
<tr>
<td>British Columbia</td>
<td>16.96%</td>
<td>37.55%</td>
<td>17.16%</td>
</tr>
</tbody>
</table>

^a. Based on the 2006 Census of Canadians  
b. Median age

Our sample does an adequate job of capturing those with a high school education (highschl) or less (lesshigh), a college degree or certificate (including trades) (college), as well as those who have achieved a university undergraduate degree (univdgre). However, compared to the general population of Canadians, the sample has a lower proportion of those with a post-graduate degree (postgrad).

Compared to the Canadian population in 2006, the sample has a slightly lower proportion of those whose household income was under $25,000 (incu25) in 2009, but a higher proportion with income between $25,000 and $44,999 (inc2549). As well, the sample
has a lower proportion of households with income exceeding $100,000 compared to the national average (inc100p).

Given the stratified sample plan focused on percent of population in the provinces from which we recruited, the breakdown of sample by provinces closely follows the national breakdown. Taken together, the breakdown of the sample by demographic and socio-economic dimensions closely follows the Canadian population as a whole.

Our sample does an adequate job of capturing those with a high school education (highschl) or less (lesshigh), a college degree or certificate (including trades) (college), as well as those who have achieved a university undergraduate degree (univdgre). However, compared to the general population of Canadians, the sample has a lower proportion of those with a post-graduate degree (postgrad).

Compared to the Canadian population in 2006, the sample has a slightly lower proportion of those whose household income was under $25,000 (incu25) in 2009, but a higher proportion with income between $25,000 and $44,999 (inc2549). As well, the sample has a lower proportion of households with income exceeding $100,000 compared to the national average (inc100p).

3. **Beef consumption patterns**

To help contextualize responses to the choice question, the survey asked respondents several questions designed to understand household beef consumption patterns. To this end, respondents were first asked to indicate frequency of the consumption of beef or beef containing food products either in the home or away from the home. On balance, respondents indicated a high frequency of beef consumption (see Figure 1); most noticeable is that over 80 per cent of respondents reported eating beef (in some form) at least once a week.
Respondents also indicated that steaks, ground beef and roasts were their most favourite beef products, while processed beef products (such as pre-formed hamburgers or meatballs, etc) ranked lower. When asked where they usually purchase beef for consumption in the home, over 75 per cent indicated large grocery chain, followed by butcher shops (26 per cent), discount grocery stores (25 per cent), warehouse clubs (21 per cent) and farmer’s markets (16 per cent). (Note that this was a “please select all that apply” so these per cents will add to more than 100).

Respondents were asked two questions designed to capture the factors that are relevant to them while making a beef purchase. The first question asked respondents to indicate how concerned they are about nine different aspects of beef and beef production (these are shown in Table 2) using a modified Likert scale. This Likert scale ranged from not at all concerned (given a score of one) to very concerned (given a score of five). Given the ordinal nature of these rating, and the broad dimensions covered by the items in this question, exploratory factor analysis using principle component extraction was used to explore the underlying factors of concern to respondents when making a beef purchase decision.

The Kaiser-Meyer-Olkin (KMO) statistic gauges whether the items included in factor analysis have a significant degree of correlation, and hence will factor well. A KMO over 0.7 is used as a threshold to gauge this sample adequacy. The KMO for the nine items included in this factor analysis equalled 0.895, indicating a high degree of correlation between responses to these items.
Using principle component extraction resulted in two factors having eigen values greater than one. This means these two factors explain more variance in the responses than any single variable that was included in the factor analysis. Because the key aim of factor analysis is to reduce the dimensionality of the items being analyzed, these eigen values tell us which factors should be retained and used to capture the underlying latent structure. Moreover, the other factors (with eigenvalues less than one) should not be retained, as they explain less variance on responses than any single variable included in the analysis.

Table 2 shows the nine items included in the factor analysis, as well as the factor loadings associated with each item in the two retained factors. Factor loadings are useful because they show the correlation between the responses to the item and the factor that has been extracted from the data; the higher the factor loading, the higher the correlation between that item and the extracted factor. As such, the factor loadings are used to aid in identifying the latent dimension the factor represents. Note too that when using exploratory factor analysis, it is common to only include items with factor loadings above 0.5 – a rule of thumb that is applied here.

Table 2 Results from exploratory factor analysis on items respondents consider when purchasing beef (n=1,008).

<table>
<thead>
<tr>
<th>Item</th>
<th>Factor 1 (Non-price factors)</th>
<th>Factor 2 (Price factor)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whether antibiotics are used during the raising of beef cattle</td>
<td>0.8697</td>
<td>0.1028</td>
</tr>
<tr>
<td>Whether hormones are used during the raising the beef cattle</td>
<td>0.8545</td>
<td>0.1055</td>
</tr>
<tr>
<td>Whether beef is from cattle which have been raised using enhanced animal welfare production methods</td>
<td>0.8365</td>
<td>0.1666</td>
</tr>
<tr>
<td>Whether beef is from cattle which have been produced using certified organic production methods</td>
<td>0.8129</td>
<td>0.0636</td>
</tr>
<tr>
<td>Whether beef is from cattle which are raised locally (i.e. within 100 kilometers of where I live)</td>
<td>0.6955</td>
<td>0.0863</td>
</tr>
<tr>
<td>Risk of exposure to food borne contamination</td>
<td>0.6281</td>
<td>0.4611</td>
</tr>
<tr>
<td>Risk of exposure to mad cow disease/BSE</td>
<td>0.5667</td>
<td>0.4476</td>
</tr>
<tr>
<td>The price I pay for beef at retail</td>
<td>0.0063</td>
<td>0.8828</td>
</tr>
<tr>
<td>Cholesterol and fat</td>
<td>0.4844</td>
<td>0.4392</td>
</tr>
<tr>
<td>Percent variation</td>
<td>52.4</td>
<td>11.2</td>
</tr>
<tr>
<td>Cronbach Alpha</td>
<td>0.892</td>
<td>Not calculated</td>
</tr>
<tr>
<td>Mean score</td>
<td>3.759</td>
<td>4.095</td>
</tr>
</tbody>
</table>

The factors loadings used to identify the dimension represented by each factor are included in bold in Table 2. Note that since the item “Cholesterol and fat” has a low factor loading in both retained factors, it is not included in either factor. Nevertheless, the first retained factor has heavily loadings on items related to production practices and food safety issues, while the second retained factor only has one item with a large factor loading (on “The price I pay for beef at retail”). As such, the first factor (which accounts for 52 per cent of the variation in responses) is named “Non-price factors”, while the
second factor (which accounts for 11 per cent of the variation in responses) is named “Price factor”.

The Cronbach alpha (which measures the reliability of a multi-item factor) for the non-price factors is 0.892, indicating a high degree of reliability for this factor; since the price factor only includes one item the Cronbach alpha cannot be calculated. Lastly, the mean value of the items in the non-price factor is 3.759, while the mean value of the price factor is 4.095; thus, when buying beef, respondents have a higher level of concern over the price they pay at retail than the non-price factors.

Respondents were also asked to rate the importance of seven different attributes they might consider when purchasing beef. The rating was undertaken by asking respondents to assign a total of 100 points to the seven attributes, with more points assigned to more important attributes and fewer points to attributes of lesser importance. Table 3 shows the ordinal ranking of these attributes, as well as the mean score for each. The three highest ranked products, across our entire sample, were freshness, price and region or country of origin. Interestingly, attributes most often associated with taste/sensory aspects (i.e. fat cover and marbeling) ranked in the bottom three

Table 3 Ranking of attributes by average importance score (n=1,008).

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Mean score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freshness</td>
<td>28.19</td>
</tr>
<tr>
<td>Price</td>
<td>20.78</td>
</tr>
<tr>
<td>Region or country of origin</td>
<td>12.04</td>
</tr>
<tr>
<td>Colour</td>
<td>11.70</td>
</tr>
<tr>
<td>External fat cover (fat which can be trimmed before preparation)</td>
<td>9.57</td>
</tr>
<tr>
<td>Premium brand (such as Certified Angus Beef)</td>
<td>9.44</td>
</tr>
<tr>
<td>Marbling</td>
<td>8.28</td>
</tr>
</tbody>
</table>

4. Perceptions of safety

To help understand BSE in the context of overall food safety, respondents were asked a set of questions designed to gauge impressions of food safety in Canada, as well as perceptions of the safety of various meat products produced in Canada. Figure 2 shows the breakdown of responses to the question “Overall, how do you feel about the safety of food produced in Canada?” On balance, the lion’s share (over 90 per cent) of respondents indicated they feel food produced in Canada is at least somewhat safe (i.e. somewhat safe or very safe). Such a high percentage of “at least somewhat safe” has been shown elsewhere (i.e. Asideu 2008) and is not unusual for Canada.
More interesting, however, is the breakdown (both frequency and per cent) of perceptions of the safety of different meats produced in Canada (see Table 4). Respondents have a very positive perception of the safety of meats produced in Canada; at least 40 per cent of respondents believe pork, beef and chicken produced in Canada are very safe. Moreover, upwards of 90 per cent of respondents feel these three meats are at least somewhat safe. Importantly for this project, beef was ranked as very safe by 50 per cent of respondents.

Table 4 Breakdown of perceptions of the safety of various types of meats produced in Canada (n=1008).

<table>
<thead>
<tr>
<th></th>
<th>Pork</th>
<th>Beef</th>
<th>Lamb</th>
<th>Chicken</th>
<th>Fish</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very safe</td>
<td>442</td>
<td>500</td>
<td>325</td>
<td>424</td>
<td>375</td>
</tr>
<tr>
<td>(44%)</td>
<td>(50%)</td>
<td>(32%)</td>
<td>(42%)</td>
<td>(37%)</td>
<td></td>
</tr>
<tr>
<td>Somewhat safe</td>
<td>454</td>
<td>457</td>
<td>324</td>
<td>502</td>
<td>452</td>
</tr>
<tr>
<td>(45%)</td>
<td>(45%)</td>
<td>(32%)</td>
<td>(50%)</td>
<td>(45%)</td>
<td></td>
</tr>
<tr>
<td>Somewhat unsafe</td>
<td>55</td>
<td>32</td>
<td>35</td>
<td>57</td>
<td>78</td>
</tr>
<tr>
<td>(5%)</td>
<td>(3%)</td>
<td>(3%)</td>
<td>(6%)</td>
<td>(8%)</td>
<td></td>
</tr>
<tr>
<td>Very unsafe</td>
<td>19</td>
<td>8</td>
<td>2</td>
<td>13</td>
<td>16</td>
</tr>
<tr>
<td>(2%)</td>
<td>(1%)</td>
<td>(&lt;1%)</td>
<td>(1%)</td>
<td>(2%)</td>
<td></td>
</tr>
<tr>
<td>Don’t know</td>
<td>38</td>
<td>11</td>
<td>322</td>
<td>12</td>
<td>87</td>
</tr>
<tr>
<td>(4%)</td>
<td>(1%)</td>
<td>(32%)</td>
<td>(1%)</td>
<td>(9%)</td>
<td></td>
</tr>
</tbody>
</table>

Figure 3 shows frequency of responses to the question “If a food safety problem was to occur, where do you think the problem is most likely to develop?” What is clear is that consumers surveyed for this study have a strong view of where food safety incidents arise – specifically, during food processing. It is important to point out, however, various
food recalls that received wide spread public attention and were pinpointed to have arisen during processing (such as the 2008 recall of Listeria contaminated ready-to-eat meats) may overshadow perceptions than would otherwise be borne out by such a question. It is also important to note that the question is not about exposure to a food borne pathogen, which often occurs as a result of poor food handling practices in the home. Rather the question concerns larger scale food safety problems.

Figure 3 Frequency of responses to the question “If a food safety problem was to occur, where do you think the problem is most likely to develop?” (n=1,008)

Respondents were asked to self-rate their own knowledge of food safety practices occurring between the farm level and the final consumer. A four-point response scale was used to rate own knowledge (response options were: a lot; some; not much; nothing at all). As one might expect, self-rated knowledge of food safety practices is very low for levels of the market that are further from the final consumer (see Table 5); for instance, over 50 per cent of respondents indicated they know “nothing at all” or “not much” about food safety practices on the farm. However, the closer one moves to the final consumer, the greater the percentage of respondents who selected the knowledge response option “a lot” or “some”. Nevertheless, it is important to note that respondent’s self-rated knowledge may not align with knowledge that is, in fact, accurate and correct.
Table 5 Break down of self-rated knowledge of food safety practices along the food supply chain (n=1008).

<table>
<thead>
<tr>
<th>A lot</th>
<th>In processing and packaging</th>
<th>In retail outlets, like grocery stores</th>
<th>In restaurants</th>
<th>In the home</th>
</tr>
</thead>
<tbody>
<tr>
<td>98 (10%)</td>
<td>54 (5%)</td>
<td>58 (6%)</td>
<td>112 (11%)</td>
<td>637 (63%)</td>
</tr>
<tr>
<td>Some</td>
<td>300 (30%)</td>
<td>340 (34%)</td>
<td>431 (43%)</td>
<td>435 (43%)</td>
</tr>
<tr>
<td>Not much</td>
<td>422 (42%)</td>
<td>455 (45%)</td>
<td>411 (41%)</td>
<td>363 (36%)</td>
</tr>
<tr>
<td>Nothing at all</td>
<td>188 (19%)</td>
<td>159 (16%)</td>
<td>108 (11%)</td>
<td>98 (10%)</td>
</tr>
</tbody>
</table>

5 Knowledge and Perceptions of BSE & Testing for BSE

Figure 4 shows respondent’s self-declared familiarity with BSE. While 14 per cent of respondents indicate they are very familiar with BSE, the majority (62 per cent) indicated they are somewhat familiar with BSE and only three percent say they are not at all familiar.

Figure 4 Self-declared familiarity with BSE (n=1,008).

After subjects were asked to rate their familiarity with BSE, they were provided with a brief information paragraph related to BSE:
Bovine spongiform encephalopathy (BSE), or mad cow disease, is a nervous system disease of cattle. Scientific research from around the world indicates that BSE is concentrated in specific nervous system tissues, and as such these tissues are treated as hazardous and removed from the food system. Any animals found to be positive for BSE are immediately destroyed and completely removed from the food system. As such, common cuts of beef (such as roast, steaks, and ground beef) are considered safe by the Canadian Food Inspection Agency, and international agencies such as the World Organization for Animal Health. Because of this, BSE poses an extremely low risk to human health. While Canada maintains a BSE surveillance program for Canadian cattle, it does not require mandatory testing of all cattle for BSE because there is no scientific basis for doing so.

This passage was developed based on publically available information on the websites of: Health Canada; Agriculture and Agri-Food Canada; the Canadian Food Inspection Agency; and the World Organization for Animal Health. Subjects were then asked the following question:

Suppose you were shopping for a cut of beef (such as steak or a roast) in the retail store where you typically buy beef and you notice that some packages of beef have a label saying “Tested for BSE”, while other packages of beef do not have the “Tested for BSE” label. How likely would you be to purchase a cut of beef (such as steak or a roast) that has the “Tested for BSE” label?

with a seven-point response scale that ranged from very likely (assigned a value of seven) to very unlikely (assigned a value of one). Figure 5 shows the frequency of responses to this purchase intention question. Based on the pattern of responses, three groups of different sizes can be identified:

4. Those with a low intention to purchase beef that has been labeled as being tested for BSE (i.e. those who selected response option 1, 2 or 3); this group accounts for about nine per cent of the sample.
5. An intermediate group with a moderate intention to purchase (i.e. those who selected response options 4, 5 or 6); this group accounts for 56 per cent of the sample.
6. Those with a high intention to purchase beef that has been labelled as being tested for BSE (i.e. those who selected response option 7); this group accounts for 35 per cent of the sample.

Grouping respondents into these three groups is useful as it points to some important substitution effects concerning beef. Specifically, the first group (which only accounts for nine per cent of the market) is unlikely to substitute away from conventionally labelled beef to beef that has a label indicating it has been tested for BSE. In contrast, the third group (which accounts for 35 per cent of the market) is likely to substitute from conventionally labelled beef to beef that has a “Tested for BSE” label. Moreover, as will be seen, splitting the sample into high purchase intention and low/medium purchase
intention individuals yielded important differences in estimates of willingness to pay for beef that has been tested for BSE.

**Figure 5 Frequency of responses to the purchase intention question for beef products that have a “Tested for BSE” label (n=1,008).**

The constant sum ranking of beef product attributes was also undertaken after the BSE information paragraph was presented. In this instance, however, the ranking task included a “Tested for BSE” option. The ranking of the now eight attributes, and the associated “importance scores” are shown in Table 7, along with the mean scores and ranking from the original constant sum exercise with seven attributes. Introduction of the “Tested for BSE” attribute does not change the ordinal ranking of attributes considerably, but it does reduce the importance of many. “Freshness” and “Price” continue to be the top two ranked attributes, followed by “Tested for BSE”. The ordinal ranking of most of the remaining attributes is now shifted down one position, while the importance of “Premium brand” and “External fat cover” is switched.

It is also important to note that the mean score for the original seven attributes are ALL lower than the importance scores reported in Table 3. This indicates that the importance of the original seven items diminishes when testing for BSE becomes an attribute of the beef product. Moreover, such a result points to potential trade-offs between testing for BSE and other product attributes. Specifically, consumers may be willing to forego some attributes in order to purchase beef that has been tested for BSE. As will be seen in the section addressing willingness to pay, some consumers are willing to trade-off price for testing for BSE.
Table 7 Ranking of attributes by average importance score (including “Tested for BSE”) (n=1,008).

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Mean score</th>
<th>Original score</th>
<th>Original rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freshness</td>
<td>22.63</td>
<td>28.19</td>
<td>1</td>
</tr>
<tr>
<td>Price</td>
<td>19.18</td>
<td>20.78</td>
<td>2</td>
</tr>
<tr>
<td>Tested for BSE</td>
<td>14.19</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Region or country of origin</td>
<td>11.04</td>
<td>12.04</td>
<td>3</td>
</tr>
<tr>
<td>Colour</td>
<td>10.22</td>
<td>11.7</td>
<td>4</td>
</tr>
<tr>
<td>Premium brand (such as Certified Angus Beef)</td>
<td>7.84</td>
<td>9.44</td>
<td>6</td>
</tr>
<tr>
<td>External fat cover (fat which can be trimmed before preparation)</td>
<td>7.70</td>
<td>9.57</td>
<td>5</td>
</tr>
<tr>
<td>Marbling</td>
<td>7.21</td>
<td>8.28</td>
<td>7</td>
</tr>
</tbody>
</table>

Respondents were also asked to indicate their perception of the safety of beef that has and has not been tested for BSE (see question 13 of the survey) using a five-point scale (where 1 equals very safe and 5 equals very unsafe). The frequency of responses to this question, shown in Figure 6, suggest some important differences in the perception of safety of beef that does or does not have a “Tested for BSE” label. In particular, the number of respondents indicating beef with a “Tested for BSE” label is very safe is three times higher than the number of respondents who indicated beef with no “Tested for BSE” label is very safe. In contrast, more respondents indicated that beef that has no “Tested for BSE” label is somewhat safe, somewhat unsafe, very unsafe and don’t know compared to those who indicated the corresponding level of safety for beef that has a “Tested for BSE” label.

Results from the data shown in Figure 6 need to be contextualized relative to subjects’ overall perceptions of the safety of beef. Recall from Table 4 that 50 per cent of subjects indicated that beef produced in Canada was very safe, while 45 per cent indicated that beef produced in Canada was somewhat safe. Data in Figure 6 shows that only 20 per cent of subjects indicated that beef with no “Tested for BSE” label was very safe, while about 55 per cent indicated beef with no “Tested for BSE” label was somewhat safe. Moreover, 60 per cent of respondents indicated beef with a “Tested for BSE” label was very safe, while about 37 per cent selected somewhat safe. Taken together this means 75 per cent of respondents indicated beef with no “Tested for BSE” label is at least somewhat safe, while 97 per cent indicated beef with a “Tested for BSE” label is at least somewhat safe. Compared to the baseline 95 per cent of respondents who originally indicated beef produced in Canada is at least somewhat safe (see table 4), the introduction of a beef product with a “Tested for BSE” label has a negative effect on the perception of safety of the beef that does not have a “Tested for BSE” label.
Historically, the Canadian beef sector has been an export-oriented industry. However, in light of the post-BSE environment in North America, some traditional export markets have increased the scrutiny related to beef exports from Canada and the United States. One consequence of this scrutiny (and desire to maintain market access) is the call for testing of beef destined to an export market for BSE. In contrast, the position of the Canadian industry is that the scientific evidence does not warrant universal testing of cattle for BSE. The tension created by these two views is explored here in the context of consumer perception of the safety of beef that is tested for BSE and exported versus beef that is not tested for BSE but sold on the domestic market.

To this end, consumers were asked the following question:

*Now suppose you hear a newscast where it is stated that all Canadian beef which is exported for consumption in other countries is tested for BSE (and has to be tested for BSE before it can be exported), but that beef which is sold in Canada is not tested for BSE. Compared to your current perception of the safety of the following two beef products change after hearing the newscast?*

Respondents were then asked to indicate their perceived safety of Canadian beef tested for BSE that is exported to other countries and Canadian beef not tested for BSE that is for sale in Canada. A five-point response scale (1= less safe than before; 5=safer than before) was used. Figure 7 shows the response frequency to these questions.
Three points stand out from Figure 7. First, the lion’s share of respondents perceive both types of beef as having the same level of safety as before; nearly 70 per cent of subjects indicated a perception that Canadian beef that is not tested for BSE that is for sale in Canada has about the same level of safety as before, while 60 per cent of respondents indicated a perception that Canadian beef that is tested for BSE and is exported to other countries has about the same level of safety as before. Second, there is a smaller segment (36 per cent) that feels Canadian beef that has been tested for BSE and exported is safer than before (i.e. a score of 4 or 5 on the five-point response scale). Lastly, there is a small segment (24 per cent) that believes Canadian beef for sale in Canada (which has not been tested) is less safe than before (i.e. a score of 1 or 2 on the five-point response scale).

**Figure 7** Frequency of perception of Canadian beef that is tested and exported or not tested but for sale in the Canadian market (n=1,008).

One question to ask is the extent to which perceptions of safety illustrated in Figure 7 overlap. To explore this issue, Table 8 shows cross tabulations (stated as a per cent of the sample) between responses to the question concerning perceptions of safety of Canadian beef tested for BSE that is exported to other countries and Canadian beef not tested for BSE that is for sale in Canada. About 51 per cent of respondents indicated that beef for sale in Canada and beef that is exported have about the same level of safety as before (this cell is in bold in Table 8).

The intersection of those indicating a perception that Canadian beef that is not tested for BSE and sold in Canada has about the same level of safety (i.e. a response option of 3 on the five-point scale) AND that Canadian beef that is tested for BSE and exported is safer (i.e. a response option of 4 or 5 on the five-point scale) equalled 18.2 per cent of
respondents (these cells are in italics in Table 8). The intersection of those indicating a perception that Canadian beef that is not tested for BSE and sold in Canada is less safe (i.e. a response option of 1 or 2 on the five-point scale) AND that Canadian beef that is tested for BSE and exported is safer (i.e. a response option of 4 or 5 on the five-point scale) equalled 13.4 per cent of respondents (these cells are shaded in Table 8).

On balance, these results suggest that at least half the sample believes both types of beef are at least as safe as before, while a smaller segment believes the exported beef is safer, but beef sold in Canada is less safe. While the latter segment is not large (it represents 13 per cent of respondents), it does suggest potentially harmful impacts on the domestic market if testing for BSE as a condition of export were to become a requirement.

Table 8. Cross tabulation of perception of safety of Canadian beef that is tested and exported or not tested but for sale in the Canadian market

<table>
<thead>
<tr>
<th>Canadian beef tested for BSE that is exported to other countries is...</th>
<th>Canadian beef not tested for BSE that is for sale in Canada is...</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (Less safe than before)</td>
<td>1 (Less safe than before)</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>3 (About the same level of safety as before)</td>
<td>3 (About the same level of safety as before)</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>5 (Safer than before)</td>
<td>5 (Safer than before)</td>
</tr>
<tr>
<td>1.2%</td>
<td>1.2%</td>
</tr>
<tr>
<td>0.6%</td>
<td>0.6%</td>
</tr>
<tr>
<td>3.6%</td>
<td>3.6%</td>
</tr>
<tr>
<td>1.3%</td>
<td>1.3%</td>
</tr>
<tr>
<td>5.3%</td>
<td>5.3%</td>
</tr>
</tbody>
</table>

6 **Discrete Choice & Willingness to Pay**

To understand better the impact of testing for BSE on consumer demand for beef, and to gauge willingness to pay for beef that has been tested, a contingent valuation experiment was undertaken. Respondents were asked if they would “...be willing to purchase the cut of beef [such as a steak or a roast] that has the label “Tested for BSE” when it is offered at a price that is [INSERT PERCENTAGE PREMIUM FROM CELL MATRIX] more expensive than the same cut of beef that does not have the “Tested for BSE” label?” and given the response options “Yes”, “No” and “Don’t know”. Following conventional practice, “Don’t know” responses were treated as “No” responses in the analysis that follows.

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6 The contingent valuation question was structured as a double bound contingent valuation. While the double bound contingent valuation approach does improve efficiency when estimating willingness to pay, it comes at the cost of an incompatibility bias, and an anchoring effect (see Habb and McConnell 2002 and Hanemann and Kanninen 1999 for further discussion). Consequently, in this analysis, we use only the responses to the first elicitation question for modelling choice and measurement of willingness to pay.
Respondents were assigned to one of five possible cells. Each cell had a minimum number of responses (minimum cell size was 200) and an associated percentage premium (10, 20, 30, 40 or 50%) for beef that had been tested for BSE. Figure 8 shows the proportion of respondents who indicated they would purchase the cut of beef at the assigned price premium (relative to the overall sample size). As one might expect, the proportion of respondents who said they would purchase the cut of beef that has been tested for BSE fell as the percentage premium increased. Overall, 16 per cent of respondents indicated they would purchase beef that had been tested for BSE (at the given percentage premium).

**Figure 8 Proportion of respondents who indicated they would purchase the cut of beef at the assigned price premium (n=1,008).**

To understand better consumer preferences for beef that has been tested for BSE, a discrete choice model is estimated. To couch this analysis in the published literature, and following on the recent paper by McCluskey et al. (2005), a logit model of the probability of choosing the “Yes” response in the discrete choice question is estimated. Note too that the estimated logit model enables one to recover willingness to pay for beef that has been tested for BSE (see Habb and McConnell 2002 and McCluskey et al. for details).

Initially, the logit model included the following independent variables:

- **premium**: the percentage premium assigned to the respondent in the discrete choice task. This variable is included to help measure willingness to pay.
- **beefsafe**: a dummy variable equalling one if the respondent indicated their belief that beef produced in Canada is very safe, zero otherwise. This variable is included to help control for respondent’s views concerning the safety of beef currently on the market.
- **nonpf**: the non-price factor scale. This variable is included to also help control for non-price issues of concern when respondents are considering purchasing beef.
- **pricf**: the price factor scale. This variable is included to help capture any concerns respondents might have about the price they pay for beef at retail.
- **vfamse**: a dummy variable equalling one if the respondent indicated they are very familiar with BSE, zero otherwise. This variable is included to help control for/capture respondent’s knowledge related to BSE.
- **farming**: a dummy variable equalling one if the respondent indicated they have a close friend or family member engaged in farming, zero otherwise. This variable is included to help control for people who may have information/knowledge about BSE that could impact their choice.
- **ownfoag**: a dummy variable equalling one if the respondent indicated they have expertise related to, or are employed in the food or agricultural industries. This variable is included to help control for people who may have information/knowledge about BSE that could impact their choice.
- **growown**: a dummy variable equal to one if the respondent indicated they grow any food for household consumption, zero otherwise. This variable is included to help capture broader behavioural aspects related to food and to control for level of food involvement.
- **organic**: a dummy variable equal to one if the respondent indicated they purchased any organic food products in the last three months, zero otherwise. This variable is included to also help capture broader behavioural aspects related to food. Moreover, given the premiums associated with organic food products, its inclusion could also help control for/capture respondent’s lack of price sensitivity for some foods.
- **highpint**: a dummy variable indicating whether the respondent had a high self-declared intention to purchasing a product tested for BSE

A complete set of socio-economic and demographic variables was also included:

- **male**: a dummy variable indicating the respondent is male, zero otherwise.
- **age**: the respondent’s age in years.
- **children**: a dummy variable equal to one if the respondent has children under the age of 18 in the home.
- **lesshigh, highschl, univdgre, postgrad**: dummy variables indicating if the respondent has less than high school, high school, undergraduate or post-graduate education, respectively (college diploma was the omitted group)
- **incu25, inc2545, inc7099, inc100p**: dummy variables indicating if the respondent’s household income was under $25,000, between $25,000 and $44,999, between $70,000 and $99,999, or $100,000 or higher, respectively (household income between $45,000 and $69,999 was the omitted group)
- **ac, ms, ab, bc**: dummy variables indicating whether the respondent was from Atlantic Canada, Manitoba/Saskatchewan, Alberta, or British Columbia, respectively (Ontario was the omitted group)
After initial estimation, it was noted that almost all socio-economic and demographic variables had insignificant coefficient estimates. Subsequent testing of the null hypothesis that these variables could be removed indicated that coefficients on the:

- provincial/regional dummy variables were not jointly significant (p-value=0.99),
- income dummy variables were not jointly significant (p-value=0.523),
- education dummy variables were not jointly significant (p-value=0.41),
- male dummy variable was not significant (p-value=0.531)
- age variable was not significant (p-value=0.15)
- children dummy variable was not significant (p-value=0.412)

Furthermore, removal of these variables did not affect the sign and magnitude of the estimated coefficients on the other variables. This suggests inclusion of these variables is not necessary and could, in fact, lead to imprecise estimates of the remaining parameters. Moreover, inclusion of variables that do not have significant affects could result in multicollinearity. Lastly, elimination of unnecessary variables also adds degrees of freedom. As such, these socio-economic and demographic variables were not included in the final model.

Table 9 shows estimated coefficients and z-statistics (calculated using robust standard errors) for the model estimated using the entire sample, as well as estimated on two subsets of the data. Focusing on the former, note that the magnitude of the Wald test statistic indicates failure to accept the null hypothesis that all estimated coefficients are jointly equal to zero at the 1% level (p-value<0.0001), and that the estimated model has a pseudo $R^2$ of 0.15. While the latter may seem small, in the context of a model estimated with cross-sectional data, this is actually quite good. Also note that the predicted probability of purchase is low; only about 11 per cent of respondents are expected to purchase a beef product that has been tested for BSE (and offered at a price higher than beef that has not been tested for BSE).

Results indicate that a number of important coefficients are significant. Specifically, the coefficient on the percentage premium variable ($premium$) is significant and negative (as expected); this means that as the premium increases, the likelihood of purchasing a beef cut with a label indicating it has been tested for BSE falls.

The coefficient on the non-price factor variable ($nonpf$) is positive and significant, indicating that as respondent’s concern over various non-price factors increases, the probability of purchasing beef that has been tested also increases. In contrast, the coefficient on the price factor ($pricf$) variable is negative and significant; this means as concern over the price paid for beef at retail rises, the probability of purchasing beef that has been tested for BSE falls. The latter could be rather important for households where affordability of beef is a concern or households where the primary grocery shopper is price sensitive.
Table 9 Results from the Logit regression\textsuperscript{a}

<table>
<thead>
<tr>
<th></th>
<th>All respondents</th>
<th>High intention to purchase</th>
<th>Low or medium intention to purchase</th>
</tr>
</thead>
<tbody>
<tr>
<td>premium</td>
<td>-5.278***</td>
<td>-4.898***</td>
<td>-5.831***</td>
</tr>
<tr>
<td></td>
<td>(-7.02)</td>
<td>(-4.73)</td>
<td>(-5.16)</td>
</tr>
<tr>
<td>beefsafe</td>
<td>-0.306</td>
<td>-0.247</td>
<td>-0.398</td>
</tr>
<tr>
<td></td>
<td>(-1.59)</td>
<td>(-0.90)</td>
<td>(-1.44)</td>
</tr>
<tr>
<td>Nonpf</td>
<td>0.503***</td>
<td>0.751***</td>
<td>0.301*</td>
</tr>
<tr>
<td></td>
<td>(3.48)</td>
<td>(3.53)</td>
<td>(1.63)</td>
</tr>
<tr>
<td>Pricf</td>
<td>-0.233**</td>
<td>-0.355**</td>
<td>-0.114</td>
</tr>
<tr>
<td></td>
<td>(-2.11)</td>
<td>(-2.14)</td>
<td>(-0.77)</td>
</tr>
<tr>
<td>vFambse</td>
<td>0.417*</td>
<td>0.623*</td>
<td>0.226</td>
</tr>
<tr>
<td></td>
<td>(1.68)</td>
<td>(1.65)</td>
<td>(0.67)</td>
</tr>
<tr>
<td>farming</td>
<td>0.350</td>
<td>0.155</td>
<td>0.484</td>
</tr>
<tr>
<td></td>
<td>(1.40)</td>
<td>(0.37)</td>
<td>(1.59)</td>
</tr>
<tr>
<td>ownfoag</td>
<td>-0.248</td>
<td>-0.607</td>
<td>0.056</td>
</tr>
<tr>
<td></td>
<td>(-0.62)</td>
<td>(-0.97)</td>
<td>(0.12)</td>
</tr>
<tr>
<td>growown</td>
<td>-0.325*</td>
<td>-0.310</td>
<td>-0.378</td>
</tr>
<tr>
<td></td>
<td>(-1.68)</td>
<td>(-1.09)</td>
<td>(-1.44)</td>
</tr>
<tr>
<td>organic</td>
<td>0.432**</td>
<td>0.367</td>
<td>0.534**</td>
</tr>
<tr>
<td></td>
<td>(2.25)</td>
<td>(1.28)</td>
<td>(2.04)</td>
</tr>
<tr>
<td>highpint</td>
<td>0.952***</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(5.08)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intercept</td>
<td>-1.741***</td>
<td>-1.386</td>
<td>-1.333</td>
</tr>
<tr>
<td></td>
<td>(-2.68)</td>
<td>(-1.51)</td>
<td>(-1.51)</td>
</tr>
<tr>
<td>Sample size</td>
<td>1008</td>
<td>347</td>
<td>661</td>
</tr>
<tr>
<td>Predicted probability</td>
<td>0.114</td>
<td>0.214</td>
<td>0.079</td>
</tr>
<tr>
<td>Wald</td>
<td>102.890</td>
<td>39.9</td>
<td>39.61</td>
</tr>
<tr>
<td>p-value</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Pseudo-R2</td>
<td>0.153</td>
<td>0.141</td>
<td>0.111</td>
</tr>
</tbody>
</table>

Notes:

\textsuperscript{a} z-statistics calculated using heteroskedastic robust standard errors are shown in parentheses.

*** denotes significantly different from zero at the one per cent level

** denotes significantly different from zero at the five per cent level

* denotes significantly different from zero at the ten per cent level

The coefficient on the dummy variable capturing respondents who indicated they are very familiar with BSE (\textit{vFambse}) is positive and significant. This means respondents who indicated they are very familiar with BSE are more likely to indicate they would purchase beef that has been tested for BSE (compared to respondents who indicated they have some, little or no familiarity with BSE). Such a result points to the important role of educating consumers on the facts related to BSE and debunking myths about BSE that might otherwise lead consumers to an erroneous conclusion.

Coefficients on the variable capturing respondents who grew food for their households’ consumption (\textit{growown}), or reported purchasing organic food in the last three months...
A Cost-Benefit Analysis of Voluntary BSE Testing of Cattle

(organic) were both significant. The coefficient on growown was negative, indicating that these respondents were less likely to indicate they would purchase beef that has been tested for BSE, while the coefficient on organic was positive, indicating these respondents were more likely to indicate they would purchase beef that has been tested for BSE. The coefficient on the variable capturing the purchase intention (highpint) was significant and positive (as one might naturally expect). Lastly, the intercept was negative and significant.

Similar analysis was undertaking on two sub-sets of the sample; these sub-sets were delineated on whether they had a high purchase intention or a low or medium purchase intention. High purchase intention respondents are those who indicated they would be very likely to purchase a beef product that has been tested for BSE (see Figure 5), while low or medium purchase intention respondents are those who indicated anything below a “very likely” response to the question underlying Figure 5. High purchase intention respondents accounted for 347 or the 1,008 subjects, while the low or moderate purchase intention respondents accounted for the remaining 661.

The third and fourth columns in Table 9 show the logit regression results for the model estimated using these two sub-sets of the data. Note that given the delineation of the data, the variable highpint was removed. While results for the model estimated using the high purchase intention individuals were similar to those from the model estimated with all respondents, key differences did arise. The intercept and coefficients on growown and organic were not significant, and the magnitude of the coefficient on the premium variable was smaller.

In contrast, results for the model estimated with low and medium purchase intention are different. Only coefficients on the premium, non-price factor and organic variables were significant. As well, the magnitude of the coefficient on the premium variable was larger compared to those estimated using all the data and the high purchase intention individuals.

Important in the analysis of results based on these two sub-sets are differences in the predicted probabilities. As shown in Table 9, the predicted probability for the model estimated with high intention respondents equalled 21 per cent, while that for the model estimated with the low/medium intention respondents was eight per cent. This means that even for those with a high purchase intention, only one-fifth of respondents would purchase a beef product that had been tested for BSE, while less than ten per cent of those with a low/medium purchase intention would purchase the tested product. On balance, these results suggest the market for beef products that have been tested for BSE is small.

The magnitude of the coefficient in the premium variable is very important as it plays a key role in measuring willingness to pay (WTP). The larger this coefficient, the smaller the willingness to pay, all other things held equal. To explore this further the results in Table 6.9 are used to calculate WTP for beef that has been tested for BSE. WTP is calculated following standard practice illustrated in Habb and McConnell (2002) and a similar set of calculations as presented in McCluskey et al. (2005). For purposes of this
A Cost-Benefit Analysis of Voluntary BSE Testing of Cattle

analysis, WTP is calculated at the means of the data and an associated standard error is calculated (standard errors were calculated using the delta method). The standard error is useful as it enables calculation of confidence intervals around the estimated mean WTP, and allows one to test whether the estimate of WTP is significantly different from zero.

Table 10 shows the estimates of the mean WTP, standard errors and 95 per cent confidence intervals calculated using estimates of the models reported in Table 9. Using the model estimated with all respondents, the estimated mean WTP reflects a 43 per cent premium. Based on the standard error for this estimate of WTP, the 95 per cent confidence interval ranges from 18 percent to 69 per cent. As the confidence interval does not include zero, it is concluded that the estimated mean WTP of 43 per cent is statistically significant from zero.

Table 10 Summary of WTP estimates

<table>
<thead>
<tr>
<th></th>
<th>All respondents</th>
<th>High intention to purchase</th>
<th>Low or medium intention to purchase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean WTP</td>
<td>43.14%</td>
<td>51.99%</td>
<td>27.85%</td>
</tr>
<tr>
<td>Standard error</td>
<td>13.04%</td>
<td>20.24%</td>
<td>15.31%</td>
</tr>
<tr>
<td>95% confidence interval</td>
<td>(17.57%, 68.70%)</td>
<td>(12.33%, 91.66%)</td>
<td>(-2.16%, 57.87%)</td>
</tr>
</tbody>
</table>

A similar scenario emerges when WTP is calculated using the model estimated with respondents with a high intention to purchase. Amongst these individuals, the estimated mean WTP equalled 52 per cent, with a 95 per cent confidence interval ranging from 13 to 92 per cent. While the WTP for high intention respondents is statistically different from zero, the wider dispersion of this estimate (captured via the standard error) means it is estimated with less precision compared to the WTP based on the overall sample.

The estimated mean WTP for respondents with less than a high purchase intention equalled 29 per cent with a confidence interval ranging from -2 per cent to 58 per cent. Given that the confidence interval includes zero, we cannot conclude that this estimate of WTP is statistically significant from zero (at the 95 per cent level).
Consumer Beef Survey  
10-014828-01  
Draft Questionnaire  
May 6, 2010

Cells: 1-5  
N = 200 per cell

**Screening Questions**

*First, we have a few short questions to verify that this study is relevant to you.*

**QA.**  
So we know our survey includes people of all ages, can you please select your age category?

- Under 18 years
- 18-24 years
- 25-34 years
- 35-49 years
- 50-60 years
- 61-64 years
- 65 years or older

[IF UNDER THAN 18 YEARS, THANK AND TERMINATE.]

**QB.**  
So we can understand how responses to our survey vary across Canada, can you please select the province in which you live:

- Alberta
- British Columbia
- Manitoba
- New Brunswick
- Newfoundland and Labrador
- Northwest Territories
- Nova Scotia
- Nunavut
- Ontario
- Prince Edward Island
- Québec
- Saskatchewan
- Yukon

[IF NORTHWEST TERRITORIES, NUNAVUT, QUEBEC OR YUKON, THANK AND TERMINATE.]
A Cost-Benefit Analysis of Voluntary BSE Testing of Cattle

QC. Today, we are looking for people who work in certain sectors. Are you, or is any member of your immediate family or close friends employed in any of the following sectors? (Please select all that apply.)

- TV/Radio/Press/Newspaper/Magazine
- Travel Agency
- Ad agency/Public relations
- Banking
- Market Research/Marketing
- Insurance
- None of the above

[IF TV/RADIO/PRESS/NEWSPAPER/MAGAZINE, AD AGENCY/PUBLIC RELATIONS OR MARKET RESEARCH/MARKETING – THANK AND TERMINATE]

QD. Which of the following describes you best? (Please select one only)

- I am the primary grocery shopper for my household
- I share the grocery shopping responsibility for my household
- Someone else has the responsibility for grocery shopping for my household

[IF SOMEONE ELSE HAS THE RESPONSIBILITY FOR GROCERY SHOPPING – THANK AND TERMINATE.]

QE. Have you eaten beef in the last six weeks? (Please select one only)

- Yes
- No
- I cannot recall

[IF NO OR CANNOT RECALL - THANK AND TERMINATE]
Main Questionnaire

Thank you, you qualify for this study. The survey seeks to develop a better understanding of consumer attitudes, perceptions and beliefs towards beef in general, but Canadian beef in particular. The survey will take about 15 to 20 minutes to complete.

First of all, we would now like to ask you some questions about your household's beef consumption.

1. Typically how many times do you eat some form of beef - either prepared and/or eaten at home or away from home? Be sure to include all meals with beef, such as steaks and roasts, spaghetti with meat sauce, hamburgers, etc. (Please select one only):
   - Daily
   - More than once a week, but not every day
   - At least once a week
   - At least once a month, but less than once a week
   - Less than once a month

2. Which are your favorite types of beef product? (Please select all that apply):
   - Steaks
   - Roasts
   - Ground beef
   - Pre-formed hamburgers or meatballs
   - Beef sausages, hot dogs or frankfurters
   - Other (specify): ______________

3. From where do you usually buy beef for consumption in the home? (Please select all that apply)
   - Large Chain Grocery Stores (e.g. Loblaw's, Zehrs, Dominion, A&P, Sobey's, Safeway, Metro, Maxi, etc.)
   - Discount grocery stores (e.g. FoodBasics, No Frills, Price Chopper etc.)
   - Independent grocery stores (e.g. Coleman's, Longo's, Freson's, Thrifty's, Strong's Markets, Quality Foods, Farm Boy, Highland Farms, Bruno's, Vince's, L&M, Michael-Angelo's, Dennigers etc.)
   - Ethnic grocery stores
   - Health Food stores
   - Mass merchandisers or discount department stores (e.g. Zellers, Walmart etc.)
   - Warehouse club stores (e.g., Costco, Sam's Club)
   - Butcher shops
   - Farmers markets or directly from a farm or farmer
   - Other (Please specify) ______________________
Next, we would like to ask you a few questions related to food safety.

4. Overall, how do you feel about the safety of food produced in Canada? *(Please select one only)*
   - Very safe
   - Somewhat safe
   - Somewhat unsafe
   - Very unsafe
   - Don’t Know

5. Overall, how do you feel about the safety of the following meats produced in Canada? *(Please select one only per row)*
   [RANDOMIZE ROWS]
   **COLUMNS**
   - Very safe
   - Somewhat safe
   - Somewhat unsafe
   - Very unsafe
   - Don’t Know
   **ROWS**
   - Pork
   - Beef
   - Lamb
   - Chicken
   - Fish

6. If a food safety problem was to occur, where do you think the problem is most likely to develop? *(Please select one only)*
   - At the farm level
   - During food processing
   - At the grocer or retailer level
   - In restaurants
   - In the home
   - During transportation
   - None of the above
7. How much would you say you know about food safety practices between the farm level and you, the final consumer? *(Please select one only per row)*

[COLUMNs]
A lot
Some
Not much
Nothing at all

[ROWS]
On the farm
In processing and packaging
In retail outlets, like grocery stores
In restaurants
In the home

8. When you typically buy beef how concerned are you about each of the following? *(Please select one only per row)*

[COLUMNs]
Very concerned
Somewhat concerned
Neither concerned nor unconcerned
Somewhat unconcerned
Not at all concerned

[ROWS]
Cholesterol and fat
Risk of exposure to food borne contamination
Whether antibiotics are used during the raising of beef cattle
Whether hormones are used during the raising the beef cattle
Risk of exposure to mad cow disease/BSE
Whether beef is from cattle which have been raised using enhanced animal welfare production methods
Whether beef is from cattle which have been produced using certified organic production methods
Whether beef is from cattle which are raised locally (i.e. within 100 kilometers of where I live)
The price I pay for beef at retail
9. The following question asks you to divide 100 points between a set of items you might consider when purchasing a cut of beef (such as a steak or a roast). Distribute the 100 points across these items, giving the more important item a greater number of points. The computer will prompt you if your total does not equal exactly 100 points. [PROGRAMMER: CONSTANT SUM EXERCISE. AUTO SUM MUST ADD TO 100%] [RANDOMIZE LIST]

LIST
Price
Region or country of origin
Premium brand (such as Certified Angus Beef)
Colour
Marbling
External fat cover (fat which can be trimmed before preparation)
Freshness

10. How familiar are you with ‘mad cow’ disease, or bovine spongiform encephalopathy (BSE)? (Please select one only)

- Very familiar
- Somewhat familiar
- Not very familiar
- Not at all familiar

On the next screen you will see a description of mad cow disease/BSE. Please read/review the description – and after you’ve finished reading the description, follow the instructions in the next questions.

Bovine spongiform encephalopathy (BSE), or mad cow disease, is a nervous system disease of cattle. Scientific research from around the world indicates that BSE is concentrated in specific nervous system tissues, and as such these tissues are treated as hazardous and removed from the food system. Any animals found to be positive for BSE are immediately destroyed and completely removed from the food system. As such, common cuts of beef (such as roast, steaks, and ground beef) are considered safe by the Canadian Food Inspection Agency, and international agencies such as the World Organization for Animal Health. Because of this, BSE poses an extremely low risk to human health. While Canada maintains a BSE surveillance program for Canadian cattle, it does not require mandatory testing of all cattle for BSE because there is no scientific basis for doing so.

11. Suppose you were shopping for a cut of beef (such as steak or a roast) in the retail store where you typically buy beef and you notice that some packages of beef have a label saying “Tested for BSE”, while other packages of beef do not have the “Tested for BSE” label. How likely would you be to purchase a cut of beef (such as steak or a roast) that has the “Tested for BSE” label?
12. The following question asks you to divide 100 points between a set of items you might consider when purchasing a cut of beef (such as a steak or a roast). Distribute the 100 points across these items, giving the more important item a greater number of points. The computer will prompt you if your total does not equal exactly 100 points. [PROGRAMMER: CONSTANT SUM EXERCISE. AUTO SUM MUST ADD TO 100%] [RANDOMIZE LIST]

**LIST**
- Price
- Region or country of origin
- Premium brand (such as Certified Angus Beef)
- Colour
- Marbling
- External fat cover (fat which can be trimmed before preparation)
- Freshness
- Tested for BSE

13. Suppose you are shopping for a cut of beef (such as steak or a roast) in the retail store where you typically buy beef and you notice that some packages of beef have a label saying “Tested for BSE”, while other packages of beef do not have the “Tested for BSE” label. Based on your existing perception of the safety of Canadian beef, what is your perception of the safety of... (Please select one only per row) [RANDOMIZE ROWS]

**COLUMNS**
- Very safe
- Somewhat safe
- Somewhat unsafe
- Very unsafe
- Don’t Know

**ROWS**
- The package of beef with no “Tested for BSE” label
- The package of beef with a “Tested for BSE” label
A Cost-Benefit Analysis of Voluntary BSE Testing of Cattle

**CELL MATRIX**

<table>
<thead>
<tr>
<th>CELL #</th>
<th>PERCENTAGE PREMIUM</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10%</td>
</tr>
<tr>
<td>2</td>
<td>20%</td>
</tr>
<tr>
<td>3</td>
<td>30%</td>
</tr>
<tr>
<td>4</td>
<td>40%</td>
</tr>
<tr>
<td>5</td>
<td>50%</td>
</tr>
</tbody>
</table>

14. Following on the previous question, would you be willing to purchase the cut of beef that has the label “Tested for BSE” when it is offered at a price that is [INSERT PERCENTAGE PREMIUM FROM CELL MATRIX] more expensive than the same cut of beef that does not have the “Tested for BSE” label?

   Yes
   No
   Don’t Know

[IF YES IN Q.14 – CONTINUE]
[IF NO OR DON’T KNOW IN Q.14 – SKIP TO Q.16]

15. Would you be willing to purchase the cut of beef that has the “Tested for BSE” label when it is offered at a price that is [INSERT PERCENTAGE PREMIUM SHOWN IN Q.14 + 5 PERCENTAGE POINTS] more expensive than the same cut of beef that does not have the “Tested for BSE” label?

   Yes
   No
   Don’t Know

[IF NO OR DON’T KNOW IN Q.14 CONTINUE, OTHERWISE SKIP TO Q.17]

16. Would you be willing to purchase the cut of beef that has the “Tested for BSE” label when it is offered at a price that is [INSERT PERCENTAGE PREMIUM SHOWN IN Q.14 MINUS 5 PERCENTAGE POINTS] more expensive than the same cut of beef that does not have the “Tested for BSE” label?

   Yes
   No
   Don’t Know

[PAGE BREAK HERE WITH NO CHANCE TO GO BACK TO QUESTIONS 11 TO 16 AND CHANGE RESPONSE]

17. Now suppose you hear a newscast where it is stated that all Canadian beef which is exported for consumption in other countries is tested for BSE (and has to be tested for BSE before it can be exported), but that beef which is sold in Canada is not tested for BSE. Compared to your current perception of the safety of Canadian beef, how would your perception of the safety of the following two beef products change after hearing the newscast? (Please select one only per row) [RANDOMIZE ROWS]
COLUMNS
1 – Less safe than before
2
3 – About the same level of safety as before
4
5 – Safer than before

ROWS
Canadian beef tested for BSE that is exported to other countries is…
Canadian beef not tested for BSE that is for sale in Canada is…

Finally, we would like to ask you a little about yourself. This information is only to help us interpret the results across the people who complete this survey and will be kept strictly confidential.

18. Are you or is anyone in your family or close friends currently engaged in farming? (Please select one only)
   Yes
   No
   Don’t know

19. Do you have expertise related to, or are you currently employed in, the food or agricultural industry? (Please select one only)
   Yes
   No

20. Do you grow any food for your household consumption? (Please select one only)
   Yes
   No

21. Have you purchased organic food products in the past three months? (Please select one only)
   Yes
   No
   Not sure

22. What is your gender? (Please select one only)
   Male
   Female

23. In what year were you born? (Please type in)
   [INSERT NUMERIC TEXT BOX]
24. Are there children under 18 years of age in your household? (Please select one only)
   Yes
   No

[IF YES IN Q.24 – CONTINUE, OTHERWISE SKIP TO Q.26]

25. And how many of those children fall into each of the following age groups? (Please type in)
   [PROGRAMMER: AUTOFILL BOXES WITH “0”]

   0-4 years of age [NUMERIC TEXT BOX. RANGE 0-20]
   5-11 years of age [NUMERIC TEXT BOX. RANGE 0-20]
   12-17 years of age [NUMERIC TEXT BOX. RANGE 0-20]

26. What is the highest level of education that you have completed? (Please select one only)
   Less than high school
   High school graduate
   College diploma / degree (including trade certificates)
   University undergraduate degree
   Post-graduate university degree (e.g., Masters or Ph.D.)

27. To understand the results from this survey we need some indication of your total annual household income. We understand that some people are not comfortable providing this information but you can be assured that all information is confidential and is never associated with you as a named individual. Would you please tell us what your total annual household income was in 2009? (Please select one only)
   Under $25,000
   $25,000 - $44,999
   $45,000 - $69,999
   $70,000 - $99,999
   More than $100,000

Your participation in this survey is very important and much appreciated. Thank you very much for your time!
Appendix B

Cost-Benefit Analysis of BSE Testing in Cattle

Project Sponsored by: Alberta Prion Research Institute, PrioNet, and ALMA

The purpose of this study is to evaluate the costs and benefits of voluntary testing of cattle for BSE. One of the project objectives is to characterize the apparent demand for BSE-tested beef product.

One way to address that objective is to interview Canadian packers and cattle exporters.

Questionnaire for Canadian Packers and Cattle Exporters Regarding Cost-Benefit Analysis of BSE Testing in Cattle

1. Do customers talk to you about BSE in Canada? What is the nature of the discussions? How do you respond?
   a. Have domestic or international customers ever expressed concern over product due to BSE in Canada?
2. Has the issue of BSE-tested product ever come up? In what context?
   a. Have domestic or international customers ever requested testing for BSE product?
   b. Have customers asked you seriously about purchasing BSE-tested product? Did the discussions extend to prospective product volumes and prices?
3. Has your firm considered testing cattle for BSE post mortem or ante mortem?
4. Are you aware of methods for testing cattle for BSE?
5. What do you see as the potential benefits for your firm in testing for BSE?
   a. New customers or export markets
   b. Premiums
   c. If premiums have they been quantified
6. What do you see as the potential benefits for the Canadian industry in testing for BSE?
   a. New customers or export markets, renewed access
   b. Reputation
7. What do you see as the potential threats or risks associated with testing for BSE?
   a. Negative impact on non-tested product
   b. False positives, efficacy
   c. International recognition
8. Are you aware of the costs of post mortem or ante mortem testing?
   a. Should it be firm specific or absorbed by government
9. Where are your customers? Approximate share
   a. Canada
   b. US
   c. Asia
10. Is BSE testing a reality for the future or is it something that is going to cease to be an issue?
11. Have you previously worked on special attribute products with customers? E.g. GM-free, etc.
   a. Did you initiate those discussions or did the customer?

Kevin Grier
George Morris Centre
Appendix C

Ranchers Beef BSE Testing Information
## BSE TESTING COST ESTIMATES

### Initial Fixed One time costs

<table>
<thead>
<tr>
<th>Modular Lab</th>
<th>CPM LABFAB</th>
<th>basic cost</th>
<th>Includes Outer prep room and BSL2 lab area with 2 x 4 ft biocontainment hoods</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="http://cpminc.com/">http://cpminc.com/</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BSL2 12 x 46 ft space</td>
<td>Colorado</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Set up foundation Water/Electrical total</th>
<th>125,000 Estimates</th>
<th>Contact Kim Bergman (<a href="mailto:kimb@cpmlabfab.com">kimb@cpmlabfab.com</a>)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>375000</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bio-Rad Instrumentation</th>
<th></th>
<th>225,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precess 48 Homogenizer</td>
<td></td>
<td>NOTE: One system and 3 techs can routinely process 700 samples/8 hour shift</td>
</tr>
<tr>
<td>NSP automation Robotics</td>
<td></td>
<td>Time to result 5 hours</td>
</tr>
<tr>
<td>DW40 Deep Well washer</td>
<td></td>
<td>500/day = 1shift</td>
</tr>
<tr>
<td>1575 Microplate washer</td>
<td></td>
<td>1000/day = 2 shifts</td>
</tr>
<tr>
<td>680 Reader</td>
<td></td>
<td>2000/day = 3 shifts</td>
</tr>
<tr>
<td>Incubation heating block</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Computers(2)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Non Bio-Rad Instrumentation              |                  |                                        |
| Pipettors                                | 1000             |                                        |
| 4 decimal balance                        | 5000             |                                        |
| Assorted Lab acc's                       | 35000            |                                        |
| fridge freezer                           |                  |                                        |

| GRAND TOTAL                              | 641,000          |                                        |

### Personnel

| 3 Technicians @ 55K/annum                | 165K/ Annum      |

### TeSeE Cost per test

| 16.5                                     | 0.2              |
| Associated consumables tips plates etc   |                  |
### COST / TEST Amortizing Fixed cost over 3 years

<table>
<thead>
<tr>
<th></th>
<th>Cost /test</th>
<th>Cost /test</th>
<th>Cost /test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>500/day</td>
<td>1000/day</td>
<td>2000/day</td>
</tr>
<tr>
<td>200 working days</td>
<td></td>
<td>200 working days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 shift</td>
<td>2 shifts</td>
<td>3 shifts</td>
</tr>
<tr>
<td>Year 1,2,3</td>
<td>$20.49</td>
<td>$19.42</td>
<td>$18.47</td>
</tr>
<tr>
<td>Portable lab cost overrun provision/100K</td>
<td>$1.00</td>
<td>$0.50</td>
<td>$0.25</td>
</tr>
<tr>
<td>Year 4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lab and equipment costs paid off</td>
<td>$18.35</td>
<td>$18.35</td>
<td>$17.94</td>
</tr>
<tr>
<td>Costs for service contracts based on est 48,000/annum to cover service agreements for lab equipment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>$0.48</td>
<td>$0.24</td>
<td>$0.12</td>
</tr>
</tbody>
</table>

Bio-Rad also offers complete sampling kits with Sample collection spoons, bar coded samples vials identification lables gloves etc

Cost per sample 4.25
Turn-Key Solution For BSE Testing

Abbott Diagnostics
And
Enfer Scientific

Abbott Laboratories Ltd., Diagnostics Division
7115 Millcreek Drive
Mississauga, Ontario
Canada L5N 3R3
Phone: 800.387.8378
www.abbottdiagnostics.com
January 11, 2006

Mr. Tony Martinez, President
Rancher’s Beef Ltd.
Box 6
Balzac, Alberta
T0M 0E0

Mr. John Ross, Assistant Director – Red Meat Section
Agriculture and Agri-Food Canada
Animal Industry Division
1341 Baseline Road, Tower 7, 7th Floor
Ottawa, Ontario K1A 0C5

Gentlemen,

In response to the request from the Beef Industry Value Chain Roundtable for a complete turn-key solution for BSE testing, Abbott Laboratories Ltd., Diagnostics Division, on behalf of Enfer Scientific Limited, is pleased to submit the following proposal.

This proposal details the specifications and expenditure requirements to facilitate the commissioning of an efficient BSE testing facility which incorporates an internal process capacity of 500, 1000, 2000 and 4000 samples per day. The assumption is that this number of samples will be available to test five days a week for the entire year. The capital costs will be written off over a three year period.

Assumptions:

General:
- CFIA’s proposed position is that a private laboratory conducting market access BSE testing should not be located within a packing plant.
- The ownership and operation of the lab should not be under the control of the packing plant owners or management.
- Separate ownership and management will be required.
- A location immediately adjacent to the plant would be acceptable.
- Laboratory inspections will be required by the Standards Council of Canada, the Bio-safety division of CFIA and by the CFIA’s BSE reference lab.

Site:
- The proposal is based upon the Rancher’s Beef plant providing in close proximity to the plant, a graded and level site serviced with water, sewer, gas, electrical and telephone utilities to the laboratory building location.
- The location is assumed to have an access road suitable for semi-trailer delivery of modular laboratory units up to sixty feet in length.
- For laboratory staff, use of Rancher’s Beef employee facilities – washrooms, lunchroom & coffee facilities, vehicle parking, etc. is assumed to be provided.

There should be adequate electrical power supply (3 phase/80 amps)
There should be a clean water supply and waste drainage facilities.

.../2
Building Requirements:
Sample Reception/Office
Sorting and Dissection area
ELISA lab
Storage area for reagents and disposables.

The lab will meet BS 2+ standards.

Building Size:

The general building layout will be the same for the 4 different throughput options.

<table>
<thead>
<tr>
<th>Sample Throughput per day</th>
<th>Lab dimensions L x D (ft.) / Area sq.ft</th>
</tr>
</thead>
<tbody>
<tr>
<td>500</td>
<td>30 x 24 / 720</td>
</tr>
<tr>
<td>1000</td>
<td>30 x 24 / 720</td>
</tr>
<tr>
<td>2000</td>
<td>40 x 24 / 960</td>
</tr>
<tr>
<td>4000 (double shift)</td>
<td>40 x 24 / 960</td>
</tr>
</tbody>
</table>

500 samples/day:
1000 samples/day:

Sample sorting bench
Sorting & Dissection Lab.
Gowning Area
Sample Reception
Storage - Reagents & consumables
Cabinet 5

2000 samples/day or 4000 samples per day (double shift):

Sample sorting bench
Sorting & Dissection Lab.
Gowning Area
Sample Reception
Storage - Reagents & consumables
Cabinet 5
Cabinet 6
### Equipment

<table>
<thead>
<tr>
<th>Equipment Item</th>
<th>500 samples per day</th>
<th>1000 samples per day</th>
<th>2000 or 4000 samples per day</th>
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</thead>
<tbody>
<tr>
<td>Centrifuge</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Luminometer</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Skatron Washer</td>
<td>2</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Incubator (9 place)</td>
<td>1</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Safety Cabinet (6ft)</td>
<td>3</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>ETDS VIII</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>PC</td>
<td>2</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Barcode Printer</td>
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<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Fridge</td>
<td>2</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Freezer</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Single Pipettes</td>
<td>5</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Multichannel Pip</td>
<td>4</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Misc</td>
<td>1</td>
<td>1</td>
<td>2</td>
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</table>

### Staff:

<table>
<thead>
<tr>
<th>Samples Per Day</th>
<th>Dissection Staff</th>
<th>Analytical Techs</th>
<th>Total Staff</th>
<th>Sample Taking Total Staff</th>
</tr>
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<tr>
<td>500</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>1</td>
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<tr>
<td>1000</td>
<td>3</td>
<td>3</td>
<td>6</td>
<td>2</td>
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<tr>
<td>2000</td>
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<td>4</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td>4000</td>
<td>10</td>
<td>8</td>
<td>18</td>
<td>4</td>
</tr>
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</table>

### Disposables:

<table>
<thead>
<tr>
<th>Item</th>
<th>Units/Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETDS Tube</td>
<td>1</td>
</tr>
<tr>
<td>Sample Cutter</td>
<td>1</td>
</tr>
<tr>
<td>Weigh Boat</td>
<td>1</td>
</tr>
<tr>
<td>Tongue Depressor</td>
<td>½</td>
</tr>
<tr>
<td>1000uL Tip</td>
<td>1</td>
</tr>
<tr>
<td>2000uL Tip</td>
<td>2</td>
</tr>
<tr>
<td>Misc</td>
<td>1</td>
</tr>
</tbody>
</table>

Miscellaneous: Waste disposal – SRM and normal lab waste
Electricity
Telephone
Fuel
Water rates etc.

### Cost Summary

<table>
<thead>
<tr>
<th>Number of Samples Per Day</th>
<th>500</th>
<th>1000</th>
<th>2000</th>
<th>4000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Cost Per Test</td>
<td>$18.10</td>
<td>$16.90</td>
<td>$16.19</td>
<td>$15.88</td>
</tr>
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</table>
Should you have any further questions, please do not hesitate to call at 1-800-387-8378.

Thank you for your interest.

Sincerely,

ABBOTT LABORATORIES, LIMITED

[Signature]

Graham Tolfree
Laboratory Area Director
Diagnostics Division

GTms
Enfer TSE Kit
Version 2.0

04J06 (1100 duplicate tests)

An immunoassay for the detection of the prion protein PrPsc in cattle and sheep

For in vitro veterinary diagnostic use only

Manufactured by
Enfer Scientific Limited
Boxer House, Unit 4
Newbridge Industrial Estate
Newbridge, Co. Kildare
Tel.: +353 454 35997

Manufactured for:
Abbott Laboratories
100 Abbott Park Road,
Abbott Park, IL 60064-3500
USA

Distributed in Europe by:
ABBOTT
Max-Planck-Ring 2
65205, Wiesbaden
Germany
Tel.: +49 6122 580

Key to symbols used:

Lot: Store at -25°C to -15°C

Use by Store at 2°C to 8°C

Store at 2°C to 30°C

Store at 10°C to 30°C

Note Changes Highlighted
General Information

Transmissible Spongiform Encephalopathies (TSEs) are a group of degenerative neurological diseases. There are a number of examples of TSEs including BSE (Bovine), Scrapie (Ovine), CJD (Human), GSS (Human), Kuru (Human), Transmissible Mink Encephalopathy, Chronic Wasting Disease (Mule Deer), Feline Spongiform Encephalopathies and other diseases found in animals such as elk, nyala, greater kudu, gemsbok and tigers. It has also been reported that BSE can be transmitted to mice and pigs under laboratory conditions. This crossing of the species barrier by the infective agent has led to increased concern that transfer to humans could occur.

Post-mortem of infected animals reveal a characteristic pattern of vacuolation in the brain tissue due to destruction of neural cells and the deposition of unusual protein fibres, which give the brain a spongy texture. The agent thought to be responsible for TSEs is an infective protein known as a ‘Prion’. The prion is an infectious particle believed to comprise of protein only and no nucleic acid. One protein, PrPSc, has been found to co-purify with infectivity and is the only known component of the characteristic protein fibres deposited in the brain tissue of infected animals.

Intended Use

The Enfer TSE Kit Version 2.0 is a qualitative immunological method for the detection of the unique identifier of Transmissible Spongiform Encephalopathies, the prion protein PrPSc, in central nervous tissue of cattle and sheep. The kit is intended for screening and research purposes only.

Principle of the procedure

A sample of central nervous tissue is dissected from the hind brain (including the Obex region) or upper cervical spinal column, transported to the testing laboratory, homogenised under defined conditions and centrifuged. The supernatant is incubated in prepared microwells: during this incubation any PrPSc in the sample is bound to the wells. After a washing step the wells are treated with Enfer Buffer 3. After a second washing step rabbit anti-PrP is added to the well and incubated; if any PrPSc is present on the well this antiserum will specifically bind to it. After a third washing step goat anti-rabbit IgG conjugated to horse radish peroxidase is added to the wells and incubated; if any rabbit anti-serum is present on the well the conjugate will be bound. After a fourth wash any bound conjugate is detected using a luminogenic substrate for peroxidase.

Reagents

Enfer TSE Kit Version 2.0 (04J06) comprising of:

- 04J06-06, Reagent Pack (25 plate)
- 04J06-12, Antibody Pack (25 plate)
- 04J06-26, Buffer Pack (25 plate)
- 04J06-31, Wash Pack (25 plate)

Accessory reagent for Enfer TSE Kit Version 2.0 (04J06)

- 04J06-50, Enfer Buffer 1
Kit Components

Reagent Pack

1. **Enfer Buffer 3**  
   1 bottle containing 400 ml of a ready to use solution.

2. **Enfer Wash 1**  
   1 packet containing 1.25 kg of powder.

3. **Normal Goat Serum**  
   1 bottle containing sufficient material for 1100 tests.

4. **Enzyme-conjugate – 2° Ab (goat anti-rabbit)**  
   1 bottle containing sufficient material for 1100 tests.

5. **Substrate Solution A**  
   1 bottle containing 250 ml of a ready to use solution.

6. **Substrate Solution B**  
   1 bottle containing 250 ml of a ready to use solution.

7. **Centrifuge Plate**  
   30 plates ready to use.

8. **Enfer Test Plate**  
   25 plates ready to use.

9. **Peptide Indicator Wells**  
   64 wells ready to use.

10. **Blank Control Reagent**  
    1 bottle containing 30 ml of a ready to use solution.

Antibody Pack

1. **Enfer Buffer 2**  
   2 bottles each containing 60 ml of a ready to use solution.

2. **Anti-PrP – 1° Ab (rabbit)**  
   1 bottle containing sufficient material for 1100 tests.

Buffer Pack

1. **Enfer Buffer 1**  
   1 bottle containing 10 L of a ready to use solution.
   
   Ensure that buffer is crystal free prior to use.

   The Enfer Buffer 1 supplied with this kit may be used interchangeably with reagents from another Enfer TSE Kit Version 2.0.

Wash Pack

1. **Enfer Wash 2**  
   1 bottle containing 10 L of a 10x concentrate solution.
   
   Ensure that material is crystal free prior to use.

Stability and Storage

Store Reagent Pack at 2 to 8°C.

Store Antibody Pack at -25 to -15°C.

Store Buffer Pack at 10 to 30°C.

Store Wash Pack at 10 to 30°C.
Enfer Buffer 1 must be stored at 10 to 30°C; Enfer Buffer 3 and the Blank Control Reagent must be stored at 2 to 30°C; Enfer Buffer 2 must be stored at -25 to -15°C.

Enfer Wash 1 is a solid and must be stored at 2 to 30°C. Store reconstituted Enfer Wash 1 for up to 6 months at 2 to 8°C.

Enfer Wash 2 concentrate must be stored at 10 to 30°C. Prepared Enfer Wash 2 is stable at 10°C to 30°C for up to two weeks. Store at 2 to 8°C for up to 1 month.

Anti-PrP – 1°Ab must be stored at -25 to -15°C.

Enzyme-conjugate – 2°Ab must be stored at 2 to 8°C.

Normal Goat Serum must be stored at 2 to 8°C.

Enfer Test Plates must be stored in sealed bags, with desiccants, at 2 to 30°C until required. Enfer Test Plates must be at the temperature of the room before starting the assay. Return unused wells to the storage bag with desiccant. Do not, under any circumstances, freeze Enfer Test Plates.

Peptide Indicator Wells must be stored in sealed bags, with desiccants, at 2 to 8°C until required. Peptide Indicator Wells must be at the temperature of the room before starting the assay.

Substrate Solution B must be stored at 2 to 8°C under dark conditions.

Substrate Solution A must be stored at 2 to 8°C.

Working strength Anti-PrP – 1°Ab plus Normal Goat Serum (NGS) must be used on the day of preparation. Working strength Enzyme-conjugate – 2°Ab must be used within 2 hours of preparation.

Substrate Solution must be prepared at least one hour before it is used to allow the working strength substrate solution to come to room temperature. Substrate Solution must be kept dark and used on day of preparation. Return unused Substrate Solutions A and B to 2 to 8°C directly after preparing the working strength Substrate Solution.

Warnings and Precautions

The reagents are solely for in-vitro veterinary diagnostic use on Bovine or Ovine samples.

For professional use only.

Please refer to the manufacturer’s safety data sheet and the product labelling for information on potentially hazardous components.

Perform the sample preparation, sample transfer to the Enfer Test Plate and Wash Step 1 in a laminar flow cabinet.

Health and safety information

Enfer Buffers 1, 2 & 3 should be handled with care. Avoid contact with skin, eyes and clothes. Do not inhale the reagents, wash immediately with water should contamination occur. Please note hazards identified on individual container labels.

Enfer Buffer 2 contains protease, which is classified per applicable European Economic Community (EEC) Directives as harmful (Xn). The following are the appropriate risk phrases.

<table>
<thead>
<tr>
<th>Xn</th>
<th>R42/43</th>
<th>S35</th>
<th>S36/37</th>
<th>S46</th>
</tr>
</thead>
<tbody>
<tr>
<td>☒</td>
<td></td>
<td>May cause sensitisation by inhalation and skin contact</td>
<td>This material and its container must be disposed of in a safe way</td>
<td>Wear suitable protective clothing and gloves</td>
</tr>
</tbody>
</table>
Enfer Buffer 3 contains guanidinium chloride, which is classified per applicable European Economic Community (EEC) Directives as harmful (Xn). The following are the appropriate risk phrases.

<table>
<thead>
<tr>
<th>Xn</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>R22</td>
<td>Harmful if swallowed</td>
</tr>
<tr>
<td>R36/38</td>
<td>Irritating to eyes and skin</td>
</tr>
<tr>
<td>S35</td>
<td>In case of contact with eyes, rinse immediately with plenty of water and seek medical advice</td>
</tr>
<tr>
<td>S36/37</td>
<td>This material and its container must be disposed of in a safe way</td>
</tr>
<tr>
<td>S36/37</td>
<td>Wear suitable protective clothing and gloves</td>
</tr>
<tr>
<td>S46</td>
<td>If swallowed, seek medical advice immediately and show this container or label</td>
</tr>
</tbody>
</table>

Enfer Buffer 1 and the Blank Control Reagent contain methanol, which is classified per applicable European Economic Community (EEC) Directives as toxic (T). The following are the appropriate risk phrases.

<table>
<thead>
<tr>
<th>T</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>R10</td>
<td>Flammable</td>
</tr>
<tr>
<td>R20/21/22</td>
<td>Harmful through inhalation, in contact with skin and if swallowed</td>
</tr>
<tr>
<td>R23/24/25</td>
<td>Toxic by inhalation, in contact with skin and if swallowed</td>
</tr>
<tr>
<td>R36/38</td>
<td>Irritating to eyes and skin</td>
</tr>
<tr>
<td>R39</td>
<td>Danger of very serious irreversible effects</td>
</tr>
<tr>
<td>S46</td>
<td>Keep away from sources of ignition. No smoking</td>
</tr>
<tr>
<td>S26</td>
<td>In case of contact with eyes, rinse immediately with plenty of water and seek medical advice</td>
</tr>
<tr>
<td>S35</td>
<td>This material and its container must be disposed of in a safe way</td>
</tr>
<tr>
<td>S36/37/39</td>
<td>Wear suitable protective clothing, gloves and eye/face protection</td>
</tr>
<tr>
<td>S45</td>
<td>In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)</td>
</tr>
</tbody>
</table>

Information for European Customers: For products not classified as dangerous per European Directive 1999/45/EC, Safety Data Sheet for professional user on request.

As is standard when working with biological material, sufficient protective clothing (including protective overalls, protective overgloves, cut-resistant and disposable safety gloves, safety glasses and hair covers) should always be worn when handling potentially infectious material such as central nervous tissue.

Contaminated surfaces must be cleaned by swabbing with 1M NaOH or 6° chlorometric sodium hypochlorite solutions, rinsed with distilled water, alcohol and dried. To decontaminate used wash fluid add 5M NaOH in the ratio 1 of 5M NaOH to 10 of waste and leave overnight.

Prior to disposal, any materials coming into contact with potentially infectious tissue must be treated by soaking in 1M NaOH or 6° chlorometric sodium hypochlorite solutions for 1 hour at room temperature or autoclaved at 138°C for 20 minutes.

Central nervous tissue samples must be disposed of as Specified Risk Material according to local regulations.
See SI No. 146 of 1994 (EU guidelines) for relevant regulations on Safety, Health & Welfare at Work, for an extensive review of recommended safety procedures when working with potentially infectious biological material.

**Specimen collection, transport and storage**

Samples of central nervous tissue from the hindbrain (including the Obex region) or upper cervical spinal cord of cattle or sheep can be tested. No other tissue can be used. Samples must be obtained using a method that guarantees no cross-contamination.

No special shipping conditions are required for transportation of samples to the laboratory but when storage of samples is required they can be stored for up to 24 hours at 2 to 8°C or at −25 to −15°C for longer periods. Fixation with formalin for any proposed confirmatory analysis using histopathological or immunohistochemical processes must be done immediately after the samples are taken. Samples for such confirmation must be transported in such a way as not to destroy the sample and must not be frozen, under any circumstances, before formalin fixation is complete.

**Procedure**

**Materials provided:**

Sufficient reagents are provided to assay 1100 (25 plate kit) samples.

**Materials required but not provided**

*High quality deionised, distilled or reverse osmosis water, indicated by H$_2$O must be used throughout.*

Seward Stomacher 80*

Interscience homogeniser bags (with filter)

2 Skatron Skanwaser® 300 microplate washer*

Thermo LabSystems iEMS incubator/shaker*

Thermo LabSystems Ascent microplate chemiluminescence reader*

Microplate centrifuge capable of 2750 g

Bottle roller or shaker to help dissolve Enfer Wash 1

Microplate sealers

Multichannel pipettes (5 to 50 μl and 50 to 300 μl)

Micropipettes (5 to 50 μl, 50 to 200 μl, 100 to 1000 μl, 5 ml)

Variable volume reagent dispenser

Dissection blades

Weigh boats

Tongue depressors

Glass containers for dilution of the Anti-PrP and the Conjugate

Glass or polypropylene containers for dilution of other reagents

Positive and Negative Tissue Controls (See **Preparation of Tissue Controls**)

*This apparatus is essential for running the assay

**Instrument set-up parameters**

The following parameters must be programmed into the recommended instruments. Other instruments have not been validated.
**Washer**

2 separate washers are required for running this test.

**For both protocols:**

Air pressure: 0.25 bar
Volume/Flow rate, adjustment offset \( \sigma v : 1.00 \)
Aspirate position (usually between 3.00mm and 4.00mm)
Dispense position: 0.00mm

**Protocol 1** (used with Enfer Wash 1 and washer 1. This wash must be performed in a laminar flow cabinet.)

Steps:

# 1 Aspirate 6 seconds
# 2 Dispense 300 µl
# 3 Soak 5 seconds
# 4 Aspirate 4 seconds
# 5 Wash 5 seconds
# 6 Soak 5 seconds
# 7 Aspirate 3 seconds
# 8 Wash 2.5 seconds
# 9 Soak 5 seconds
# 10 Aspirate 2 seconds
# 11 Wash 2 seconds
# 12 Soak 5 seconds
# 13 Aspirate 5 seconds
# 14 End Wash

**Protocol 2** (used with Enfer Wash 2 and washer 2)

Steps:

# 1 Aspirate 4 seconds
# 2 Wash 3 seconds
# 3 Soak 5 seconds
# 4 Aspirate 2 seconds
# 5 Wash 3 seconds
# 6 Soak 5 seconds
# 7 Aspirate 2 seconds
# 8 Wash 3 seconds
# 9 Soak 5 seconds
# 10 Aspirate 2 seconds
# 11 Wash 2 seconds
# 12 Soak 5 seconds
# 13 Aspirate 4 seconds
# 14 End Wash

**Shaking incubator:** shake value 5, 34°C.

**Chemiluminometer:** plate acceleration: 10; settle delay: 100; filter: none; measurement type: single; integration time: 300; [tag time: 30 seconds]; measurement count: 1; photomultiplier (PMT) voltage: default; plate type: 96 well; scale factor: \( \sim 8 \)
Preparation of tissue controls

Negative Tissue Control
Use of a negative tissue control is very strongly recommended.

To a sample of verified negative CNS tissue, add an equal volume of H₂O, e.g. to 10 g of tissue add 10 ml of H₂O.

Homogenise the tissue vigorously (sufficiently that the homogenate can be pipetted) using a domestic hand held blender. Do not use a high speed high sheer blender such as the Ultraturrax or Silverstone homogeniser.

Aliquot into desired volumes (e.g. 1 ml) and store at −25°C to −15°C until required.

Once thawed negative tissue control must not be re-frozen and must be used on the day it is thawed.

Once thawed dilute the sample 1:15 in Enfer Buffer 1, e.g. to 1 ml sample add 15 ml of Enfer Buffer 1 and mix.

This tissue is potentially infectious and must be handled following strict safety procedures.

Never pool tissues from different animals for the purpose of preparing negative tissue control as pooling samples can lead to ambiguous results.

Positive Tissue Control

Intact tissue stored at −70°C should be used.
Preparation of reagents

Enfer Wash 1

Prepare Enfer Wash 1 by adding 50 g of solid per litre of H₂O. Allow to solubilise on a rotating bottle shaker for 10 minutes, or until in solution, before use.

Enfer Wash 2

Perform a 1/10 dilution of wash concentrate by adding, for example, 100 ml of wash concentrate to 900 ml deionised water as required.

Anti-PrP – 1°Ab plus Normal Goat Serum (NGS)

The Anti-PrP – 1°Ab and the Normal Goat Serum must be diluted in working strength Enfer Wash 2 solution. PREPARE THE DILUTIONS ACCORDING TO THE DIRECTIONS ON THE GOAT SERUM AND ANTI-PRP – 1°AB MICROVIAL LABELS. Mix by inversion. Prepare only the required volume of Anti-PrP – 1°Ab for the number of tests to be carried out, each strip of 8 wells requires 2.0 ml working strength Anti-PrP – 1°Ab plus NGS. Working strength Anti-PrP – 1°Ab plus NGS must be stored at 2 to 8°C and used on day of preparation.

Enzyme-conjugate – 2°Ab

PERFORM THE DILUTION STATED ON THE LABEL, OF ENZYME-CONJUGATE – 2°AB IN WORKING STRENGTH ENFER WASH 2 SOLUTION. Mix by inversion. Prepare only the required volume of Enzyme-conjugate – 2°Ab for the number of tests to be carried out, each strip of 8 wells requires 2.0 ml working strength Enzyme-conjugate – 2°Ab. Working strength Enzyme-conjugate – 2°Ab must be stored at 2 to 8°C in the dark and used within 2 hours of preparation.

Enzyme substrate solution

Add an equal volume of Substrate Solution A to Substrate Solution B. Prepare only the required volume of Substrate Solution for the number of tests to be carried out. Each strip of 8 wells requires 2.0 ml of working strength Substrate Solution. Prepare the Substrate Solution at least one hour before use to allow it to come to the temperature of the room. It must be kept dark and used on the day of preparation. Return unused Substrate Solutions A and B to 2 to 8°C directly after preparing the Working Strength Substrate Solution.

Procedural notes

The Enfer Buffer 1 supplied with this kit may be used interchangeably with reagents from another Enfer TSE Kit Version 2.0. No other reagents may be interchanged between kit lots.

Antisera and enzyme substrate solutions must be reconstituted in glass containers. All other reagents must be prepared in clean glass or polypropylene bottles.

POLYSTYRENE CONTAINERS MUST NOT BE USED FOR STORAGE OR RECONSTITUTION OF MATERIALS.
It is very important that high quality deionised or distilled water is used to reconstitute and dilute reagents as horseradish peroxidase is readily inactivated by pollutants common in laboratory water supplies.

Once the assay has been started it must be completed without interruption.

Use separate dissection and transfer equipment and disposable tips for each sample to prevent cross-contamination.

All reagents must be crystal free prior to use.

Reverse pipetting is recommended for all reagent additions and for transfer of sample from homogeniser bag to Centrifuge Plate but not for the transfer into the Enfer Test Plate.

Remove plate sealers carefully in a laminar flow cabinet to avoid contamination by aerosols, before the first wash step in the assay procedure.

Turn on the incubators at least 30 minutes before they are used to ensure they reach 34°C.

Replace the thermal microplate-holder in the incubator slot directly after removing the plate; this ensures it maintains a constant temperature.

**Procedure**

**Sample Preparation**

A new blade, tongue depressor, weighing boat and homogeniser bag must be used for each sample to prevent cross contamination.

Label a homogeniser bag with the identity of the sample it will contain, the label now indicates the front of the bag.

**Cut a thin cross section of CNS tissue weighing approximately 1.0 g, strictly no less than 0.5 g of tissue must be used to prepare the homogenate.**

Prepare the cross section by removing the end of the tissue to avoid any cross contamination which may have occurred during sampling. Take a thin cross-sectional slice from the cut end. If this weighs less than 0.5 g then a fresh cross section must be cut. For autolysed samples between 1.5 g and 2 g of tissue must be used.

Weigh the sample and place it in front of the filter in the homogeniser bag, ensuring that the sample is pushed to the bottom of the bag. Squash the sample between thumb and forefinger to aid subsequent homogenisation.

Add the required quantity (15 ml of buffer per 1 g of tissue, see Table 1) of Enfer Buffer 1 to the homogeniser bag. The buffer dispenser must not come into contact with the bag to prevent cross contamination of samples.

Homogenise the sample for 2 minutes at speed setting ‘high’ in a stomacher. Ensure that the tissue sample has been broken down and a clear light brown solution can be seen behind the filter. The assay will be affected if this step is not done correctly.

After homogenisation the samples must be left in the homogeniser bag for between 5 and 10 minutes to allow the bubbles to subside.

**DO NOT STORE HOMOGENISED SAMPLES, USE THEM WITHIN 3 HOURS OF PREPARATION.**
Table 1: Sample Dilutions in Enfer Buffer 1

<table>
<thead>
<tr>
<th>Sample Weight (g)</th>
<th>Volume of Enfer Buffer 1 (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.51 to 0.55</td>
<td>8.25</td>
</tr>
<tr>
<td>0.56 to 0.60</td>
<td>9.00</td>
</tr>
<tr>
<td>0.61 to 0.65</td>
<td>9.75</td>
</tr>
<tr>
<td>0.66 to 0.70</td>
<td>10.50</td>
</tr>
<tr>
<td>0.71 to 0.75</td>
<td>11.25</td>
</tr>
<tr>
<td>0.76 to 0.80</td>
<td>12.00</td>
</tr>
<tr>
<td>0.81 to 0.85</td>
<td>12.75</td>
</tr>
<tr>
<td>0.86 to 0.90</td>
<td>13.50</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample Weight (g)</th>
<th>Volume of Enfer Buffer 1 (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.91 to 0.95</td>
<td>14.25</td>
</tr>
<tr>
<td>0.96 to 1.00</td>
<td>15.00</td>
</tr>
<tr>
<td>1.01 to 1.05</td>
<td>15.75</td>
</tr>
<tr>
<td>1.06 to 1.10</td>
<td>16.50</td>
</tr>
<tr>
<td>1.11 to 1.15</td>
<td>17.25</td>
</tr>
<tr>
<td>1.16 to 1.20</td>
<td>18.00</td>
</tr>
<tr>
<td>1.21 to 1.25</td>
<td>18.75</td>
</tr>
</tbody>
</table>

Immuoassay Procedure

All reagents including wash solutions, Enfer Test Plates, Peptide Indicator Wells and Centrifuge Plates must be at the temperature of the room (between 18 and 30°C) and be crystal free before starting the assay. If crystals are present in Enfer Buffer 1, Wash 2 concentrate or Blank Control incubation at 37°C for a short period is recommended. Storing these buffers in a transparent container is highly recommended so that any crystals are easily visible.

1) Dispense 180 µl of negative tissue control, positive tissue control and each sample in duplicate onto a Centrifuge Plate, add 180 µl of Blank Control Reagent in quadruplicate onto the Centrifuge Plate. The positive tissue control, if used, should be placed in positions A1, A2, otherwise do not fill these wells.

ALWAYS pipette from behind the filter in the homogeniser bag. Take great care not to allow the pipette to be contaminated on the outside by material from within the homogeniser bag. Ensure that only the disposable tip is inserted into the bag.

2) Cover the plate with a plate sealer.

3) Centrifuge the plate at 2750 g for 5 minutes at 18 to 30°C. DO NOT centrifuge at 2 to 8°C.

4) Add 20 µl of Enfer Buffer 2 to all the wells of the Enfer Test Plate. It is very important that this buffer is pipetted to the very bottom of the wells: it has a tendency to stick to the sides of the wells and this must be prevented.

5) Remove the plate sealer and transfer 100 µl of each centrifuged sample, Blank Control Reagent and tissue controls to the corresponding position on the Enfer Test Plate containing Enfer Buffer 2. Handle the centrifuge plate very carefully to avoid disturbing the pellet and take care not to transfer any solid material to the Enfer Test Plate.

6) Cover the plate with a plate sealer.

7) Incubate the plate, shaking, for 60 minutes at 34°C.

8) Remove the plate sealer and wash the plate using Enfer Wash 1 solution and wash protocol 1.

9) Invert the plate on a wad of tissue and tap it to remove any remaining liquid.

10) Add 150 µl of Enfer Buffer 3 to all the wells.

11) Cover the plate with a plate sealer.
12) Incubate the plate, shaking, for 15 minutes at 34°C.
13) Remove the plate sealer and wash the plate using Enfer Wash 2 solution and wash protocol 2.
14) Invert the plate on a wad of tissue and tap it to remove any remaining liquid.
15) If using Peptide Indicator Wells, remove positions A1 and A2 from the Enfer Test Plate and replace with Peptide Indicator Wells.
   It is extremely important to ensure that these wells are inserted properly – the top of the wells MUST be flush with the tops of all the other wells on the plate.
16) Dispense 150 µl of prepared Anti-PrP – 1°Ab plus NGS into each well.
17) Cover the plate with a plate sealer.
18) Incubate the plate, shaking, at 34°C for 40 minutes.
19) Remove the plate sealer and wash the plate using Enfer Wash 2 solution and wash protocol 2.
20) Invert the plate on a wad of tissue and tap it to remove any remaining liquid.
21) Dispense 150 µl of prepared Enzyme-conjugate– 2°Ab onto the plate.
22) Cover the plate with a plate sealer.
23) Incubate the plate, shaking, at 34°C for 30 minutes.
24) Remove the plate sealer and wash the plate using Enfer Wash 2 solution and wash protocol 2.
25) Invert the plate on a wad of tissue and tap it to remove any remaining liquid.
26) Add 150 µl of prepared Substrate Solution to the plate.
27) Cover the plate with a plate sealer.
28) Incubate the plate, shaking, at 34°C for 10 minutes.
29) Remove the plate sealer and read the light signal immediately using a chemiluminometer.

**Validation of Test Performance**

The control results must be validated before the sample results can be interpreted.

Determine the mean luminescence of Peptide Indicator Wells, Positive and Negative Controls and calculate the median value for the Blank Control Reagent.

**Acceptable Range of Means:**

The values given are for measurements made on an Enfer recommended chemiluminometer.

**Blank Control Reagent**

To calculate the median value of the Blank Control Reagent, arrange the four Light Unit values in ascending numerical order. The median is the arithmetic average of the two middle values.

The median value of the Blank Control Reagent must be below 4.0 LU.
Peptide Indicator Well:
(Applicable only when the Peptide Indicator Wells, supplied by Enfer Scientific Limited are used)
See the value for the provided lot of Peptide Indicator Wells.
The value must be equal to or above the limit supplied with the Peptide Indicator Wells (after subtraction of the median blank value).

Negative Tissue Control
The mean must be less than 3.0 LU (after subtraction of the median blank reading).
If the above criteria are not met, the EIA run is invalid and must be repeated.

Sensitivity
The threshold light signal for a suspect positive determination is 5.5 LU (after subtraction of the median blank reading) as measured on an Enfer recommended chemiluminometer.
All samples yielding values greater than 5.5 LU must be retested in duplicate, starting from the tissue.

Samples that are reactive in one or both duplicate wells must be considered as initial reactive samples. These samples must be repeated in duplicate, starting from the tissue.

Limitations of the Procedure
As with any biological test, this test may give a false positive or a false negative result owing to local conditions. A test should be interpreted in the context of all available clinical, historical and epidemiological information relevant to the animal(s) under test. Further confirmatory testing may be required in certain circumstances.

A negative result with a qualitative immunological method does not preclude the possibility of infection with the prion protein PrPSc.

These performance data were obtained using the procedure described. Any change or modification of the procedure might affect the results.

Results obtained for TSE positive material may vary as prion distribution in the tissue varies and stability of stored tissue cannot be guaranteed.

Responsibility for test interpretation and consequent animal husbandry decisions rests solely with the user and any consulting veterinarian and appropriate animal health advisors or authorities. Enfer Scientific Limited accepts no responsibility for any loss or damage, howsoever caused, arising out of the interpretation of test results.

Disclaimer & Reservation of Rights
Enfer Scientific Limited gives no warranty of any kind, whether expressed or implied, in regard to the carrying out of the Enfer TSE Kit Version 2.0, or for the stability and storage of the Enfer kit, or for the procedure used. Without prejudice to the foregoing, Enfer Scientific Limited disclaims all responsibility for merchantability and fitness for use after it leaves Enfer Scientific Limited. Enfer Scientific Limited shall not be liable, under any circumstances, for damages, direct or consequential.
## Recommended Plate Layout

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
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<tbody>
<tr>
<td>A</td>
<td>P</td>
<td>P</td>
<td>S5</td>
<td>S5</td>
<td>S13</td>
<td>S13</td>
<td>S21</td>
<td>S21</td>
<td>S29</td>
<td>S29</td>
<td>S37</td>
<td>S37</td>
</tr>
<tr>
<td>B</td>
<td>B</td>
<td>B</td>
<td>S6</td>
<td>S6</td>
<td>S14</td>
<td>S14</td>
<td>S22</td>
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<td>S30</td>
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<td>B</td>
<td>B</td>
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<td>S7</td>
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<td>S15</td>
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<td>N</td>
<td>N</td>
<td>S8</td>
<td>S8</td>
<td>S16</td>
<td>S16</td>
<td>S24</td>
<td>S24</td>
<td>S32</td>
<td>S32</td>
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<tr>
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<td>S28</td>
<td>S36</td>
<td>S36</td>
<td>S44</td>
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</tr>
</tbody>
</table>

**P** = Positive Control: (Peptide Indicator Well or Tissue Positive Control)

**B** = Blank Control Reagent

**N** = Negative Tissue Control from a central nervous tissue sample not containing PrPsc

**S** = Test Samples in duplicate

---

C034J06GB

July 2002
Abbott Laboratories offer a complete testing solution for TSE testing labs:

- Reagent Kit
- disposables
- Instrumentation
- Service and support

Front End Automation
Do you have 10 seconds ...
to prepare a BSE sample homogenate?

The Enfer TSE Front End Automation has been designed to optimise and facilitate sample preparation in BSE testing laboratories. New instruments and disposables have been developed and validated to allow:

- Safe and fast sample cutting
- Rapid homogenisation
- Reduced single sample handling

![The ETDS VIII](image)

**Homogenises 8 samples in only 10 seconds**

- Designed for single-use only
- No time-consuming cleaning procedures
- Cap clip-on feature instead of screwing
- Allows automated pipetting

**The Enfer sample cutting tool**

- Increased laboratory safety
- Rapid sampling
- Easy disposal
- Uniform cuts

---

**Performance**

<table>
<thead>
<tr>
<th></th>
<th>%</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity*</td>
<td>100%</td>
<td>94%</td>
</tr>
<tr>
<td>Specificity*</td>
<td>100%</td>
<td>98%</td>
</tr>
</tbody>
</table>

*The Enfer TSE Kit 2.0 automated sample preparation was evaluated by the European Commission. Results were published in the "Scientific Report of the European Food Safety Authority on the Evaluation of Seven New Rapid dpr/motm. BSE Tests".
The Enfer TSE Test

BSE

Date: November 2005

Author: Dr. Sandra Luley
Who is Enfer Scientific?

- The **largest** tester of beef carcasses for BSE in the world.
- Developer of designer diagnostic screening tests for the food & agriculture industries e.g. Enfer β-Agonist Detection Assay, Enfer Equine Fertility Assay, Enfer TSE Diagnostic Assay.
- Testing routinely 1000-4000 samples/night ⇒*the biggest BSE lab in the world*
ENFER IN EUROPE

• EU countries started testing January 2001
• Abbott signed distribution agreement with Enfer in March 2001;
  European registration started
• Currently Enfer used in Ireland, Denmark, Germany, France, Lithuania, Slovenia, Italy, Slovakia, Czech Republic and Japan
• Ca. 10 million BSE tests were done in EU for 2004
  ~2 million (20%) were done on the Enfer Assay
THE ABBOTT/ENFER PARTNERSHIP

Responsibilities

Enfer Scientific:
- Production
- Quality Control
- Reference Lab
- Training/Troubleshooting
- R&D

Abbott GmbH & Co. KG:
- Sales
- Marketing
- Training/Troubleshooting
- Regulatory Affaires
- Production control/Audits
- QA control
- Logistics
- R&D

The Enfer TSE Test
Nov. 2005

Abbott
A Promise for Life
Sales / Marketing:

- Abbott offices in more than 130 countries

- European headquarter in Delkenheim
THE ENFER TEST IN EUROPE

Approval Status

Regulatory Affairs:

- Controled by Abbott/ Murex
- Approval also for USA, Argentina and Japan

The Enfer TSE Test
Nov. 2005
THE ABBOTT/ENFER PARTNERSHIP

Control of test production:
- Abbott/Murex QA specialists conduct regular audits of Enfer's test production

Control of Quality Assurance:
- Abbott standards
- Batch release testing done at Enfer
- Results controlled by Murex
- Each component tested single and as kit component
- Every Enfer TSE kit is tested on BSE positive material before released for sale by Murex
- Additional testing of 1000 negative samples/batch
THE ABBOTT/ENFER PARTNERSHIP

Logistics

Test production Enfer/Ireland

Quality control Enfer/Ireland

QA docs sent to Murex

QA docs checked by Murex QA specialist

Reagents shipped to Delkenheim (refrigerated)

Distribution to customers from Delkenheim
R&D labs at Abbott/Murex and Enfer Scientific
Additional validation studies at customer sites, e.g. FE automation
THE ENFER TSE TEST

- Rapid post-mortem test for the detection of PrP\textsuperscript{sc}, the unique identifier of TSEs, in Central Nervous Tissue

- ELISA technique utilizing a 96 well microtitre plate

- Chemiluminescent Technology

- Sample preparation time (45 samples) – < 1 hour

- Total plate incubations – 2.5 hours

\Rightarrow 3 - 3.5 hours to analyze 45 samples in duplicate
THE ENFER TSE TEST

1,2,3 Assay principle

1. Sample dissection & Sample preparation involving a series of 3 Enfer buffers to liberate \( \text{PrP}^{sc} \).

2. Qualitative enzyme immunoassay based on the sequential addition of sample, antibody, antibody-enzyme conjugate and chemiluminescent substrate.

3. Data reduction / calculation with light intensity.
TEST PRINCIPLE

• Homogenisation & incubation with Enfer buffers 1 & 2 (EB 2 contains proteinase k) digest the PrP<sup>c</sup> leaving only PrP<sup>sc</sup>.

• The PrP<sup>sc</sup> which is left is then bound to the Enfer coated plate by non-antibody mediated adsorption.

• The primary antibody used for detection is specific for the prion protein.

• Recognising both BSE & Scrapie.

• The peptide used to generate the primary antibody is the same peptide used for the positive control.
ASSAY PROCEDURE

Passive adsorption of PrP\textsuperscript{Sc}

- Proteinase K is added directly to the test plate, followed by the homogenized sample
- PrP\textsuperscript{c} is digested. Solubilised PrP\textsuperscript{sc} is adsorbed onto the well
- Incubation is at 34°C, shake speed 5
- Followed by a wash step in 5% NaCl
- Proteinase K is inactivated by denaturation in Guanadine HCl and NaOH
- This unfolds PrPSc allowing more Ab to bind
- Followed by a wash in Tween PBS
ASSAY PROCEDURE

Enzyme Immunoassay

Primary Antibody binds to PrP<sup>sc</sup>
- Rabbit anti-PrP
- Shaking incubation at 34°C
- Wash in Tween PBS

Secondary Antibody binds to the primary antibody
- Goat anti-rabbit Ig, labelled with HRPO

Light signal generated from chemiluminescent substrate
PRINCIPLE OF PRION PURIFICATION

Positive Sample

PrP^sc + PrP^c \rightarrow EB1 \rightarrow Solubilisation of Prions \rightarrow EB2 Digestion

PrP^sc aggregates
& captured by Enfer-test plate

Aggregated PrP^sc (prion) \rightarrow Microtitre well

Negative Sample

PrP^c only

No prion aggregation

Microtitre well \rightarrow No PrP^sc (prion)
ENFER TSE ELISA

Substrate

Secondary antibody

Primary antibody

PrP\text{sc} (prion)

Microtitre well

Chemiluminometer

LIGHT
THE ENFER TSE KIT v.2.0
(autom.sample.prep.)
AUTOMATED SOLUTION

Front End

- Blade
- Stomacher
- Manual sample transfers/PK digestion

Washer
Incubator
Luminometer

- Safety
- Speed
- Uniformity
- Speed
- Ease
- Auto pipetting
- Workflow

All-In-One
e.g. Stratec 4PS
- Replaces all 3 back-end instruments

All-In-One
e.g. Hamilton FAME
- Targets high-volume labs

Coming 2006

The Enfer TSE Test
Nov. 2005
BENEFITS OF ENHANCED SAMPLE PREPARATION

OLD

Safer Sample Cutting

NEW

- No sharps
- Standard cuts
- Easy disposal
- Rapid
- Inexpensive

Faster Sample Homogenization

1 ETDS (new) is 24x faster than 2 stomachers (old)
→ 8 samples in 10 seconds versus 4 minutes

Easier Sample Handling

Sample tube moves through process and is more easily handled than bag
STATUS OF DEVELOPMENT AND LAUNCH

EC approved Feb. 05

Commission approves new BSE tests, opening up competition in the field

The European Commission today approved seven new rapid BSE tests: CediTest BSE test, Enfer TSE Kit version 2.0, IDBiX HeroChek BSE Antigen Test Kit (EIA), Institut Pourquier Speedit BSE, Prionics Check ProSTRIP, Roboscreen Beta Prion BSE EIA Test Kit, Roche Applied Science PrionScreen.

This means that there are now a total of 12 tests that can be used to monitor BSE, which considerably opens up competition in this field. Following a laboratory evaluation carried out by the Commission and subsequent field trials carried out by the test producers under the supervision of the Joint Research Centre (JRC), the European Food Safety Authority (EFSA) recommended that the seven new tests should be approved for use. The tests are designed to detect BSE in brain material collected from animals at the slaughterhouse or which have died on the farm.

Until now, tests designed to detect BSE in live animals have not been evaluated. In the EU all healthy bovine cattle slaughtered at an age above 30 months and all fallen stock above 24 months have to be tested for BSE, with some derogations for some countries. The five previously approved tests can also be used to check for TSE in sheep and goats. Formal evaluations of additional tests for this purpose are ongoing.

• Launched Feb. 28th

Front End Automation
Do you have 10 seconds...

The Enfer TSE Test
Nov. 2005

Abbott
A Promise for Life
New European Parts List

- All disposables associated with the new instruments will be offered by Abbott

Benefits:

- Possibility to offer a complete solution to the customer
- All major parts required to run the assay come from 1 manufacturer
WORKFLOW IMPROVEMENTS

- Increased safety – plastic tool unlikely to cause injury; no sharps or needles required
- Single sample handling is reduced to sample taking and EB 1 addition
- No difficult homogenizer bag handling
- Smooth sample flow
- ETDS VIII – automated homogenizer processes 8 tissue samples 24 times faster vs. 2 stomachers
- Tecan Freedom Evo 150 – pipetter accommodates sample rack from ETDS VIII and provides walk-away capability
NEW Workflow Organisation
Placing Samples In ETDS Tubes

The sample is placed at the bottom of the barcoded ETDS tube

The method is simple and rapid
Use of Sample Boxes

Samples for one plate can be organized in special plastic boxes
TUBE TRANSFER FROM BOXES TO TECAN RACKS

When tubes are closed, remove tubes from the box and put into 8 position TECAN racks

Once the tubes are in the racks, they are ready for the ETDS VIII
Place a rack in the ETDS, push both buttons together to homogenize samples. Homogenization takes 10 seconds.

8 position TECAN racks are placed on ETDS VIII.
Rack arrangement on TECAN

• After homogenization on the ETDS VIII sample racks are then transferred to the TECAN (continuous load possible)

• Approx 10min/88 samples (homogenised and transferred)
Theoretical presentation of the Tecan capacity according to the programme used

(Time (h) vs._EVENTS (Number of samples))

Tecan programme with 3 steps
Tecan programme with 2 steps only
Tecan programme with one step only

Number of samples

230 240 250 260 270 280 290 300
0 15 30 45 60 75 90 105 120 150 180 200 225 250 275 300
Comparison of the number of technicians needed according to the method used
No. Tech = Fct (no. of samples)
AUTOMATION SUMMARY

- Automating the front end will enhance the sample preparation with a focus on safety, speed and ease
- All new disposables needed will be provided by Abbott
- EC approved Feb. 2005
- Very positive customer feedback:

Helen Jones, Manager BSE operations LGC/UK:

“The use of the ETD and the Tecan platform in the purification phase of the test gave improved reproducibility of results overall.......The procedure was straightforward to perform, with no stage being technically difficult.”
Costs of BSE Testing in Canada
Information Package

Market restrictions imposed after 4 cases of BSE were detected in Canada prevent Canadian Meat producers from exporting beef. This has devastated the industry.

This document is intended to provide information to assist interested parties in exploring the possibility for BSE testing in Canada for marketing purposes.

The bottleneck of all BSE testing procedures is sample registration and preparation. All brain samples have to be entered into a dedicated database, the proper region of the brain selected, dissected and then homogenized before the rapid test can start. This step is the most labour intensive.

The Prionics®-Check PrioSTRIP represents the newest generation of BSE testing with results from 470 samples achievable in approximately 3 hours. This technology significantly reduces the duration and costs of the complete process.

The summary of our cost estimate for testing of 500, 1000, 2000 or 4000 samples per day is:

<table>
<thead>
<tr>
<th>Samples per day</th>
<th>500</th>
<th>1000</th>
<th>2000</th>
<th>4000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full costs (CAN$)</td>
<td>29.97</td>
<td>28.72</td>
<td>26.27</td>
<td>24.36</td>
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</tbody>
</table>

These cost estimates include all fixed and variable cost components such as the kit, container labs, equipment, labor, electricity and sample transport. All equipment is written off within 3 Years, where after testing price will decrease for another 1-2CAN$ per sample.

The following documents provide a detailed breakdown underlying the estimate and assumptions.

- Cost estimate & Assumptions
- Detailed list of variable & fixed cost components
- Showcase: Workflow for a Lab processing 2’500 samples per day
- Example of a container / lab layout
- Maps of existing Labs and Meat processing plants in Eastern & Western Canada
## Cost Estimate for BSE Testing
**Prionics AG, June 2005**

### TESTS PER DAY

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<tr>
<th>COMPONENT</th>
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<tr>
<td><strong>Variable Costs</strong></td>
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<td>PrioSTRIP® Kit</td>
<td>27.56</td>
<td>26.41</td>
<td>24.63</td>
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<td>Consumables (pipette tips etc.)</td>
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<tr>
<td>Labour Costs (Lab Manager, Technicians)</td>
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<tr>
<td>Other Costs (waste, electricity, transport)</td>
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<td><strong>Fixed Costs</strong></td>
<td>2.41</td>
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<tr>
<td>ContainerLab</td>
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<tr>
<td>Lab equipment (hoods, freezers, PC etc.)</td>
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<td></td>
</tr>
<tr>
<td>PrioSCAN® equipment (Scanner, Pipettes etc)</td>
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<td></td>
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</tr>
<tr>
<td><strong>TOTAL COSTS</strong></td>
<td>29.97</td>
<td>28.72</td>
<td>26.27</td>
<td>24.36</td>
</tr>
</tbody>
</table>

### ASSUMPTIONS

<table>
<thead>
<tr>
<th>Laboratory Setup</th>
<th>Complete Modular Lab Container or equivalent costs to upgrade existing facilities</th>
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</thead>
<tbody>
<tr>
<td>Workdays per year</td>
<td>260 workdays</td>
</tr>
<tr>
<td>Training &amp; Lab setup</td>
<td>provided by Prionics Technical Support team is included</td>
</tr>
<tr>
<td>Prices consumables</td>
<td>Enduser prices Prionics price list and third party suppliers</td>
</tr>
<tr>
<td>Prices equipment</td>
<td>Enduser prices Prionics price list and third party suppliers; to be written off in a 3 year period</td>
</tr>
<tr>
<td>Kit price</td>
<td>Third Party Supplier</td>
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<tr>
<td>Maintenance costs</td>
<td>3h for completion of PrioSTRIP test:</td>
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<tr>
<td></td>
<td>- 1h 20min sample cutting and homogenisation</td>
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<tr>
<td></td>
<td>- 1h digestion</td>
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<td>- 40 min detection</td>
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<tr>
<td>Labour time per plate</td>
<td>C$30/h Technician</td>
</tr>
<tr>
<td>Labour costs</td>
<td>C$40/h Lab Manager</td>
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</table>

### COST REDUCTION OPPORTUNITIES

| Laboratory Setup | Testing could be cheaper if existing Lab facilities are used |
| Turnaround time  | - carcasses hang overnight - grading & processing is performed next day    |
|                   | Staffing and thus turnaround time can be optimized according to every slaughterplants schedule in order to minimize either staffing needs or turnaround time |
| Transport         | Hanging of beef for at least 12h after sampling allows a transport time of >6h. This permits the utilization of existing laboratory facilities in this distance range (see map) |
| Labour costs      | The simplicity of the PrioSTRIP does not need senior level technicians. Technician: C$30/h may be overestimated |
## PrioSTRIP Cost Factors

### VARIABLE COSTS

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<tr>
<th></th>
<th>Cost per unit</th>
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<th>2000</th>
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<tr>
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### Labour Costs

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### Other Costs considered

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### FIXED COSTS

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<td>Freezer (-20°C)</td>
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<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Telephone / Fax</td>
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<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Ultrapure Water station</td>
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<td>1</td>
<td>1</td>
<td>1</td>
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### Suppliers

- Prionics Supply
- Other Suppliers
- Maintenance / Service for FASTH, Container; Biosafety Hoods
## PrioSTRIP Workflow

(2500 samples) 27 plates

<table>
<thead>
<tr>
<th>Time</th>
<th>Event Description</th>
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<tbody>
<tr>
<td>09:00 AM</td>
<td>Begin of slaughter process</td>
</tr>
<tr>
<td>09:00 AM - 09:20 AM</td>
<td>Break at slaughter plant</td>
</tr>
<tr>
<td>09:40 AM-10:30 AM</td>
<td>Every 15 min 94 samples arrive at laboratory</td>
</tr>
<tr>
<td>10:30 AM</td>
<td>Break at slaughter plant</td>
</tr>
<tr>
<td>11:00 AM</td>
<td>Every 15 min 94 samples arrive at laboratory</td>
</tr>
<tr>
<td>01:00 PM</td>
<td>Every 15 min 94 samples arrive at laboratory</td>
</tr>
<tr>
<td>02:00 PM</td>
<td>Every 15 min 94 samples arrive at laboratory</td>
</tr>
<tr>
<td>03:00 PM</td>
<td>Every 15 min 94 samples arrive at laboratory</td>
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### Number of people working in parallel

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<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
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<tbody>
<tr>
<td>04:00 PM</td>
<td>1</td>
<td>4</td>
<td>7</td>
<td>7</td>
<td>9</td>
<td>8</td>
<td>9</td>
<td>8</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>05:00 PM</td>
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<td>11</td>
<td>9</td>
<td>13</td>
<td>12</td>
<td>8</td>
<td>3</td>
<td>3</td>
<td>9</td>
</tr>
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<td>06:00 PM</td>
<td>12</td>
<td>12</td>
<td>10</td>
<td>#</td>
<td>9</td>
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<td>10</td>
<td>#</td>
<td>9</td>
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<td>1</td>
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</table>

### Time to Result

- **11 h**

### Technician hours total

- **79.2**

### Maximum Number of technicians working simultaneously

- **13**
PrioSTRIP
Lab / Container layout
(500 samples)

WP 1 = Workplace 1 - Sample Scanning
WP 2 = Cutting
WP 3 = Homogenization & Masterplate
WP 4 = Digestion & Incubation
WP 5 = Scanning & Result Interpretation

= Working Step
Western Canada
Time/Distance to Closest Lab and Capacity
Eastern Canada
Time/Distance to Closest Lab
Business Case for BSE Testing for the Japanese Market
Contents:

Introduction

Key Assumptions

Pricing Comparison on Japan Export versus the Domestic Market

Cost Analysis for BSE Lab

Conclusions
**Introduction:**

As most of you are well Rancher’s Beef has been in contact with a number of customers in Japan and their position particularly at the retail level is that BSE testing will be necessary to gain market access. That being said Rancher’s Beef is not opposed to BSE testing for certain markets in markets where there is a request by the customer and the economics of this test does in fact make sense.

There have been clear indications from the Japanese Government that trade will open to Cattle under 21 months of age. There are a few issues surrounding age verification like: There are only 15,000 age verified cattle in Canada out of 5 million; Beyond these cattle how accurate will the ossification test be? How many under 21 month aged cattle will be available in certain months like January, February and March?

The purpose of this report is to demonstrate that, while there is a cost to BSE testing, supplying BSE tested Canadian Beef to Japan is a very viable option.

**Key Assumptions**

- A $0.25/lb freight charge was included in the pricing model for Japan
- A cost of $55,000 per year was used for the Lab Manager and $40,000 per year for the lab technicians. There was a benefit load of 1.3 applied to these salaries
- Assumed 250 working days per year
- A daily slaughter of 800 head or 200,000 per year
- Accounted for a 1 year pay back on the modular lab – Felt that after a year of testing it may no longer be a request by Japan once the confidence of no BSE detection has been achieved
<table>
<thead>
<tr>
<th></th>
<th># per Head</th>
<th>lbs per Pc.</th>
<th>lbs Per Head</th>
<th>% Export</th>
<th>Export lbs per head</th>
<th>Export $/lbs</th>
<th>Export $/hd</th>
<th>Domestic $/lbs</th>
<th>Domestic $/hd</th>
<th>Value Difference</th>
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<td>20</td>
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<td>15</td>
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<td>40.8</td>
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<td>3</td>
<td>85%</td>
<td>1.95</td>
<td>6.01</td>
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<td>0.68</td>
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<td>2.2</td>
<td>50%</td>
<td>1.1</td>
<td>8.65</td>
<td>9.5</td>
<td>1.36</td>
<td>1.50</td>
<td>8.02</td>
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<td>50%</td>
<td>2.5</td>
<td>3.78</td>
<td>9.5</td>
<td>0.91</td>
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<td>1.65</td>
<td>3.8</td>
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<td>4</td>
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<td>0.68</td>
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<td>1.5</td>
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<td>30%</td>
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<td>2.55</td>
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<td>8</td>
<td>50%</td>
<td>4</td>
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<td>0.2</td>
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<td>0.40</td>
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<td>2.5</td>
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<td>2.25</td>
<td>1.4</td>
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<td>0.2</td>
<td>0</td>
<td>0.00</td>
<td>0.19</td>
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<td>0.9</td>
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<td>0.95</td>
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<td>0.26</td>
<td>50%</td>
<td>0.13</td>
<td>1.32</td>
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<td>0</td>
<td>0.00</td>
<td>0.17</td>
</tr>
<tr>
<td>Sweet Breads/thymus gland</td>
<td>1</td>
<td>0.5</td>
<td>0.5</td>
<td>75%</td>
<td>0.38</td>
<td>0.6</td>
<td>0.2</td>
<td>0.45</td>
<td>0.17</td>
<td>0.06</td>
</tr>
<tr>
<td>Weasand/esophagus</td>
<td>1</td>
<td>0.5</td>
<td>0.5</td>
<td>25%</td>
<td>0.13</td>
<td>0.46</td>
<td>0.1</td>
<td>0.1</td>
<td>0.01</td>
<td>0.06</td>
</tr>
<tr>
<td>Tri-Tip</td>
<td>2</td>
<td>4</td>
<td>8</td>
<td>30%</td>
<td>2.4</td>
<td>2.85</td>
<td>6.8</td>
<td>2.5</td>
<td>6.00</td>
<td>0.84</td>
</tr>
<tr>
<td>Strip loin</td>
<td>1</td>
<td>12</td>
<td>12</td>
<td>30%</td>
<td>3.6</td>
<td>5.75</td>
<td>20.7</td>
<td>4.75</td>
<td>17.10</td>
<td>3.60</td>
</tr>
<tr>
<td>Tenderloin</td>
<td>1</td>
<td>6</td>
<td>6</td>
<td>30%</td>
<td>1.8</td>
<td>9.75</td>
<td>17.6</td>
<td>7.5</td>
<td>13.50</td>
<td>4.05</td>
</tr>
<tr>
<td>Butt Tender</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>50%</td>
<td>1.5</td>
<td>9.75</td>
<td>14.6</td>
<td>9.1</td>
<td>13.65</td>
<td>0.98</td>
</tr>
<tr>
<td>Flank Steak</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>25%</td>
<td>1</td>
<td>4.75</td>
<td>4.8</td>
<td>4.35</td>
<td>4.35</td>
<td>0.40</td>
</tr>
<tr>
<td>Chuck Roll</td>
<td>2</td>
<td>21</td>
<td>42</td>
<td>25%</td>
<td>10.5</td>
<td>2.4</td>
<td>25.2</td>
<td>1.9</td>
<td>19.95</td>
<td>5.25</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>116.37</td>
<td>248.1</td>
<td>58.53</td>
<td>139.6</td>
<td>108.58</td>
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</tr>
</tbody>
</table>
# BSE Test Cost Analysis

## Variable Costs

<table>
<thead>
<tr>
<th>Variable Costs</th>
<th>Cost per Unit</th>
<th>800</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prio Strip Kit</td>
<td>9870</td>
<td>1.7</td>
<td>$16,779.00</td>
</tr>
<tr>
<td>Pyrcpcons</td>
<td>3.2</td>
<td>800</td>
<td>$2,560.00</td>
</tr>
<tr>
<td>Sample Container</td>
<td>0.21</td>
<td>800</td>
<td>$168.00</td>
</tr>
<tr>
<td>Solution reservoirs</td>
<td>1.52</td>
<td>8</td>
<td>$12.16</td>
</tr>
<tr>
<td>Pipette tips 250ul</td>
<td>0.08</td>
<td>4800</td>
<td>$384.00</td>
</tr>
<tr>
<td>Pipette tips 1000ul</td>
<td>0.09</td>
<td>800</td>
<td>$72.00</td>
</tr>
<tr>
<td>Pipette tips 5000ul</td>
<td>0.17</td>
<td>6</td>
<td>$1.02</td>
</tr>
<tr>
<td>Gloves</td>
<td>0.3</td>
<td>20</td>
<td>$6.00</td>
</tr>
<tr>
<td>Forceps</td>
<td>1.98</td>
<td>6</td>
<td>$11.88</td>
</tr>
<tr>
<td>Scalpel</td>
<td>0.78</td>
<td>6</td>
<td>$4.66</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td><strong>$19,988.62</strong></td>
</tr>
</tbody>
</table>

Cost per head: $25.00

## Labour Cost

<table>
<thead>
<tr>
<th>Labour Cost</th>
<th>Cost per hour</th>
<th>Hours</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lab Manager</td>
<td>$35</td>
<td>2.5</td>
<td>$87.50</td>
</tr>
<tr>
<td>Technicians</td>
<td>$25</td>
<td>25</td>
<td>$625</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td><strong>$712.50</strong></td>
</tr>
</tbody>
</table>

Cost per Head: $0.89

## Other Costs

<table>
<thead>
<tr>
<th>Other Costs</th>
<th>Cost per head</th>
<th>Units</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waste</td>
<td>0.04</td>
<td>800</td>
<td>$32</td>
</tr>
<tr>
<td>Electricity</td>
<td>0.42</td>
<td>800</td>
<td>$336</td>
</tr>
<tr>
<td>Labour for Sample</td>
<td>1</td>
<td>800</td>
<td>$800</td>
</tr>
<tr>
<td>Extraction and transfer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td><strong>$1,168</strong></td>
</tr>
</tbody>
</table>

## Total Variable Costs

**$21,879.12**

## Total Variable Costs per Head

**$27.35**

## Fixed Costs

<table>
<thead>
<tr>
<th>Fixed Costs</th>
<th>Cost per Unit</th>
<th>Units</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Container Lab</td>
<td>600000</td>
<td>1</td>
<td>$600,000</td>
</tr>
<tr>
<td>FASTH</td>
<td>25336</td>
<td>3</td>
<td>$76,014</td>
</tr>
<tr>
<td>MediFasth</td>
<td>3952</td>
<td>0</td>
<td>$0</td>
</tr>
<tr>
<td>PrioScan</td>
<td>12160</td>
<td>2</td>
<td>$24,320</td>
</tr>
<tr>
<td>Autoclave</td>
<td>18240</td>
<td>1</td>
<td>$18,240</td>
</tr>
<tr>
<td>Biosafety-Hood</td>
<td>35568</td>
<td>6</td>
<td>$213,408</td>
</tr>
<tr>
<td>Microplate Incubator</td>
<td>3192</td>
<td>5</td>
<td>$15,960</td>
</tr>
<tr>
<td>Multichannel Pipette 5-50 ul</td>
<td>1824</td>
<td>3</td>
<td>$5,472</td>
</tr>
<tr>
<td>Multichannel Pipette 5-300 ul</td>
<td>1125</td>
<td>3</td>
<td>$3,375</td>
</tr>
<tr>
<td>Singlechannel Pipette 10-100ul</td>
<td>578</td>
<td>3</td>
<td>$1,734</td>
</tr>
<tr>
<td>Singlechannel Pipette 10-1000ul</td>
<td>578</td>
<td>3</td>
<td>$1,734</td>
</tr>
<tr>
<td>Singlechannel Pipette 1-5ml</td>
<td>578</td>
<td>2</td>
<td>$1,155</td>
</tr>
<tr>
<td>Dilumat</td>
<td>12122</td>
<td>3</td>
<td>$36,366</td>
</tr>
<tr>
<td>Cutting Board</td>
<td>18</td>
<td>3</td>
<td>$54</td>
</tr>
<tr>
<td>Freezer (-20°C)</td>
<td>988</td>
<td>1</td>
<td>$988</td>
</tr>
<tr>
<td>Fridge (+4°C)</td>
<td>1284</td>
<td>2</td>
<td>$2,568</td>
</tr>
<tr>
<td>PC</td>
<td>456</td>
<td>1</td>
<td>$456</td>
</tr>
<tr>
<td>Telephone/Fax</td>
<td>380</td>
<td>1</td>
<td>$380</td>
</tr>
<tr>
<td>Ultrapure Water Station</td>
<td>7600</td>
<td>1</td>
<td>$7,600</td>
</tr>
<tr>
<td>Maintenance costs/service</td>
<td>35000</td>
<td>1</td>
<td>$35,000</td>
</tr>
<tr>
<td>Total Fixed Costs</td>
<td></td>
<td></td>
<td><strong>$1,044,825</strong></td>
</tr>
</tbody>
</table>

Total Fixed Cost per Head: **$5.22**

Total Testing Cost Per Head: **$32.57**
Conclusion

BSE Test Cost per Head = $32.57

Additional Costs
Marketing
Trips to Japan  $20,000
Packaging Upgrades and Demos  $42,000
Total  $62,000

Cost per Head  $.30

Cost of BSE Testing per head  $32.57

Total Cost per head  $32.87

<table>
<thead>
<tr>
<th>Japan Primal Value per Head</th>
<th>$248.15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domestic Primal Value per Head</td>
<td>$139.57</td>
</tr>
<tr>
<td>Cost to enter Japan Market per Head (Includes BSE Test)</td>
<td>$32.87</td>
</tr>
<tr>
<td><strong>Net Value Differential per Head</strong></td>
<td><strong>$75.71</strong></td>
</tr>
</tbody>
</table>

Based on the numbers provided above it is evident that our value per head is significantly increased (by $75.71) with access to the Japan market. I will mention that we were conservative on our product values to Japan because we are not sure how accessible all products will be to their market, in particular some of the offal cuts, when the border does open.

From the data we’ve shown it certainly shows that testing for the Japanese market makes economic sense and provides greater value to our company. If we were to assume that we only gained 30% of the net differential ($75.71) for the Japan market we would still have a payback on the Lab of approximately 4 months.