



*Fourth Draft 06-23-08: Comments Welcome*

## **Managing Prion Disease Risks: A Canadian Perspective**

**Paper prepared for PrioNet Canada Workshop**

**Washington, D.C.**

**July 10, 2008**

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**Abstract:** This paper reviews the history of the development by governments, beginning in the 1980s in the United States, of formal schemata intended to represent the necessary steps in arriving at a credible and robust risk management decision. The paper illustrates the challenge posed by the emergence of BSE, by summarizing the nature of prion disease risks, the experience of many different countries (including Canada), as analyzed in a series of detailed case studies, in seeking to assess and manage the risk of BSE and other prion diseases in the period after 1988. Particular attention is paid to the new approaches that are needed in the areas of risk estimation, public perception of risk, and the assessment of psychosocial factors, owing to their importance in estimating the likely consequences of major hazards. The paper presents and illustrates a revised format for an integrated risk management framework,

including a set of specific and explicit objectives that should guide the use of this framework in the risk management decision making process, and concludes by raising policy issues that are currently outstanding with respect to the management of prion diseases.

**Keywords:** Risk Management Frameworks, bovine spongiform encephalopathy, prion diseases, Canada, risk estimation, risk assessment, risk perception, psychosocial impacts, public policy issues.

## **1 Introduction.**

Risk management has been called “a comprehensive, systematic process that assists decision makers in identifying, analyzing, evaluating, and treating all types of risks, both internal and external to the organization.” Further, “the objective of risk management is to ensure that significant risks are identified and appropriate action is taken to manage these risks to the extent that is reasonably achievable” (Jardine et al., 2003, p. 129).

Here we propose a more concise definition, referring to risk management as *an attempt to anticipate and prevent or mitigate harms that may be avoidable*.

For the past quarter-century governments have been constructing and fine-tuning formal schemes which are intended to represent the necessary stages in risk management [RM] decision-making. Throughout this time they have been regularly revised in order to incorporate an up-to-date version of “best practices” in this domain. When they are applied rigorously, these schemes can provide a level of transparency, accountability, and credibility to RM decision-making that is hard to achieve by using less formal strategies—and that can contribute to an enhanced level of public confidence in the management of public health risks.

However, during this same period the formalized practice of risk management has been severely challenged by ongoing public controversies about some well-known risk

issues, such as industrial chemicals (Leiss, 1994, 2004) and civilian nuclear power (Mehta, 2005); by egregious cases of mismanagement, such as drinking water (Hrudey and Hrudey, 2004) and the blood supply (Picard, 1995; Krever, 1997); and by novel risks, such as BSE (Leiss, 2004) and SARS (Tyshenko, forthcoming). These and other challenges indicate that the process of risk management decision-making is still in need of further development and renewal. This paper uses the experience of over twenty countries with managing the risk of BSE as a guide to the types of improvements in RM frameworks that might be made.

The paper first looks in detail at the experience of many different countries with BSE, then reviews the history of the development of risk management frameworks, lists the major policy issues raised by the long BSE saga, and finally proposes an updated, integrated risk management framework. By the term “integrated,” we mean the need to unify the results of separate, and qualitatively different, decision inputs into an overall judgment of the severity of the risk, taking into account both expected frequency and expected consequences.

## **2 Overview of the Current State of Scientific Knowledge on Prion Diseases.**

*(In preparation by Neil Cashman)*

## **3 Key Findings of the Country Case Studies.**

Understanding the long history of how individual countries as well as international agencies have responded to the challenge of BSE and vCJD will, one hopes, improve our ability to deal with similar challenges in the future. The country case study findings that are reported in a series of papers (see Appendix I) are very instructive in this regard. For our ability to derive useful guidance from the past is dependent upon our having detailed chronologies of key events that provide a basis for comparative analysis; the case studies satisfy this requirement admirably. Second, the set of case studies as a whole raises a host of issues that are relevant to the development of a more effective risk management framework. This paper seeks to synthesize some of the common elements in the case studies which are particularly relevant to identifying what are “best practices” in risk management. And a clear apprehension of best practices is needed so that the fundamental objectives of good risk management may be better realized. The synthesis and analysis of the BSE case studies is preceded by an overview of the situation of BSE and vCJD as it stands at present.

In the series of articles published in a “Special Issue on The Future of BSE Risk Assessments,” appearing in a recent issue of the journal *Risk Analysis*,<sup>1</sup> the following points are made:

- 1) The most recent studies confirm that the sole direct risk factor for BSE is the recycling of infected material in ruminant MBM;<sup>2</sup>
- 2) The principal risk control options responsible for bringing the epidemic of BSE under control are: (a) banning the use of ruminant MBM, first in cattle feed and later in all animal feed; (b) banning trade in live cattle; (c) removal and incineration of bovine SRMs; (d) rendering of remaining bovine carcass under high temperature and pressure.

- 3) The incidence of BSE in Europe peaked in 1992 (37,280 UK reported cases plus 36 elsewhere) and declined, for the last full year of reporting (2006), to 114 UK and 215 elsewhere, for a total of 229.<sup>3</sup>
- 4) The fact that the number of non-UK reported cases peaked in 2002 at 935 is due to the introduction of active surveillance throughout the EU in 2001; cases in Europe have been declining rapidly since that time.
- 5) As of July 2007, there were 165 vCJD cases in the UK and 35 in the rest of the world. (The peak exposure period in the UK lasted from 1988 to 2003.)<sup>4</sup>
- 6) “Assuming that BSE and vCJD have a similarly wide distribution in the incubation period, we could relate the total of approximately 200 vCJD cases to the total of 161,679 BSE cases reported until 1995. This means that 808 BSE cases lead to one vCJD infection (under the given circumstances).”<sup>5</sup>
- 7) The research effort to estimate the true prevalence of BSE in France continues to yield some startling and instructive findings. According to the OIE listing of reported cases, France found—using passive (clinical) surveillance—only 28 cases up to mid-1997, and only 241 cases in total prior to the onset of active surveillance at the beginning of 2001. According to the latest back-calculation, however: “Between July 1987 and June 1997, an estimated 51,300 (CI = [24,300—84,700]) cattle were infected in France.”<sup>6</sup>

*Ranked list of country totals for indigenous BSE cases (as at March 2008).<sup>7</sup>*

I. Countries reporting a large number of total confirmed BSE cases (>50):

1. UK (184,553)
2. Ireland (1,613)
3. Portugal (1,023)
4. France (987)
5. Spain (681)
6. Switzerland (464)
7. Germany (409)
8. Italy (137)
9. Belgium (133)
10. Netherlands (82)
11. Poland (56)

II. Countries reporting a moderate number of BSE cases (5-50):

12. Japan (32)
13. Czech Republic (26)
14. Slovakia (23)
15. Denmark (14)
16. Canada (13)
17. Slovenia (7)
18. Austria (6)

III. Countries reporting a small number of BSE cases (<5):

19. Luxembourg (3)
20. Liechtenstein (2)
21. US (2)
22. Finland (1)
23. Greece (1)
24. Israel (1)
25. Sweden (1)

IV. Sample of countries and regions reporting no BSE cases:<sup>8</sup>

1. Australia
2. New Zealand
3. Argentina
4. Brazil
5. Russia
6. India
7. Costa Rica
8. South Korea
9. China
10. Continent of Africa

With reference to this last list of countries, it should be noted that the UK continued to export infected MBM to various regions in the world for eight years after the imposition of its own domestic ban in July 1988; exports to Europe peaked in 1989 and continued until 1994.<sup>9</sup> After 1989, exports from the UK to non-EU countries (including Africa, the Middle East, and Asia) rose quickly to 30,000 tons annually (Phillips et al., *The BSE Inquiry*, vol. 10, p. 72 [Figure 7.1]). But in addition, European firms often repackaged and re-exported MBM from the UK both to EU and non-EU countries (Phillips et al., vol. 3, p. 185). Countries that imported large amounts of MBM from the UK between 1980 and 1996 included Indonesia (600,000 tonnes) and Thailand (185,000 tonnes); other purchasers included Czechoslovakia, Kenya, Lebanon, Liberia, Nigeria, Puerto Rico, Russia, Sri Lanka, South Africa, and Turkey. Between 1991 and 1996, other EU countries tripled their own exports of MBM, and half of that total went to a single

country, Poland.<sup>10</sup> Therefore it is highly likely that some of these countries, in addition to the former Czechoslovakia, have incubated BSE in their cattle herds.

### *Major Issues.*

Listed in order of importance, the major issues raised by the case studies for the risk management framework are as follows:

- A. Failure of the passive (clinical) surveillance method to detect the actual number of cases of BSE in national herds, as shown by the large increases in confirmed cases after active surveillance was introduced in Europe and Japan in 2001.
- B. Failure of affected countries to design and implement a method for estimating the true prevalence of BSE in their national herds after BSE was first diagnosed as a spongiform encephalopathy in late 1986, in relation to what was known *at that time* about the long incubation period of SEs (the element of transmissibility was assumed to be true as of mid-1988).<sup>11</sup>
- C. Following the first discoveries of the disease outside the UK, in Ireland (1989), Switzerland (1990), and France (1991), the inappropriate initial responses of other countries—e.g., Spain, Germany, Canada—which were “in denial” about the probability that they might also have or develop indigenous cases.
- D. The erratic nature of the imposition of risk control measures in many countries, especially the delays in imposing bans on MBM in ruminant feed.
- E. The confusing and changing sets of country risk categories as designated by OIE and EFSA.
- F. The non-compulsory character of OIE prescriptions on BSE risk and the resulting “anarchy” in international trade sanctions.

Each of these issues is discussed below, and in the following section the impact of these issues on the proposed risk management framework is noted.

#### *1. Surveillance.*

The prompt detection of diseased animals is necessary so that they may be removed from the human food supply and to ensure that the non-food parts of the carcasses are

not sent for normal rendering. The issue of surveillance policy for the detection of diseased animals is, therefore, a critical part of food safety – but especially so in the case of a disease with a long incubation period, where obvious symptoms normally occur only at a later stage in the process. BSE is a disease that can take on average five years to develop to the point where the animal will eventually succumb to it.<sup>12</sup>

Therefore, it is highly likely that what is known as “clinical” surveillance will fail to detect some significant percentage of the cases of BSE that are incubating in an infected herd.<sup>13</sup> The definitive confirmation of this view came with the imposition of the EU requirements for the testing of all cattle over 30 months of age, which went into effect in early 2001.<sup>14</sup> Here are the results from the OIE (2000) and EU (2001)<sup>15</sup> country tables:

**Table 1: Comparison of BSE Cases in Selected Countries before and after the Introduction of Active Surveillance in the EU**

<u>Country</u>	<u>2000 cases</u>	<u>2001 cases</u>
Belgium	9	46
Germany	7	125
Italy	0	50
Netherlands	2	20
Spain	2	83

These figures demonstrate that the EU achieved a more accurate accounting of the scope of the BSE epidemic only after instituting an active surveillance policy, in which the test for the disease is carried out while the meat is being held in temporary storage before being released upon receipt of negative results.<sup>16</sup> Japan adjusted its active surveillance policy in April 2005, after it found a case of an infected animal that was 21 months old—

the earliest age yet discovered—to cover all cattle aged 21 months and older (Matibag et al., 2005; Yamanouchi and Yoshikawa, 2007).<sup>17</sup>

The differences in country responses to the issue of what is an adequate surveillance policy, for a disease such as BSE, offers one reason why countries may respond differently to the discovery of BSE in the herds from which they are importing beef or beef products; see below, #6, for further remarks on this point.

## *2. True Prevalence.*

Surveillance policy is, of course, closely related to the issue of true prevalence or incidence, since only active surveillance provides a solid evidence base for discovering the total disease burden in a national herd. Thanks to the pioneering efforts of some scientists (see Section 5, below), we now have a back-calculation method that can assist us, in retrospective studies, in attempts to understand better the estimated true incidence for a slowly-developing disease such as BSE. However, in the context of making improvements to the existing risk management framework, it is important to emphasize the need for risk managers to make a determined effort to assess the true prevalence at the time when effective risk control measures should be imposed in order to try to limit the future consequences of an actual or potential epidemic.

The OIE country year-to-year record for BSE shows clearly that many countries continued, for far too long, to take comfort in the belief that the only cases of BSE in their herds were in animals that had been already infected at the time when they had been imported from other countries—in other words, that they had no indigenous cases.

For example, Germany was reporting imported cases from 1992 onwards, but no indigenous cases until 2000, when it listed 7; however, when active surveillance started in 2001, the number jumped immediately to 125.<sup>18</sup> Italy announced 2 imported cases in 1994, but no indigenous cases whatsoever through the year 2000; in 2001, 50 cases were detected.

Spain and Portugal were, however, the worst offenders in this regard. Portugal, which as of now has the third-highest accumulated total of BSE cases (1,023), and in 2003 had the highest incidence rate per million head of cattle of any country in the world,<sup>19</sup> tallied only imported cases until 1993—when the developing catastrophe in its own national herd could no longer be concealed. Spain, which now has the fifth-highest accumulated total (681), reported no cases at all, imported or indigenous, until 2000, when it recorded only 2; the numbers for the years thereafter (to 2006), reflecting active surveillance, are 83, 127, 167, 137, 98, and 68. Even Canada, with its single imported case in 1993, followed by a decade-long “clear” record and then by thirteen indigenous cases over the period 2003-2008, shows a pattern that appears to indicate that the true prevalence of the disease in the national herd was higher than what it is confirmed to be.

### *3. Delayed Responses.*

The comfortable illusions supplied and reinforced by the passive surveillance policy prompted a number of countries to pretend to the rest of the world that they were entitled to regard themselves as being BSE-free, long after this was in fact an unreasonable proposition to advance. As a result of this strategy, in some cases the impact of the confirmation of indigenous BSE, when it finally happened, was far more

severe than it might have otherwise been. In the case of Spain, for example, the EU's geographical risk assessment, produced in early 2000, rated that country as Level III—likely to be infected but as yet unconfirmed. The Spanish government reacted with fury, calling the assessment “wrong” and sending its lobbyists to Brussels to protest; alas, confirmation of the first indigenous case came a mere few months later. The domestic market declined immediately, and a number of countries imposed import bans.<sup>20</sup>

In Portugal, by 1996 the population had come to the conclusion that the comforting messages from the authorities were no longer to be trusted, and beef consumption fell precipitously for a while.<sup>21</sup> In Germany the long-held illusions about BSE only being a problem in other countries collapsed overnight at the end of the year 2000; federal ministers resigned, beef sales plummeted, and an entirely new federal department of food safety was created, all in a matter of months.<sup>22</sup> And in Canada, truly catastrophic economic and social impacts followed the announcement of the first indigenous case in 2003: Within weeks 39 countries had imposed import bans on Canadian beef, but the US participation in the border closures was especially severe, since 90% of Canadian beef exports had gone to that country alone.<sup>23</sup> The fact that such border closures, notably by the United States, were in technical violation of the OIE procedures was simply ignored by the countries that took them.<sup>24</sup>

#### *4. Delays in Risk Control Measures.*

The UK announced its ban on the use of “ruminant-derived protein in ruminant feed” (MBM) in July 1988, about twenty months after the definitive diagnosis of the initial cases of BSE in November 1986, thus in effect identifying what turned out to be the

major risk factor for the spread of the disease. (Another risk factor, which impacted countries such as Canada, was the importation of infected live cattle from the UK, or other countries with infected herds, materials from which later entered the domestic rendering system and resulted in producing infected MBM fed to ruminants.) In the intervening period, the first technical publication revealing a case of a “novel progressive spongiform encephalopathy in cattle” had appeared in the UK.<sup>25</sup>

As a result of this publication, and the UK domestic MBM ban that was imposed shortly thereafter, British officials began receiving inquiries from their colleagues in other countries concerning the implications of these developments. Some uncertainties remain about how forthcoming the British officials were in response to these inquiries, and thus about what conclusions were drawn in other countries about how serious this new issue actually was.<sup>26</sup> What is clear from the case study record, however, is that there were significant delays, in some instances, in the imposition of effective risk control measures, which had the inevitable effect of prolonging the BSE epidemic. The case of France is especially telling in this regard. Throughout the 1980s, while the BSE epidemic was raging uncontrolled in the UK herd, France imported from the UK both large numbers of live cattle and significant quantities of infected MBM. The French authorities did not impose the MBM ban until 1990, two years after the UK’s initial action; in the case of the SRM ban, a full six years elapsed. Since the period from 1998-1990 was a critical time in the implementation of risk control measures, this relatively short delay in imposing the MBM ban undoubtedly accounts for a significant portion of France’s total burden of BSE cases. And, since France has the second-highest

prevalence of vCJD in the world, these delays contributed to that country's burden of human disease as well (Al-Zoughool et al., 2008: Appendix I, #13).

The following table (from Tyshenko, 2008<sup>27</sup>) illustrates the time lapses, for various countries, between (a) the discovery of domestic BSE, (b) the year BSE was made a notifiable disease, (c) the first MBM ban (UK, 1998), (d) initial SRM ban (UK, 1989), (e) the new EU rendering rules (1996), and (f) the ban on importation of live cattle from the UK:

**Table 2**  
Case country data for various bans and time anchor events listed by year

Country	Domestic BSE (Year)	BSE Notifiable (Year)	MBM Ban (Year)	SRM Ban (Year)	Rendering Standard-EU (Year)	UK Cattle Ban (Year)
Argentina	na	1990	1995	2002	na	1990
Australia	na	1994	1997	na	na <sup>a</sup>	1988
Belgium	1997	1990	1994	1998	1997	1996
Brazil	na	1990	1996	na	na	1991
Canada	2003	1990	1997	2003	2004	1990
Costa Rica	na	2001	2001	na <sup>c</sup>	nc	1980 <sup>b</sup>
Czech Rep.	2001	1991	1991	2000	1962	1994
Denmark	2000	1990	1990	2000	1997	1990
France	1991	1990	1990	1996	1994	1990
Germany	2000	1990	1994	2001	na	1996
India	na	1998	1999	1999	1993	2001
Israel	2002	1992	1996	1996	2001	1988
Italy	2001	1991	1994	1996 <sup>d</sup>	2000	1996
Japan	2001	1996	1997	2001	2001	1997
Netherlands	1997	1990	1994	1997	1996	1988
New Zealand	na	1989	2000	na	nc	1998
Poland	2002	1997	1997	2001	1997	1987
Portugal	1994	1990	1994	1997	1998	1990
Russia	na	1990	1996	na	1990	1989
Slovakia	2001	1993	1994	nc	1962	1996
Slovenia	2001	1995	1996	1996	1981	1996
Spain	2000	1990	1994	2001	1997	1989
Switzerland	1990	1990	1996	1990	1998	1996
UK	1986	1988	1988	1989	1996	na
USA	2005	1986	1996	2004	nc	1989

**na:** not applicable, does not apply to countries without reported BSE; no value for countries without SRM bans in place or countries that fail to meet EU rendering standards.

**nc:** non-compliant, values not available as countries have failed to meet standards country-wide.

a. Australia- rendering applied for EU exports only.

b. Costa Rica- no official cattle ban but no UK imports since 1980.

c. Costa Rica- SRM not banned but used exclusively for pet (dog) foods.

d. Italy- SRM rule applies to imported animals only.

At least through the year 1989, some countries—notably France, Portugal, the former Czechoslovakia, and perhaps others—had imported large numbers of live cattle from the UK, whereas Spain had had similar imports from France; the epidemic was of course very extensive in the UK as of the end of the 1980s, and very well may have been extensive in France at that time. France imported very large quantities of MBM from the UK until 1991 and there were also significant exports from the UK to the rest of Europe during this period. The long delays in implementing the full set of risk control measures, especially the MBM ban, played a large part in the unfolding of the total set of social, economic and political consequences of the BSE episode.

Special note should be made of the failures in the design, management and implementation of the ban on feeding ruminant-derived MBM to ruminants, which is indicated in Table 2. Since this was by far the most important risk control measure for BSE, these failures were very serious indeed; they include (a) not issuing a recall of the existing stock of feed and (b) not taking effective steps to ensure that cross-contamination did not occur at feed mills. Limitations on the effectiveness of the MBM ban are regarded as the primary risk factor for the so-called “born after the ban” cases of indigenous BSE cases, which have appeared in many countries, including the UK,

France, and Canada (Department of the Environment, Food and Rural Affairs, 2008a; Ducrot et al., 2000; Coulthart et al., 2008).

### *5. Changing Risk Categories.*

As the international community sought to respond to the challenge of the spreading BSE epidemic in the late 1990s, a number of risk classification schemes were developed and applied to various countries. The European Food Safety Authority [EFSA], for example, used a four-tiered scheme in its “geographical BSE risk assessments” between 2000 and 2006:

Level I:	Highly unlikely
Level II:	Unlikely but not excluded
Level III:	Likely but not confirmed
Level IV:	Confirmed

At about the same time, the OIE was working with its own, and different, five-tiered scheme:

1. BSE-free;
2. Provisionally free;
3. Minimal Risk;
4. Moderate Risk;
5. High Risk.

The example of South America shows the resulting confusion: During one period of time, two countries (Brazil and Chile) had the same OIE status—controlled risk—while having a different EFSA status (levels II and III). Then in May 2005 OIE changed its scheme to one that is highly simplified:<sup>28</sup>

1. Negligible risk [basically, no cases or only imported cases];
2. Controlled risk [indigenous cases found, but specified risk control measures are in place];
3. Undetermined risk.

As of August 2007, the following countries were certified as having “negligible risk”: Australia, Argentina, New Zealand, Singapore, and Uruguay; and countries having “controlled risk”: Brazil, Canada, Chile, Switzerland, Taipei China and United States of America. The two lists together name eleven countries in all. *No countries were listed in the “undetermined risk” category.* To add to the confusion, two countries (Iceland and Paraguay) remained in an earlier category—“provisionally free”—that was now discarded (it seems this category was to disappear entirely as of May 2008).<sup>29</sup> Given that, as of 2006, the OIE list of countries with confirmed cases for that year included seventeen countries, and among them only Switzerland is named, the usefulness of the most recent OIE exercise is unclear.<sup>30</sup>

#### *6. Anarchy in International Trade.*

All of these elaborate analyses of country risk had a twofold purpose: first, to help plan ongoing risk control strategies to contain the BSE epidemic, and second, to provide a reasoned basis for maintaining the flow of international trade in beef and beef products. So far as the second objective was concerned, this was largely a wasted effort, because all across the globe individual countries made arbitrary and often inconsistent decisions, on a case-by-case basis, as the epidemic spread. In this context the “reasoned” risk-based choices were completely swamped by the higher imperatives involved in nations trying to protect both their domestic and export markets from the worst consequences of others’ perceived risks and self-interested actions (often, to no avail). The paper on OIE policy use (Tyshenko, 2008: Appendix I, #23) gives a number of good examples of national actions that were internally inconsistent, arbitrary, purely self-interested, and

in clear violation of OIE recommendations.<sup>31</sup> Clearly there is room for much improvement in this regard.

*Summary.*

The objectives of the country case studies were to review the chronology of BSE and vCJD in the individual countries; compare the timing and policies used in various countries; ascertain the various tools used to manage BSE and vCJD risks, for example new legislation, regulations, policies (in scope, timing and compliance), warnings, voluntary plans, surveillance systems, education, training and risk communication efforts that occurred in different countries; and to determine a set of “best practices” and lessons learned for BSE and vCJD management.

Analysis included qualitative literature review (PUBMED and grey literature searches) to assess expert and non-expert information for BSE and vCJD policy. Semi-quantitative and non-parametric statistics for country to country policy comparisons were also performed. Analysis determined correlations between the timing of events and risk reduction policies.

Comprehensive case studies with extensive regulatory activity and detailed chronologies were completed for: Asia (China, India, Japan, South Korea); European Union member countries (Belgium, Denmark, Norway, Finland, France, Germany, Italy, Netherlands, Portugal, Spain, Sweden, Switzerland, United Kingdom); Central and Eastern Europe (Czech Republic, Poland, Russia, Slovakia, Slovenia); North America (Canada and United States); Latin America (Costa Rica); South America

(Brazil, Argentina); South Pacific (Australia, New Zealand); Middle East (Israel); Africa (Regional assessment) and others (OIE activity, WHO activity). The case studies provide an overview of the international initiatives, response activities, trade agreements, codex implementation of policies and risk communication that have been implemented during the BSE outbreak. Country case studies have also been analysed for qualitative and semi-quantitative comparisons.

Understanding the long history of how individual countries as well as international agencies have responded to the challenge of BSE and vCJD will improve our ability to deal with similar challenges in the future. Having detailed chronologies of key events provides a basis for comparative analysis and derivation of “best practices” for management. The collection of international case studies has also documented the psychosocial impact of BSE crises in different countries. The type of evidence and the metrics differ significantly from traditional risk modeling, however, we hope to develop an algorithm that will allow integration of these yet unaccounted for parameters.

Non-parametric statistical analysis of the case studies from these jurisdictions led to a number of interesting conclusions (Tyshenko, 2008: Appendix I, #21):

- Knowledge of the UK BSE outbreak was not a significant driver for BSE policy in any other country that later reported BSE.
- Policies (as drivers) to reduce external challenge (UK cattle bans, MBM bans) were linked most closely in time with 1996 knowledge of vCJD human health associated with consumption of BSE agent contaminated meats.
- Policies (as drivers) to reduce internal challenge (recycling/amplification SRM bans and approved rendering-disposal protocols) were most closely linked in time to the occurrence of domestic BSE and the peak of non-UK BSE in 2001-2002.

- In countries with imported BSE the detected case acted as a signal event and resulted in responses to reduce external (live cattle bans, meat and bone meal bans) but not internal challenge (internal recycling of contaminated materials, high risk material bans, rendering standards to reduce BSE agent).
- Domestic BSE acted as a signal event that induced BSE policy implementation. However, knowledge of BSE in other nearby countries was not a driver for policy.
- Non-BSE countries were not more precautionary for signal events than the worst-BSE- affected countries.

Analysis of the country case studies has provided benchmarks and insights for policy and decision-making for managing BSE. The case studies allow for a relative ranking of how Canada managed this risk comparatively and defined a set of collective best practices for BSE risk management. As a global, zoonotic disease BSE decision-making required the integration of international activities within the decision-making framework.

*Significance of the above Issues for the Risk Management Framework.*

Among the provisional considerations that emerge from the foregoing discussion are the following:

- The need for surveillance policy and risk estimation methods to be sufficiently robust so as to best capture the true incidence of a disease as quickly as possible (in order to judge the adequacy of risk control measures).
- The need for rapid, clear and credible dissemination—among both experts and the public—of early scientific findings, especially where a novel disease is concerned.
- The need for far better coordination and quicker application of approved risk control measures among all affected countries.

- The need for a common, credible process for the categorization of levels of risk that is driven primarily by the need for adequate risk control measures.
- The need to make progress toward an international basis for common action that is accepted and implemented by individual countries.

#### **4 Assessing and Managing the Risk of BSE in Canada.**

Canadian authorities completed their first formal assessment of the risk of BSE in the domestic herd in May 1994, in a document entitled “Risk Assessment on Past Importations of Cattle from France, Switzerland and the U. K.” This eleven-page document was prepared by a federal group (no authors are named) called the Animal, Plant and Food Risk Analysis Network (APFRAN), but never published or released to the public (it was obtained by W. Leiss pursuant to a formal request under Canada’s Access to Information legislation). The report states: “The probability of entry of BSE infected cattle through the 1982-89 importation of 183 cattle from the U.K. appears to be very high” (APFRAN, 1994, p. 11). But no public mention to it was ever made until almost nine years later, when it turned up in one of the references cited in the December 2002 risk estimation of BSE prepared by the Government of Canada’s Canadian Food Inspection Agency (CFIA).<sup>32</sup>

A similar fate awaited a draft report prepared by two scientists at Health Canada, entitled “Risk Assessment of Transmissible Spongiform Encephalopathies in Canada.” The document surfaced years later as a result of a private lawsuit against the Government of Canada. This report reiterated the key conclusions from the 1994 paper, about the source of infectivity in the Canadian herd, but covered all the possible exposure pathways in far more detail (Orr and Starodub, 2000, see esp. Figure 3.2.1).

But once again, it was never published or referred to publicly by Canadian government officials; indeed, it does not appear even to have been completed. The document is replete with incomplete sections which are marked by queries addressed to CFIA officials; the implication, in the end, is that there was insufficient inter-departmental cooperation on the study.

Canada's ban on feeding ruminant materials to ruminants had taken effect in mid-1997. In December 2002 CFIA released an elaborate three-part risk estimation, the major conclusions of which are:

1. "The estimated probability of at least one infection of BSE occurring prior to 1997 was  $7.3 \times 10^{-3}$  and therefore the likelihood of establishment of BSE in Canada was negligible" (CFIA, 2002, Executive Summary);
2. "The risk was even further reduced by the mitigating measures in place since 1997" (CFIA, 2002, Executive Summary);
3. "The risk estimate ... indicates a negligible probability that BSE was introduced and established in Canada" (Morley et. al., 2003, p.157<sup>33</sup>);
4. "The impact of the introduction and establishment of BSE in Canada would be extreme, based on the animal and human health impacts, trade impacts, effect on industry and costs of eradication" (CFIA, 2002, "Consequence Assessment," Sect. 5, final sentence).

There is good reason to think that the qualitative term ("negligible") used to describe—in the published article quoted in point #3 above—the probability of the *introduction* of BSE in Canada was inconsistent with the evidence used to formulate the quantitative frequency estimation, that is,  $7.3 \times 10^{-3}$  (Leiss and Nicol, 2006, pp. 896, 898-9 n. 11; this paper, endnote 33). Ironically, initial indications of the first indigenous case of BSE in Canada came just after the CFIA risk estimation was released (the final confirmation occurred in late May 2003).

The appearance of a novel animal pathogen that became known as BSE presented a number of interconnected risks to the nations whose herds came to be infected. There were actually three different risks present:

- A. Animal health risk (probability of occurrence [P] of BSE, consequence [C] of BSE in the national herd);
- B. Human health risk (P and C): not formally estimated, but said to be “very low” by Health Canada;
- C. Socio-economic risk to farmers and financial risk to federal and provincial governments (in conditions where even one case means that the export trade would be cut off immediately).

The “extreme” consequences (to use the language of CFIA’s risk estimation) were not the direct result of the appearance of one case in the national herd; rather, they followed from the international policy of border closures. The result of this imprecise risk estimation is that, although almost a decade elapsed (1994 to 2003) from the first risk estimation to the appearance of the first case of BSE, in all that time the true (multi-dimensional) risk was never fully and adequately assessed.

The long delay between the first, crude—but nevertheless prescient—estimation, completed in May 1994, and the elaborate quantitative frequency estimation (published in December 2002), occurred in a specific larger context: During all this time, provincial government economic development policy, especially in Alberta, was encouraging both the expansion of the national herd and the degree of reliance on cross-border movement of live cattle between Canada and the US (the growth of huge feedlots around Lethbridge for “finishing” cattle shortly before their trip to the slaughterhouse). What this meant was that Canada’s exposure to the consequences of a sudden and long-

lasting border closure—and thus, the scope of Canada’s economic risk—was rising steadily and dramatically during that entire time, i.e., 1994-2003 (Sparling and Caswell, 2006). This “dynamic” character of Canada’s unique risk profile was never captured in any analytical instrument used in the risk management of BSE.

As indicated earlier, CFIA officials published in a scientific journal their risk assessment of BSE for Canada two months before the index case occurred in May 2003 (Morley et al., 2003). This assessment is characterized by an elaborate, quantitative frequency estimation; but this is accompanied by a severely truncated, purely qualitative consequences estimation. In their words (p. 170):

Consequence assessment consists of describing and quantifying the relationship between specified exposures to a risk agent and the economic consequences of those exposures. The consequences of disease outbreaks are associated with animal losses, production losses, costs of control and eradication, costs of monitoring and surveillance and trade embargoes and restrictions.

The impact of the introduction and establishment of BSE in Canada would be extreme, based on the animal and human health impacts, trade impact, impact on industry and the cost of eradication as exemplified in other countries.

Note the complete absence of any reference to psychosocial impacts, except for the oblique reference to “human health impacts.” The other relevant passage is as follows (p. 171):

*Impact on Industry:* The occurrence of BSE in Canada would affect many sectors of the cattle industry, including farmers, meat processing, rendering, transportation and distribution, and retail, among others. It could result in a substantial decline in the consumption of beef and beef products due to a perception of risk to human health and safety.

Ironically, although there is a passing reference to consumer risk perception here, it turned out to be wrong (see below, Section 6). The following observations may be made:

- Consequences are here limited exclusively to economic measures;
- The assessment of consequences is purely qualitative, even though there are well-established methods for estimating direct and indirect economic costs;
- The level of effort in the assessment as a whole is badly skewed, as between the estimation of frequency and consequences.

Thus this was not a true quantitative risk estimation at all, for two reasons: First, since risk is the product of probability times consequences ( $R=P \times C$ ), and only probability had been estimated, the end result was, in terms of measured effects, simply a frequency estimation. Second, although this calculation was issued in December 2002, the quantitative estimation was valid only for the period prior to 1997; the period after that date was characterized by a simple “guesstimate,” i.e., the unsupported statement that “the risk was further reduced” by mitigating measures.

The issue of *who* is responsible for carrying out effective risk management is one of the most contentious matters in this area. In many (if not most) cases in our society, key responsibilities are likely to be shared. In the case of BSE, it would probably be agreed that they would be shared between beef producers, on the one hand, and the federal and provincial governments, on the other; but exactly *how* the whole set of responsibilities are divided up is not exactly clear.

However, established practices demonstrate that it is federal authorities who assume responsibility for undertaking the relevant risk assessments. Beef producers

would have the duty to carry out the directives for farm practices that are based on those assessments. For example, when the partial feed ban (feeding ruminant materials to ruminants) was announced in 1997, it was not accompanied by a mandatory recall of feed already produced and sold. Therefore, it would have been up to beef farmers to make their own judgments about previously-produced feed that they had purchased, and also about the level of effort required to purge their feed troughs of any residues of that potentially-contaminated feed.

In addition, individual beef producers were, at least theoretically, in a position to make other types of risk management decisions during the period from 1990 (when wide awareness of the UK epidemic of BSE in herds could be presumed) until May 2003, when the index case occurred in Canada. However, general knowledge of what was happening in the UK, and in other countries in Europe and Asia, would have been of limited value to Canadian beef farmers. In order know what steps it might have been prudent for them to take, they would have had to be provided – by the federal authorities – with information on *the risk of BSE in the Canadian herd*. They got no such information at all until December 2002, when CFIA’s quantitative risk estimation was released—and even then, as noted above, this estimation only covered the period *prior to 1997*; in other words, it could not provide any guidance to potentially affected parties at the time when it actually appeared. They could have had some preliminary guidance as early as 1994, when Canadian authorities became aware that there was a “very high” probability that BSE was incubating in the Canadian herd. That potentially devastating information was never made public.<sup>34</sup>

The social, economic and financial impacts of Canada's BSE episode have been nothing short of catastrophic: Various estimates of the purely economic cost (direct and indirect have been made, all of them adding up to many billions (Burnett et al., 2008: Appendix I, #22).<sup>35</sup> There is no existing count of the non-financial human impacts, however; adding these types of considerations to the risk management framework is, of course, one of the main objectives of the project discussed in this paper. We are compelled to raise the issue, at the very least, as to whether deficiencies in this country's risk management processes then in place were a contributing factor in the full scope of the adverse consequences that followed upon the first and succeeding cases of BSE.

The experience with BSE has challenged all aspects of the established risk management frameworks and practices for zoonotic diseases in many countries (for the UK, see Phillips et al., *The BSE Inquiry*). In the Canadian context, a major re-thinking of important aspects of risk management is proposed here, especially in three important dimensions: the scope of risk estimation, public perception of risk, and the evaluation of psychosocial factors in risk assessment. With reference in particular to perceived risk and psychosocial factors, an important task that remains to be done is to develop a quantitative algorithm for these dimensions of risk management, so that the results of analysis can be more easily integrated into the overall estimation of potential consequences of the exposure to hazards. An overview of the current work is presented in the following three sections.

## **5 The Scope of Risk Estimation.**

Even though BSE is on decline in Europe thanks to the strict feed bans and other control measures, cases continue to be diagnosed in other parts of the world, including Canada. Understanding and developing risk models of prion diseases is becoming even more important. In particular, risk models of prion disease are necessary to estimate the actual size of vCJD infection and the risk of secondary iatrogenic infection through surgery, blood transfusion, and organ and tissue transplant. Those estimates become an essential tool for policy makers and public health practitioners to evaluate the appropriate measures and allocate resources to control the spread of prion diseases. Prion disease risk models may also provide a platform for future development of risk models for other infectious zoonotic diseases and public.

The long and variable duration of incubation period entails that significant number of infected animals may die of other causes (e.g., slaughter) before showing clinical symptoms. Adding to this complexity that clinical signs of BSE are not easily recognized and identification of cases is difficult (Konold et al., 2006). Judging the scale of the epidemic based on number of reported cases would be misleading. Therefore, risk assessment and management efforts has to rely on risk modeling to estimate retrospectively the actual number of infections and project the future course of the epidemic.

Methods that estimate the historical rate of infections such as back-calculation models showed that number of number of reported BSE cases in the UK and France was considerably underestimated (Calavas et al., 2007; Donnelly et al., 2002). The estimated number of infected cattle in the UK have been in the range of 900,000 to 1,130,000 with

between 460,000 and 482,000 slaughtered for human consumption before the introduction of the specified bovine offal in 1989 (Ferguson et al., 1997). In France it was estimated that about 51,300 were infected in the 1987-1997 period compared to only 103 clinical BSE cases detected by the passive surveillance system up to June 2000 (Supervie and Costagliola, 2006). Back-calculation models also found that under-reporting and differential survival were the major factors in BSE case underestimation and suggested that passive surveillance system implemented at the beginning of the epidemic was ineffective monitoring system. The system was later amended to the systematic histological examination of brains of cattle older than 30 months slaughtered for human consumption (Brown et al., 2001).

Retrospective tracking of infection trends during the epidemic has also been used to evaluate the efficiency of various feed bans and other control measures. Spatio-temporal analysis of infection risk showed that cases detected after the July 1988 ban on feeding ruminant-derived meat and bone meal (MBM) to ruminants in the UK were related to cross-contamination of cattle feed with feed for other species (Stevenson et al., 2005). Similarly cases born in France after the 1989 ban on import of MBM from the UK and the 1996 decision of removal of specified risk materials from MBM have arisen because of non-compliance and cross-contamination (Abrial et al., 2005; Savey et al., 2000). In other countries such as Germany (Zentek et al., 2002), Switzerland (Hornlimann et al., 1994), Sweden (Wahlstrom et al., 2002) and Japan (Sugiura, 2004), infection risk was related to import of live cattle and MBM from the UK. The results of this analysis pointed to the difficulty and inefficiency of implementing partial feed bans. Subsequent control measures and agricultural trade policies were more stringent and have been

implemented more efficiently which is reflected in the apparent decline in BSE incidence worldwide.

Back-calculation models estimated several epidemiological parameters important in disease transmission and dynamics such as incubation period and age-dependent risk of infection. Estimation of the average incubation of about five years implied that the impact of preventive measures on disease incidence might not be immediately evident. The same models have been extended to analyze data from reported testing of healthy animals at abattoirs and testing data from animals reported as sick or dying on the farm in the UK (Ferguson and Donnelly, 2003). This extension allowed more precise and ongoing assessment of human exposure to BSE infectivity and evaluation of possible risk-reduction strategies, in addition to testing various scenarios of changing infectivity and test sensitivity. The results of analysis suggested that changes in policies to allow older animals (alternative to less than 30 months rule) increase human exposure by small amounts compared to previous human exposure throughout the BSE epidemic. The results also suggested that the ban on specified risk materials reduced per-animal infectivity entering human food supply by twenty-fold.

The recent BSurvE model has been developed to estimate infection incidence in the standing cattle population (Prattley et al., 2007). The model can be applied to evaluate current national surveillance programs, and provide tools to improve surveillance strategies for BSE-affected and non-affected countries. Outputs of the number of infected animals have important public health relevance since those numbers can be converted into estimates of human exposure to BSE infectivity in the form of

ID50 of beef and beef products to estimate the risk of developing vCJD (Cooper and Bird, 2003).

Similar to BSE, vCJD is also characterized by long incubation period. Various risk models were developed to estimate the actual number of vCJD infections and predict the future size of any epidemic. One type of the models relate past pattern of BSE epidemic to the vCJD epidemic. Typically this relies on relating the number of infected cattle slaughtered for human consumption to the incidence of vCJD stratified by age and time (Ghani et al., 1998). The other type of models use data on dietary consumption of BSE-infected meat in the form of mechanically recovered meat (MRM) and neural tissue to investigate epidemiological parameters of vCJD and provide short-term predictions (Cooper and Bird, 2003). Both types of models showed that exposure to infectivity varied by time according to regulations to prevent entry of BSE into beef products. For example in the UK, models suggested that this risk have peaked in the mid-1980s and dropped significantly after the ban on specified bovine offal (SBO) for domestic consumption in 1989, although a small level of risk remained due to noncompliance (d'Aignaux et al., 2003). Further measures were taken in 1996 such as broadening of the SBO ban and exclusion of animals older than 30 months from human food may have lowered the risk to zero. Using the back-calculation model of d'Aignaux et al. (2003), sensitivity analysis was conducted to examine the effect of different levels of the 1989 SBO ban on the future estimate of vCJD risk. Similar pattern of exposure profile can be assumed for other countries with a time course that followed the introduction of BSE infectivity until the appropriate protective measures have been adopted.

Iatrogenic transmission of vCJD might arise from infection due to blood transfusion or transplantation of infected biological products and exposure to contaminated surgical instruments. Recent identification of four cases of vCJD caused by blood transfusion has increased the fears of a secondary epidemic (Hewitt et al., 2006). Recent models conducted to evaluate the risk of secondary infection due to blood transfusion and surgery (Clarke et al., 2007; Garske et al., 2006) has important health implications because of the necessity and scale of those health services and may help improve current policies in hospital and other health facilities to prevent the transmission of infectious agents.

The general goal of the current project is to develop a flexible, comprehensive model that quantifies prion disease risk in animals and humans in Canada. The research methodology will use a stepwise process that starts with currently available figures on reported BSE cases in Canada to estimate the actual number of BSE-infected animals in the past (which is likely to be somewhat greater than the reported number of cases) and the future number of cases (likely to be declining to near zero, with the BSE control measures Canada has implemented to date). The estimated BSE infection rate will subsequently be used to determine the extent of human exposure, evaluate different feed policies and other regulations, provide insights on the future course of a possible vCJD outbreak, and estimate the risk of secondary human-to-human disease transmission by blood transfusion and surgery.

A long-term goal of this project is to create a framework under which the above risk models can be combined to form an integrated system of quantitative risk

assessment. This system will be a flexible, comprehensive model that will facilitate the assessment of different aspects of prion diseases in Canada. The integrated dynamic simulation model will incorporate, as inputs, important parameters influencing the spread of prion infectivity in the cattle herd and the risk of transmission to humans via infected beef, blood and surgical instruments. The inputs will be easily updated or varied over ranges so that the overall model will be adaptable to real-time changes, new situations and urgencies involving different factors that influence the risk of BSE and vCJD. A set of scenarios and simulation analysis of different parameters and risk situations will be created to predict the behavior of the disease. Examples of such parameters and risk situations include the use of meat and bone meal, implementation and effectiveness of various feed bans, level of compliance with feed bans, removal of infectious tissues from human food chain, amendments to BSE surveillance systems, variability in BSE case reporting rates, changes in the incubation period distribution.

The model can also be used to evaluate the impact of past risk management interventions, such as the 1997 feed ban, prohibiting rendered protein products derived from mammals from being used in ruminant feed, and subsequent measures: the prohibition of import of ruminant-derived meat and bone meal (MBM) from category 1 and 2 countries (those with some residual BSE risk), the removal of SRM from human food systems (2003), and the enhanced SRM regulations (2007), covering all animal feed, pet food, and fertilizers. In addition, the impact of other recommended regulations can also be assessed, e.g., (a) a requirement for dedicated lines for production of animal feeds containing prohibited (i.e. ruminant derived) protein in facilities producing both

prohibited and non-prohibited material, and (b) prohibition of all meat and bone meal (including poultry and fish protein) in ruminant feed.

The model will provide decision makers with a more intuitive and direct quantitative risk tool to adopt the appropriate control measures to eradicate prion diseases. In addition to being a tool for decision makers, the integrated model will also provide a platform for future development of risk models. As much as possible, the integrated model will be modular and open. The implementation of the integrated simulation model will be centered on a high level of re-usability. In this way, the different components can be easily modified or replaced and the system will be open to maintenance and further development by an active BSE/vCJD quantitative risk modeling community.

## **6 Public Perception of BSE Risk in Canada.**

A national public survey on public perceptions of prion disease risk in Canada was conducted from October to December 2007. The survey aimed at documenting the public's perceptions of prion diseases within the broader context of food safety, in establishing parameters of risk acceptability, and in delineating social values and ethics that can guide Canada's future policies on prion disease risk management. The survey also served to establish baseline data against which to monitor the evolution of the public's views on and understanding of this important risk issue. A total of 1,517 Canadians were randomly selected to be representative of the adult population by region, age, and gender, as per the 2001 Census. This section presents descriptive

findings from the survey regarding perceived risk, perceived control, uncertainty, sources of information, trust and knowledge and beliefs pertaining to BSE.

First, mad cow disease and chronic wasting disease rank low as a source of worry to Canadians. Among 18 food items, mad cow disease ranked 12<sup>th</sup>, with much higher risk levels allocated to food items such as growth hormones and imported food. This indicates that Canadians do not perceive mad cow disease as a very salient risk, a finding that is compatible with the focus groups results. In qualitative interviews, participants explained that reasons for this were perceived low probabilities of occurrence and infection. The focus groups also revealed that higher and more significant media coverage on other health risks such as avian flu or *E. coli* plays a role in the low perceived risk of BSE (Lemyre et al., 2007).

Participants perceived the risk of mad cow disease as higher for the health of other Canadians than for their own health. This echoes the commonly observed phenomenon of optimistic bias, a theory that describes person's tendency to view the risks as lower for themselves than for others (Hoorens and Buunk, 1993; Perloff, 1987; Taylor, 1989; Weinstein, 1982, 1987). The results of this survey really point to the fact that for most Canadians, the mad cow crisis was less of a public health issue than an economic, political, social, and foreign trade issue. For example, according to the general public, the most likely consequence of the discovery of mad cow disease is that countries will stop importing Canadian beef. Clearly, the health risk associated with prion diseases is not a major concern to Canadians, and reframing prion disease risk as

an economic and socio-political issue would better match Canadians' understanding of the nature of this risk issue.

Other consequences of a discovery of a case of mad cow disease include the bankruptcy and the psycho-social distress of farmers. In fact, the stronger risk perceptions regarding economic issues and the psychosocial consequence of a potential crisis on the farmers might be related to the extensive coverage on those facets of mad cow disease by the media in previous outbreaks of the disease. Nonetheless, it seems that it is indeed the economic impact of a future outbreak of BSE that is considered most likely to affect the lives of the majority of individuals in Canada, rather than the direct personal health impact.

Participants were somewhat familiar with the BSE crisis and they are somewhat knowledgeable about the disease. Nevertheless, there is still work to be done in informing Canadians about the nature of mad cow disease. For instance, the public should be more informed regarding the symptoms an animal can show if infected, the human transmissibility of the disease, and whether wild game can develop diseases similar to mad cow disease. A small number of participants reported having modified their beef consumption after the 2003 crisis, but the results showed that a much higher percentage would change their diet if another crisis were to occur. These findings seem to reflect unrealistic optimism, the tendency to believe that the present is better than the past and that the future will be better as well, especially when it relates to oneself (Armor and Taylor, 2002). The fact that a significant number of Canadians reported

they would modify their diet if another crisis were to occur reflects that they have a positive belief they could face and deal with another BSE outbreak.

About half of the respondents believed that the current government monitoring programs put in place to handle mad cow disease make the food supply safer and that the government was doing enough. Focus group results also concluded that Canadians are somewhat satisfied with current government initiatives. Some focus group participants wanted to believe that the measures and the standards Canada has put in place were adequate and efficient. They stated the few cases Canada has had are evidence that the measures currently in place are adequate. However, if an outbreak of mad cow disease were to take place, they would lose trust in their government. In addition, almost all focus group participants thought that there should be more information given to the public regarding the measures the government has taken concerning BSE (Lemyre et al., 2007).

In terms of policies regarding mad cow disease, the survey findings reveal that Canadians are somewhat prepared to pay a premium to have a safer food supply, although not to the same extent that they wish for extra measures such as a ban on feeding cows to cows and labelling the origin of beef. It is possible that people felt less strongly about this policy than others because they were aware of the expenses it would incur. It is important for policy makers to take these findings into consideration if they are considering such measures (Lewis and Tyshenko, 2008). It would also be interesting to find out what factors play into making these different policies more or less acceptable for the Canadian general public.

Canadians value research scientists the most as trustworthy sources of information: they have the most confidence in them, would seek credible information from them, and, would comply the most to recommendations made by them. Canadians reported these findings while there was no BSE crisis. As a point of comparison however, research scientists were somewhat mistrusted following the BSE crisis in Europe (Green et al., 2005): it would be interesting to see if the same would happen in Canada if another crisis related to mad cow disease were to occur. Trustworthiness can be considered more important than expertise, so it is crucial to take this into account when establishing effective risk communications strategies (Smith et al., 1999). Moreover, only a small number of Canadians would turn to politicians, the Internet, or the media for information regarding mad cow disease, nor follow their recommendations, a finding which may be due to a lack of trust in the mainstream media and politicians. This could be explained by previous treatment of the issue of BSE by the media and politicians, who were perceived as sometimes hiding some uncertainties or risks related to mad cow disease (Miles and Frewer, 2003; Shaw, 2002). Even though the Internet was rated as a somewhat non-credible source of information, this medium should not be completely discarded as it is very accessible and convenient for many Canadians. Policy-makers, therefore, need to work to make risk communication and the information on BSE and mad cow disease that is posted and broadcasted via the Internet more credible and reliable (Krewski et al., 2006).

## **7 Psychosocial impacts of BSE in Canada.**

*“The biggest risk is the lack of understanding and empathy by*

*those developing risk management programs.”*

The events following the discovery of a single indigenous case of BSE in the Canadian cattle herd on May 20, 2003 has had and continues to have significant ongoing socio-economic impacts on farmers, their families and communities from coast to coast. Although much emphasis has been placed on the economic impact of BSE on the cattle industry, little has been done to understand the psychosocial implications of the BSE crisis—in particular, its impact on the mental and social health of individuals from rural and farm communities. Here we report preliminary results from the “Socio-economic Impact of BSE on Rural and Farm Families in Canada,” a project which aims to engage farmers, their families and agricultural community organizations to identify key issues, gaps and possible policy recommendations for the BSE crisis.

The Community Impact Study used multi-site and multi-method qualitative research with the purpose of identifying the economic and psychosocial impact of BSE on rural and farm family health and socio-economic well-being including community resiliency, in Canada. To reach this objective, the research team methods were threefold. First, two preliminary literature reviews, one with a Canadian focus and the other with an international focus, provided an assessment of the information gaps pertaining to the psychological effects of BSE. These specifically centred on social science literature and grey literature since 1996 addressing the impacts of BSE on farm families and rural communities (McCallum and Sutherns, 2006; Wellman, 2006). Second, twenty telephone interviews were conducted with key informants from farm crisis call lines, agricultural informational service centres and other farm support organizations to capture and analyse existing information on the impact of BSE on rural

and agricultural families (Sutherns and Amaratunga, 2007). Third, cross country focus groups engaged farm and rural Canadian households in a dialogue in order to understand the individual farmers and farm families' experience of the BSE event. These were conducted in Lethbridge, Alberta; Moose Jaw, Saskatchewan; Brandon, Manitoba; Kemptville, Ontario; and Ste-Hyacinthe, Quebec with a total of 48 participants (Pletsch and Amartunga, 2007). In addition, together with the Farm Family Health research team, an environmental scan of over 800 agricultural, rural and farm organizations and contacts from across Canada was developed to inform the recruitment campaign and develop networks and partnerships with farming stakeholders for the benefit of both studies.

To the greatest extent possible, the voice of the participants will be used to express a common theme or trend in the findings. Although focus group and interview methodology is not useful to generalize upon a population, using narrative to understand an individual's experience of a particular event or to disseminate research is becoming an increasingly recognized tool in health research (see for example, Steiner, 2007; Hinyard and Kreuter, 2007). In this way, qualitative research methodology, and especially narrative data, can be used to gain a better and holistic understanding of individual experiences related to the BSE event in the context of their daily lives.

What is striking about the data is the similarity among the provinces despite the fact that BSE cases were concentrated in the western provinces. Moreover, the findings echo a number of issues raised concerning farm stress based on studies conducted in the United Kingdom (Lobley et al., 2004; Parry et al., 2005). Similarly, prior to the BSE

event, high levels of stress amongst farm families in Canada is far from being a new phenomenon (Walker and Walker, 1987; 1988). As such, it might be hypothesized that the socio-economic impacts not only exacerbate already existing issues but also reveal a potential crisis in agriculture if these issues remain unaddressed.

As many of the participants commented, the risk posed to the farmers is of an economic and political nature which can have significant consequences for their health and well-being as well as the sustainability of their communities. Moreover, the findings highlight the way in which the ‘ripple effects’ of finding one case of BSE extend far beyond the cattle industry and affect many aspects of rural communities and agriculture such as machinery, veterinary services, schools, commercial transportation and other livestock. As such, it might be argued that the findings not only demonstrate the need to integrate stakeholders into the risk assessment and risk management process but also that other safeguards such as financial ‘safety nets’ and services need to be considered when developing population health risk management strategies to mitigate disastrous socio-economic impacts, to sustain the industry and protect the food system.

## **8 The Evolution of Risk Management Frameworks.**

The practice of displaying the sequential steps that should be undertaken in the process of risk management [RM] decision-making, in the form of schemata using flow-chart diagrams, began in the early 1980s. This was itself the outcome of the increasing interest in “formal” risk assessment practices, including the use of either quantitative or qualitative risk estimations. The landmark document in this regard is the famous “red

book,” *Risk Assessment in the Federal Government: Managing the Process* (US, National Research Council, 1983). On the very first page on this pathbreaking document, two themes are mentioned which continue to characterize the field down to the present day: (1) the domain of risk assessment involves “the intricate relations between science and policy”; (2) regulatory decisions about health hazards can be “bitterly controversial.” Another interesting aspect of this document is its statement about the need “to ensure that risk assessments are protected from inappropriate policy influences” (p. 14).

The major “structural” aspect of the flow-chart design was the distinction between the poles of risk assessment and risk management (see Figure 1). The former stands closest to science and is, in fact, represented as the intermediate stage that stands between science and policy (which includes decisions). Two other aspects of this early diagram became standard features in all later versions: (a) a “logical” breakdown of the components of each pole – e.g., hazard and exposure in assessment; (b) a sequential flow from a beginning (hazard identification) to a final end-point (the risk management decision). This early model was refined during the following years, as is shown in the Health Canada version, dated 1990 (see Figure 2). One of the main improvements in the later version is its far more comprehensive listing of the components or inputs for all of the stages, and especially for the “options analysis” box. What is especially noteworthy in the listing of factors to be taken into account at the options analysis stage is the inclusion of “public perception of risk” and “risk acceptability,” which marked a transition to later stages in the conception of the risk management process.

These early versions of the RM process were often criticized, for example by influential Environmental Non-Governmental Organizations [ENGOS] in the United States, as being “closed” and “technocratic” in character. Certainly the regulatory agencies in those early days did indeed interpret their mandates as giving them exclusive authority to “perform” the assessments and arrive at the decision, including the determination of what information was relevant and how any piece of information would be factored into the final product. The contentious issue that lay hidden behind the agency’s doors was the matter of the exercise of *judgment*. In fact, the flow-chart diagram was littered with “black boxes,” so far as the world outside the agencies was concerned: One knew what the decision inputs were, at least in abstract terms, but there was no way of telling how each of them had been evaluated and then integrated into the overall assessment; for example, the most interesting feature of the Health Canada version is that, of the eight boxes in the diagram, only the box marked “Decision” has no descriptors whatsoever. It was another ten years before this factor was brought out into the open and its importance acknowledged in a massive study, again issued by the US national academies (US, National Research Council, 1994).

During the 1980s ENGOS in the United States, some of which had large professional staffs (including both scientists and lawyers), began trying to force open the agency’s doors, seeking both to put the details of agency decision-making “on the record” and to be accepted as legitimate participants (intervenors or stakeholders) in the decision process (Leiss and Chociolko, 1994, ch. 6). By the late 1990s the addition of these newer elements was disrupting the neat linear structure of the older model. The US then altered the model’s graphical representation, showing the stages as a sequential

series of interlocking circles around a “core” labeled “engage stakeholders”; other agencies, such as Health Canada, soon followed suit (see Figure 3). While this addressed some issues, it also left in limbo, as it were, the question about who exactly was responsible for “managing the process,” to recall the subtitle of the “red book.” In addition, the important detail about what is supposed to happen, in a sequential sense, tends to drop out in the process models.

Three other key aspects of the management of risk are not shown in any of the models referred to so far. One that is especially relevant is the distribution of bureaucratic authority across various line departments, particularly where environmental risk factors are concerned. The second is the international context: Increasingly, for certain types of risks, especially infectious diseases, national governments need to work collaboratively together in the risk management business. The third is the simple length of time across which a particular risk must be managed, which raises issues about the readiness of various agencies, especially at critical junctures. For example, BSE was first identified as a novel disease in domestic cattle in the U. K. in 1986; the first Canadian case occurred in 2003; and, at the time when the ninth Canadian case was announced in early 2007, CFIA noted that it expects that BSE will not be completely eradicated in Canada until another ten years have passed, that is, in 2017—thirty years after it all started (Canada, CFIA, 2007).

### *The Need for Renewal of the Risk Management Framework*

Analysis of past cases indicates that risk management decision-making most often fails because some critical decision inputs are either missing entirely or in part, have been

carried out inadequately, or have not been delivered when needed (Hrudey and Leiss, 2003; Leiss, 2005; Jardine et al., 2003). Therefore, the framework needs to be re-examined with a view to determining whether all of the necessary decision inputs are specified; in addition, the separate inputs must be specified, as clearly as possible, in a form that can be readily *integrated* with all others. For example, the analysis of psychosocial effects and their impacts must be capable of being “rolled up” and “converted” into an *operational form*, that is, into a form that can be assimilated, along with other factors, within a decision exercise.

Thus a new framework, revised in response to earlier challenges, should be designed according to a set of key requirements derived from the study of the development of risk management models in the period after 1983, in the context of the extensive case-study literature that has grown up in the same period. These are:

1. The model must clearly indicate an agency that has “core responsibility” for a major risk issue, thus satisfying the need for clear accountability, and also show the relation between the core agency and all other associated agencies, both domestic and international;
2. The model must use a sequential decision-making structure, and also show clearly what key inputs are required, thus satisfying the need for clarity and transparency in the decision process;
3. The model must respond to the need for *timeliness* in decision-making, by incorporating a requirement for an initial phase of informal risk estimation that precedes the later, more elaborate exercises;
4. The model must stipulate the operationalization of all decision inputs, in terms of either qualitative or quantitative measures, or both, thus permitting the integration and “rolling up” of all inputs;
5. The model must be able to show interactions with external stakeholders that are specific in nature, and are related to the generation of equally specific decision inputs;

6. The model must show clearly the points where the core agency is responsible for communicating risk assessment results to the public and stakeholders;
7. The model must be sensitive to the dynamics of the interface of science and policy, and in particular, how the risk assessment may be “protected against inappropriate policy influences” (using the mechanism of independent and external peer review for the key analytical documents).

*A Renewed and Integrated Risk Management Framework (IRMF)*

The integrated risk management framework, shown in a variety of schemata in Figures 4 through 8, is the result of an attempt to respond to the kinds of challenges mentioned at the outset of this paper. (It should be noted that other agencies are currently working on updating and revising the basic risk management framework; one example, from the International Risk Governance Council (2007), is shown as Figure 9.) The IRMF responds to the seven requirements listed above by its inclusion of the following provisions which are not found in previous versions:

- A. A single agency is given lead responsibility to ensure accountability throughout the entire subsequent decision process.
- B. In Step 3, a provisional risk estimation (which may be qualitative in nature) is called for at a very early stage in the process, in those cases where early notification to potentially affected parties, and early action of a precautionary kind, may be thought to be appropriate.
- C. The “impacts estimation” phase (Step 5) specifically requires formal consideration of consequences (ideally in the form of a quantitative algorithm), including socio-economic and psychosocial dimensions, which must use standard measures (social indicators, social impact assessment, risk perception) to ensure an adequate level of methodological rigour.
- D. For the first time, this framework model uses an expanded format (Figures 7-9) so as to indicate clearly the responsibilities that the core agency should discharge with respect to both inter-agency collaboration (left side) and non-governmental partners (right side), including responsibilities for timely public communication.
- E. The model indicates that seeking an independent, external peer review of the risk estimation is a fundamental requirement of “best practices.”

Finally, we note that the public policy context—ideally—should direct risk managers to achieve certain specific objectives when they are utilizing an approved risk management framework. In fact, when such objectives are not stated explicitly in the policy process, they come to exist *de facto* when risk managers make either implicit or explicit judgments about the level of risk that is regarded as being “officially” acceptable in particular cases. We suggest that, as part of the renewal and re-constitution of the risk management framework, both the broad overriding goal, as well as a set of more specific subsidiary objectives, should be stated explicitly, and we propose the following schematic in this regard.<sup>36</sup>

*A. Goal of Risk Management:* To select the best approach for the risk management of any public health and safety issue.

*B.1: Decision Objectives:*

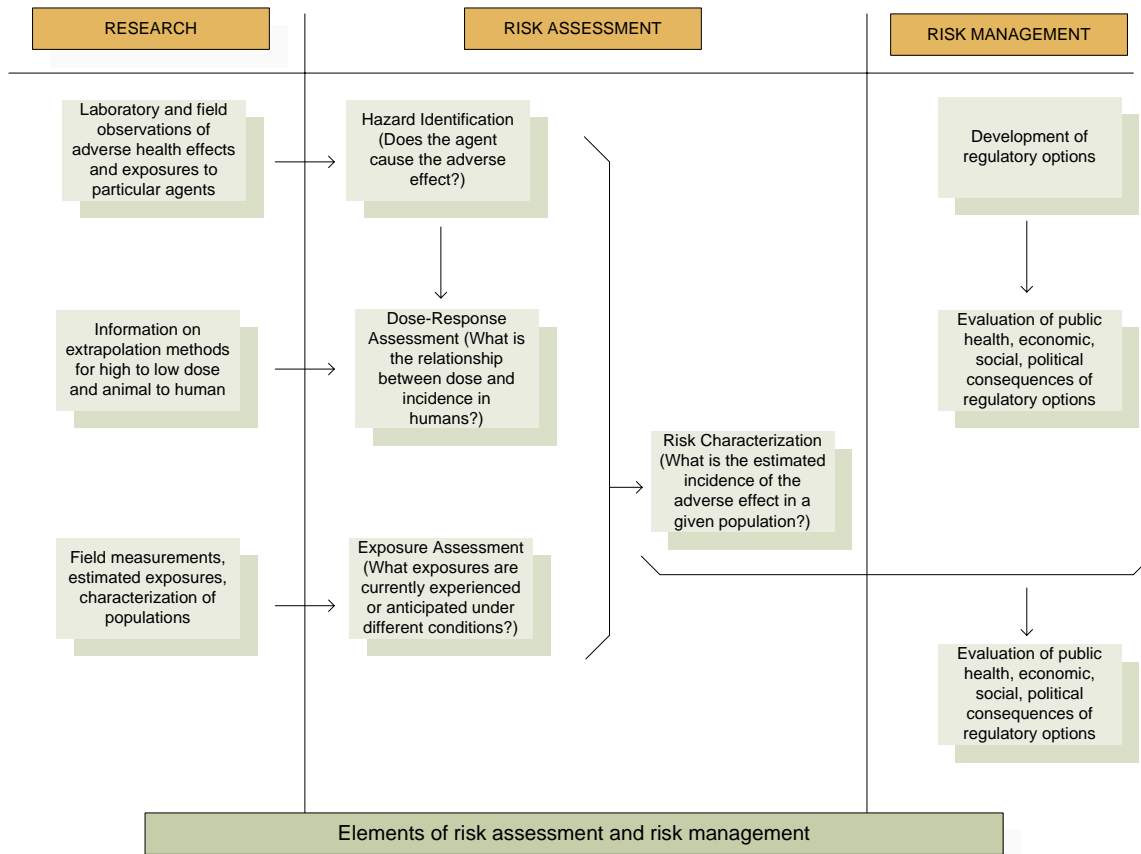
1. Achieve an acceptable level of protection for health and the environment:
  - Anticipate outcomes using a precautionary approach.
  - Prevent, reduce and mitigate risks.
2. Use appropriate decision inputs:
  - Define the problem to be managed correctly.
  - Use risk assessment methodologies, both quantitative and qualitative, for estimation of likelihood and consequences.

*B.2: Decision Processes:*

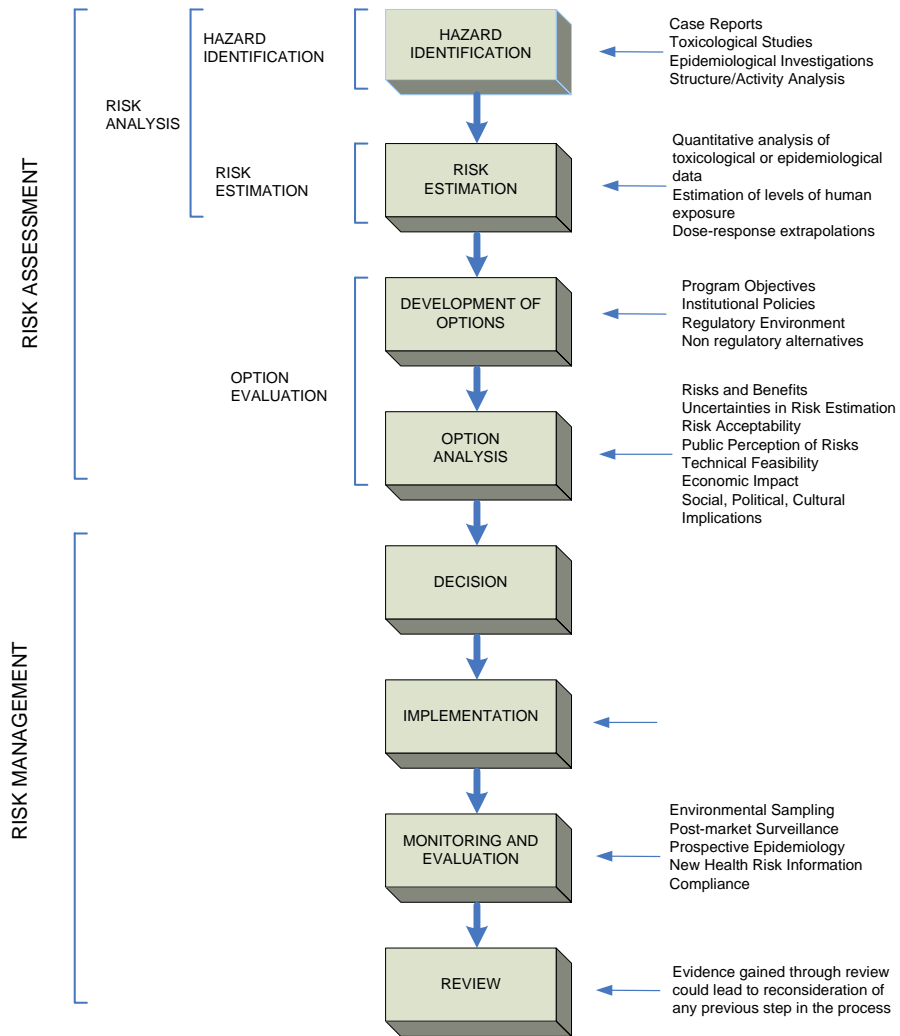
3. Maintain a high degree of transparency throughout the process:
  - Document all decision inputs and decision processes.
  - Provide timely information and analysis to stakeholders.
4. Build public confidence in effective risk management:

- Understand public perception of risk and engage the public in dialogues with good risk communication.
- Achieve equity and fairness with respect to both processes and outcomes.

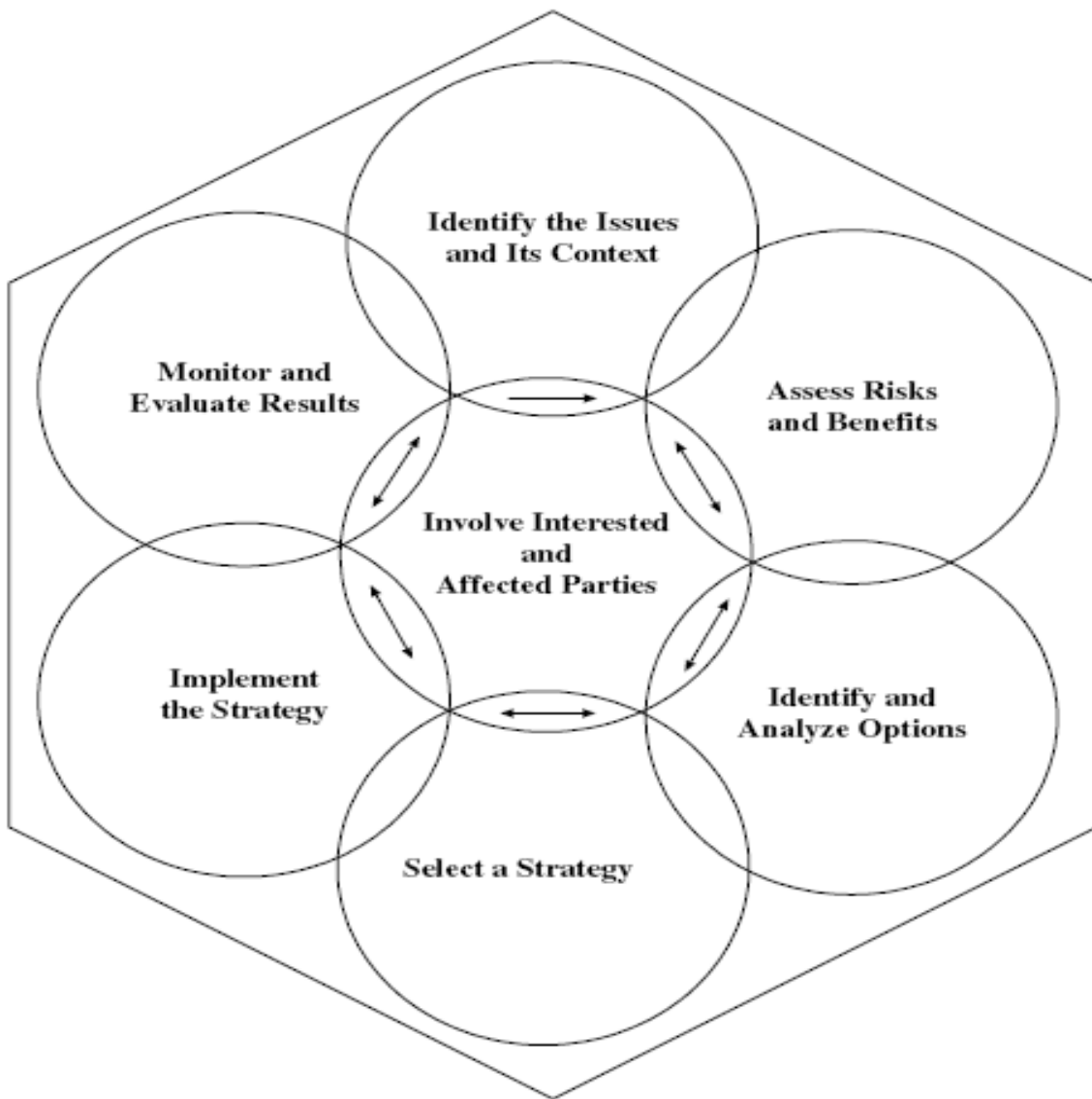
**Figure 1: “Red Book” (Risk Assessment in the Federal Government: Managing the Process, 1983)**



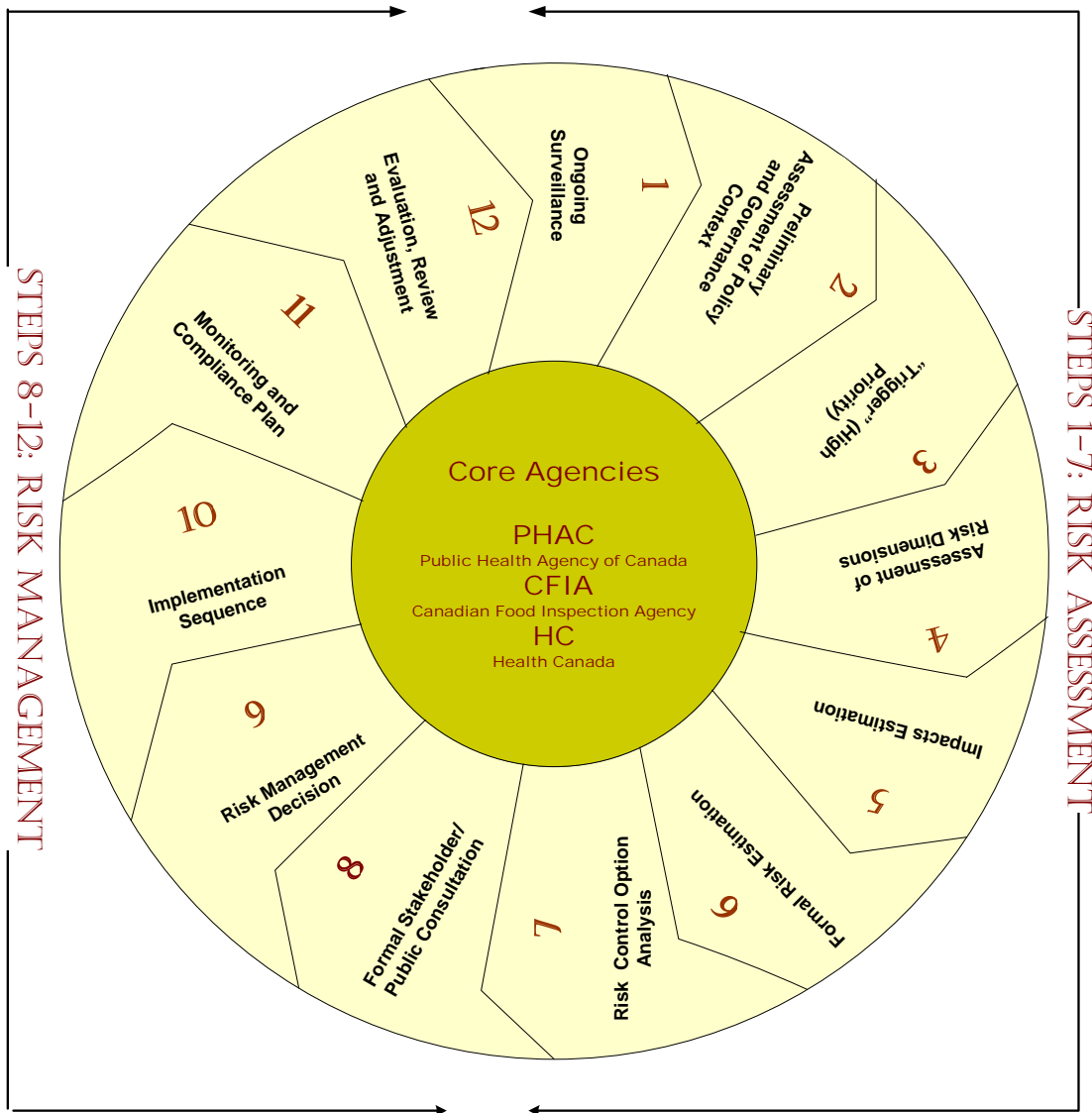
**Figure 2: Health Canada’s Risk Assessment and Risk Management model (mid-1980s), as shown in Leiss and Krewski (1989)**



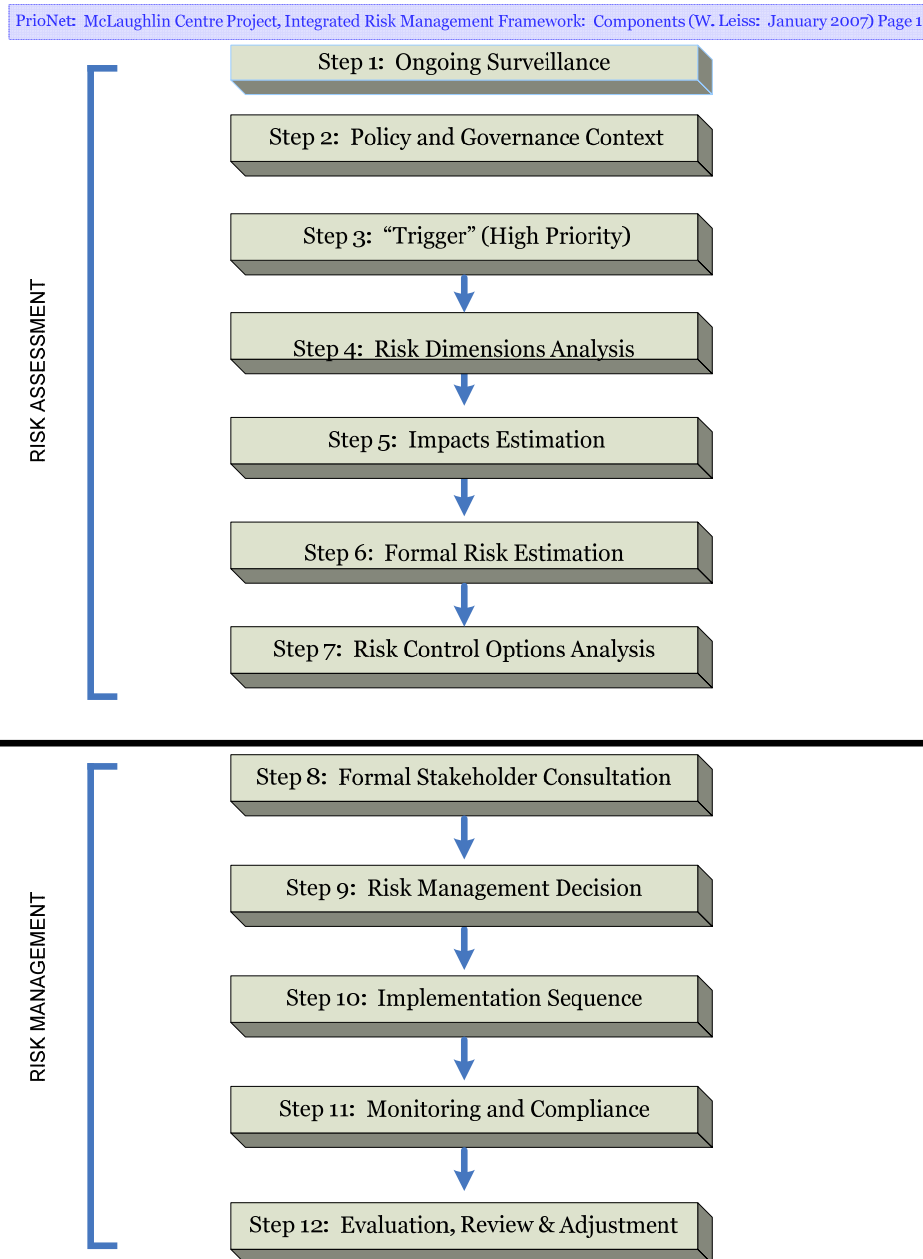
**Figure 3: (Health Canada, 2000)**



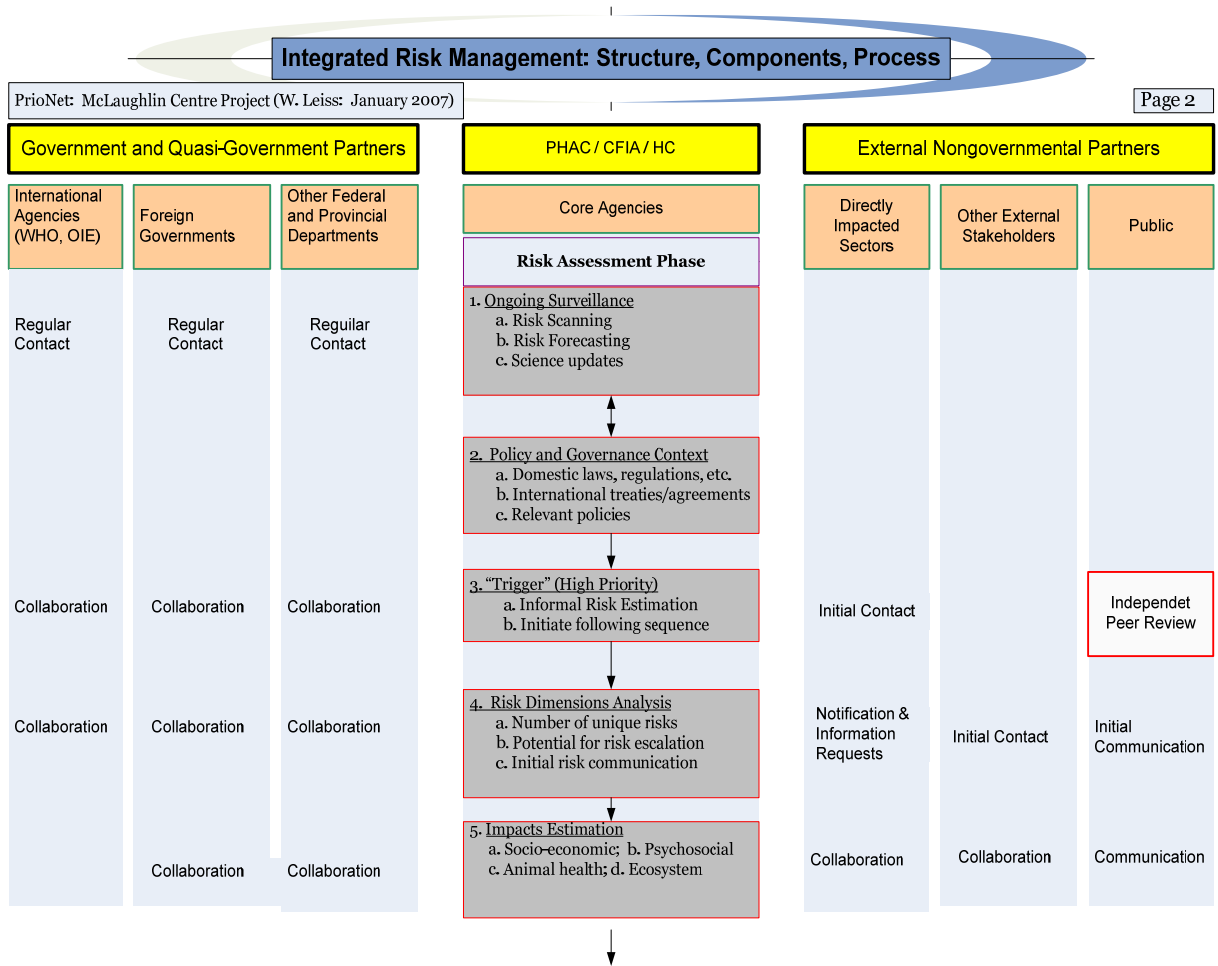
**Figure 4: Circular-flow model of IRMF (drawing by S. Darshan)**



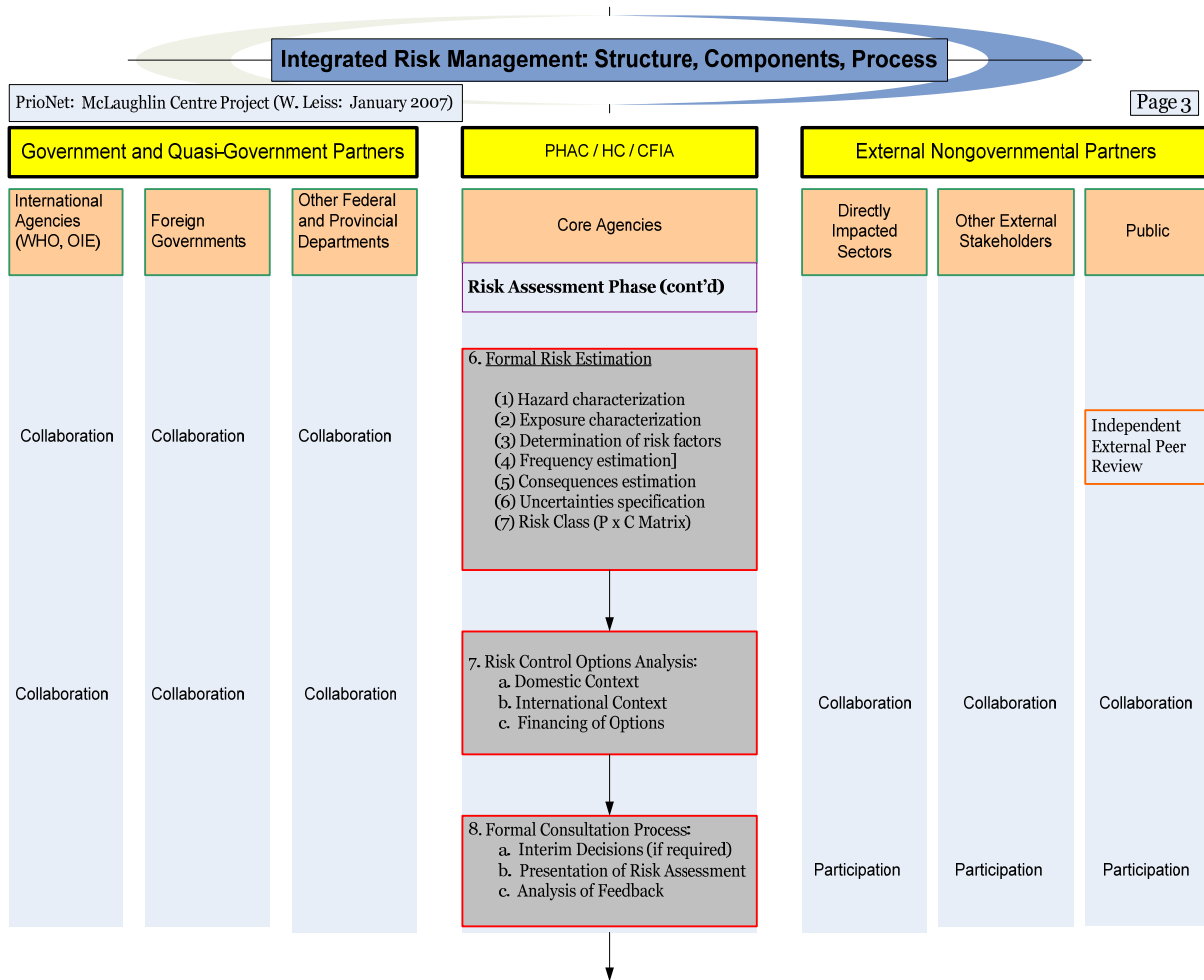
**Figure 5: IRMF-1**



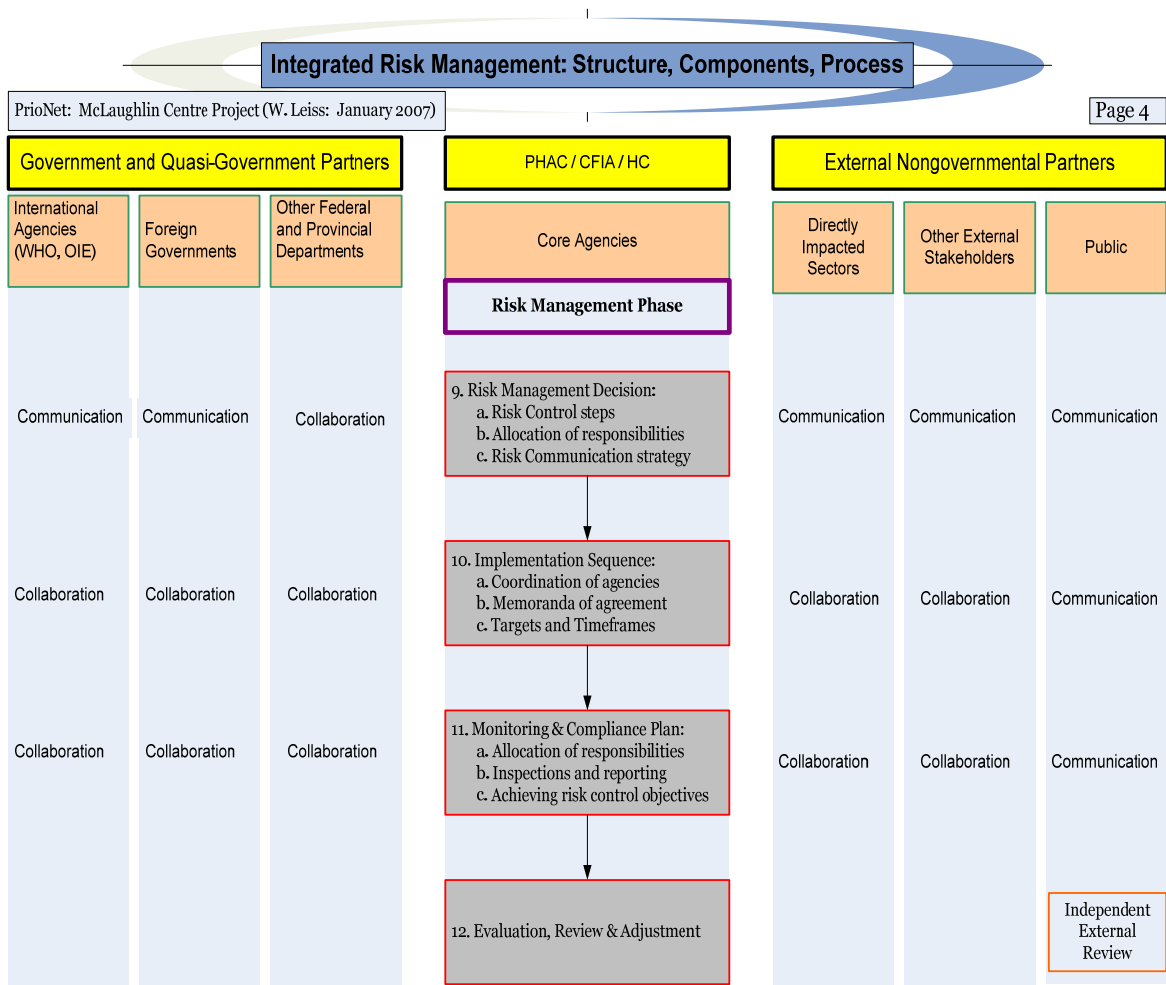
**Figure 6: IRMF-2**



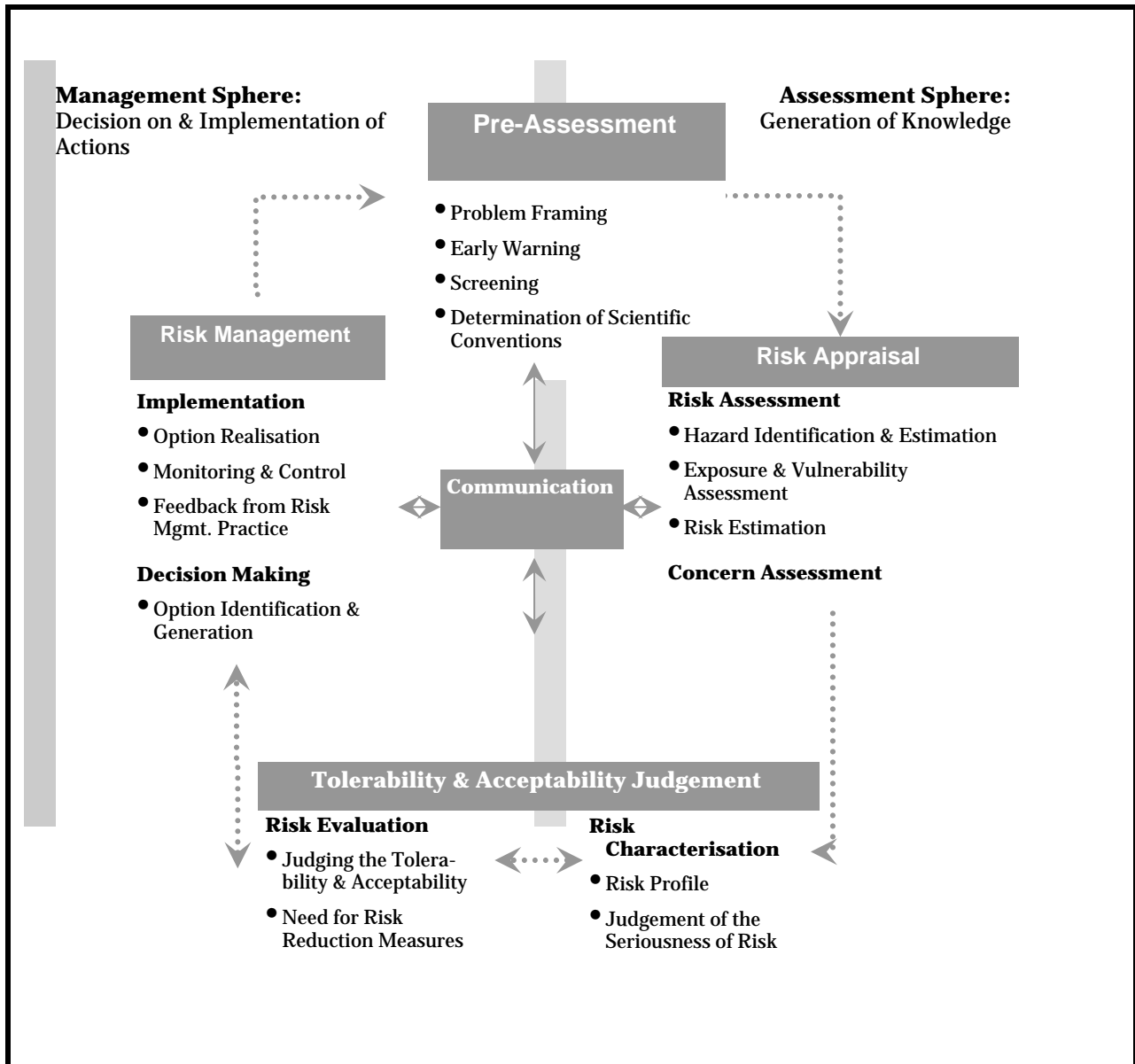
**Figure 7: IRMF-3**



**Figure 8: IRMF-4**



**Figure 9: International Risk Governance Council**



## **9 Prion Diseases: The Challenges to Policy.**

The experiences of Canada and other countries in seeking to manage the risks from prion diseases, especially BSE and vCJD, over the period 1986 onwards, presented severe challenges to established practices in the areas of zoonotic diseases and food safety. These challenges called into question the adequacy of established frameworks for managing public health risks, both within individual countries and across the international coordinating agencies, such as the World Organization for Animal Health (formerly OIE), that sought to coordinate responses to zoonotic disease risks.

A detailed analysis of the nature of those challenges, as well as suggestions for revising and strengthening those frameworks, has been offered elsewhere in this paper. In this section we deal with some of the major policy issues which were raised as a result of the responses of individual countries and international agencies to the challenges represented by TSEs generally, and by BSE and vCJD in particular. A “top ten” list of outstanding policy issues might be comprised of the following:

### A: Policy Issues in the Practice of Risk Assessment within Canada.

- A1. What risks should be assessed?
- A2. Formalizing the assessment of psychosocial factors
- A3. Early warning: The importance of preliminary risk estimation
- A4. Being proactive: What should be done about CWD?

### B: Policy Issues in International Integration of Risk Management.

- B1. Market/regulatory policy interaction
- B2. Coordination of risk control measures
- B3. Precautionary approach
- B4. Surveillance
- B5. Product labeling
- B6. Product testing

*A: Policy Issues in the Practice of Risk Assessment within Canada.*

A1. What risks should be assessed?

In the most comprehensive review of risk management frameworks yet published, the first in the list of key elements is called the “problem formulation stage,” and its instruction is: “Make sure you’re solving the right problem” (Jardine et al., 2003, p. 570). Although this might appear to be a trivial point, in fact it is a critical dimension for the entire exercise, and the BSE experience in Canada offers the strongest proof of this point. The only formal risk estimation in this case, done by CFIA in 2002, assessed the probability of finding one case of BSE in the Canadian herd in the period before 1997. What happened after the index case appeared, in May 2003, showed that it was not the animal health risk itself, but rather the risk of market collapse due to the US border closure, which was the primary determinant of the ensuing socio-economic collapse for Canadian beef producers. In this case, the consequences dimension in the conventional formula,  $R=PxC^{37}$ , overawed the estimated likelihood of occurrence, which had been qualitatively rated as “negligible.” When total socio-economic impacts are arrayed against the current number of indigenous cases in the national cattle herd (13 to date), it is clear that, of all countries where BSE has been detected, Canada almost certainly has had by far the largest average impacts per case of BSE.

The main point here is that *the risk of the closing of the US border was never formally evaluated by Canadian authorities*, despite the extremely high element of vulnerability involved, since before the closure some 90% of Canadian beef exports went to the US. This experience demonstrates clearly the importance of correct problem definition in risk management decision-making. In addition, since (as shown earlier)

Canada's risk profile worsened considerably during the time when BSE was incubating in its national herd, the problem definition must seek to capture a *changing* risk profile, where this is the case.

#### A2. Formalizing the Assessment of Psychosocial Factors:

As is well known, frequency estimations in risk assessment are now highly formalized exercises, involving elaborate quantitative algorithms (US, NRC, 2008). As a result, in the formula  $R=P \times C$ , the probability (P) estimates can be given in quantified form, and uncertainties at various confidence levels can be specified. Unfortunately, the same is not true for the "other side of the coin," namely, estimation of consequences (C). To be sure, there are standard econometric models which can be used to estimate direct and indirect economic impacts of hypothesized events, for example, possible impacts of imposing various policy measures, such as a carbon tax, in the context of climate change policies (Jaccard et al., 2002). However, such tools do not appear to be used frequently, if at all, in risk management decision-making, at least in Canada.

The situation is far worse when it comes to the dimension of psychosocial impacts. Here too, at least in the case of public perception of risk, well-recognized survey tools are available which can provide reliable guides to the nature of public thinking on specific matters of risk (Lemyre et al., 2008). But they do not seem to be used, at least not often and consistently, in risk assessments. The situation is even more difficult when it comes to social and family impacts, such as on the small beef producers. Here there do not seem to be any well-structured formal protocols that would be able to yield, in both qualitative and quantitative terms, an informed estimate about likely

impacts in the face of specific risk scenarios. The public policy issue here amounts to the simple, but urgent, need to develop or adapt the assessment tools designed to provide much more complete and authoritative accounts of potential socio-economic impacts in the consequences dimension of risk assessment.

### A3. Early warning: The Importance of Preliminary Risk Estimation.

In early 1994 an agency of the Canadian federal government completed an informal, preliminary estimation of the probability that BSE was incubating in the Canadian herd, rating that chance as “very high.” This document was never publicly released, and the formal risk estimation was not completed, and published, for another eight years. Should the findings of the 1994 study have been communicated promptly to stakeholders in the Canadian beef industry—in effect, publicly released? This question goes to the heart of the fundamental objectives of risk management decision-making.

In the context of the still-escalating BSE tragedy in Europe, Canada may have faced immediate negative impacts on its beef exports had this assessment been released. Because there exists exhaustive documentation on this matter, which has been closely examined in the course of a major public inquiry, we know that similar reasoning lay behind the decisions of British authorities to tightly restrict the circulation of information on the raging BSE epidemic in its national herd in the years between 1986 and 1989 (Phillips et al., 2000; Van Zwanenberg and Millstone, 2003, 2005.) But is the reasoning in support of secrecy in such matters now rejected, or is it still regarded as being justified?

In Canada's case, the decision by federal authorities not to disclose the existence of plausible concerns about our indigenous BSE occurred at just the time—that is, the decade of the 1990s—when federal and provincial policy was promoting an enormous increase in beef exports to the US: “The percentage of total Canadian beef production exported to the US increased from 12% in 1990 to almost 48% in 2002” (Sparling and Caswell, 2006, p. 217). In effect, this meant that Canada did not have a “stable” risk profile for BSE during this entire period; on the contrary, the risk (in the consequences dimension, which was never estimated) was escalating rapidly with each passing year. The bearers of this risk were the 90,000 small producers in the beef sector. How could it be just, or fair, to maintain that these family-farm operators were not entitled to be given a timely warning about the nature of the catastrophic and steadily escalating risk they were facing during all this time?

Thus a key policy issue, emerging from the Canadian experience with BSE, is whether it could now be regarded as obligatory for regulatory authorities to produce and disseminate a risk estimation, based on the best available information, at the time when the bearers of the risk are still in a position to control, at least in part, their own exposure to it?

#### A4. Being proactive: What should be done about CWD?

Chronic Wasting Disease is a prion disease that infects two species of deer (mule and white-tail) and one species of elk (Rocky Mountain). It was identified as a form of transmissible spongiform encephalopathy (TSE) in 1978, first in captive elk; it was first recognized in the wild in 1981. Its origins are often said to be unknown. From its

epicenter in Colorado and Wyoming, by 2006 the epidemic had spread to fourteen U. S. states and two Canadian provinces (Saskatchewan and Alberta); it was also exported in captive elk to South Korea. There is a large population of these three species in North America, estimated at some 22 million animals; prevalence ranges up to 20% of populations in the areas where it is endemic (Belay, 2004).

In 2006 infectious prions were found in the saliva and blood of deer with CWD, demonstrating a mechanism for the “efficient transmission of CWD in nature” (Mathiason, 2006). Experiments with transgenic mice to date show that there appears to be “a substantial species barrier for transmission of elk CWD to humans”; however, the researchers caution that “human disease acquired from CWD might have an unusual phenotype that is difficult to distinguish from that of sporadic CJD.”<sup>38</sup> They conclude (Kong, 2005): “This uncertainty is a serious public health concern in the United States.”

In keeping with the underlying spirit of risk management, which incorporates an ethic of prevention of harm, one could consider planning a proactive exercise on CWD risk management for Canada, perhaps as a way of using (and testing) the new IRMF.

*B: Policy Issues in International Integration of Risk Management.*

B1. Market/Regulatory Policy Interaction.

An important published study (Sparling and Caswell, 2006) emphasizes the dichotomy, with respect to US—Canada trade relations affecting beef, between the *market integration* opened up by NAFTA, on the one hand, and the lack of *regulatory integration*, on the other. Market integration means the virtually free movement of

goods across the border, where tariffs, quotas, import levies, or other trade restrictions have been completely eliminated. Regulatory integration is the idea of a common protocol and practices for risk management, ideally based on a common international set of standards. BSE showed that having one without the other is a recipe for disaster: “The BSE case illustrates the risks to which industries are exposed when economic integration outruns regulatory integration” (p. 226).

To be sure, one (but not the only) specific sub-issue, where animal health matters are at stake, is the weak structure represented by OIE. Nations are free to negotiate consensus positions at OIE sessions, and they do, but all countries remain free to interpret the requirements of those positions in their own way, and even to disregard them completely, without fear of sanctions (unlike the World Trade Organization). OIE protests against these “violations” are simply ignored. This is what happened to Canada in the BSE case. A failure of risk managers in Canada to anticipate such an occurrence—as well as the persistent and unfounded belief that, once it happened, political pressure could quickly reverse the decision—was the single most significant factor in determining the impact of discovering indigenous cases of BSE. Thus a very significant policy issue is the need to launch an effort to match the level of market and regulatory integration, both as between the US and Canada and in the international arena more generally.

## B2. Coordination of Risk Control Measures.

The BSE country case study synthesis and analysis, reported elsewhere in this paper, documents the extensive series of delays, across many BSE-affected nations, in the rigorous implementation of the designated risk control measures (live cattle ban, MBM

ban, SRM ban, rendering directives). At the time when the epidemic was at its worst, in the late 1980s and early 1990s, even relatively short delays had large consequences. Such delays worsened considerably the scope of the international BSE epidemic.

The policy issue here—namely, measures for faster implementation of common risk control measures—can only be resolved at the level of international negotiation. The years of planning for the possibility of a pandemic flu outbreak, including early specification of risk control strategies, would appear to indicate that future progress in this area for other common threats is possible. For countries such as Canada, which have federal structures, efforts to improve federal-provincial coordination in matters of risk assessment and management are also essential.

### B3. Precautionary Approach.

Since the 1990s, most developed nations, including Canada, have made formal provision for recognizing the value of the precautionary approach in risk management. However, actually incorporating this approach into the decision process has proved to be more daunting, despite the fact that the idea of anticipating adverse consequences, and taking early action to at least reduce their potential scope, instead of waiting for the worst to happen and then cleaning up the mess, is a well-recognized feature of the enterprise of risk management itself. The BSE episode is very instructive in this regard. A detailed examination of the delays in the implementation of risk control measures for BSE leads to this conclusion by Tyshenko: “The main lesson learned from the time anchor analysis is that the use of precautionary action could have reduced the magnitude of outbreaks to those countries that faced the highest external challenges.”<sup>39</sup>

Implementing a precautionary approach in a particular case is the other side of the early warning philosophy discussed above. In other words, this step would describe the range of actions that might be taken, by a variety of responsible and affected parties, in response to the articulation of an early warning message. What is necessary is a set of handy analytical tools that would allow us to calibrate both the “upside” and the “downside” dimensions of early action in close relation to the scope or range of the potential levels of risk, the availability of feasible risk control options and their costs, the likelihood of having new scientific information relevant to the case, and other factors.

#### B4. Surveillance.

The spread of the BSE epidemic from the UK to many other countries around the world has been accompanied by some intense controversies over disease surveillance methods, standards, and objectives, within the larger categories of the two basic types, “active” and “passive.” For example, following the first case of BSE in both Canada and the US, authorities in both countries invited panels of European experts to comment on their surveillance strategies. (At the same time, the OIE was regularly updating both its risk-ranking formulas and the surveillance requirements deemed appropriate for each level of country risk.) On the basis of wide European experience, those experts articulated the general rule, confirmed by much evidence there, that the more intensive is the surveillance program, the more cases of BSE one could expect to find.

For any country with large domestic cattle herds, including the US and Canada, the idea that only a wide-ranging BSE surveillance program, one that included risk

categories for apparently healthy animals (no clinical signs of disease), could give a reliable estimate of the true prevalence of the disease in the national herd, has always been problematic. The US, in particular, has been reluctant to accept any critique of its “enhanced” 2004 program; one such published critique rejected the “premise that no BSE occurs in normal adult cattle population” in that country, and concluded that “approximately 30% of the US slaughtered normal cattle population aged 30 months and over needs to be tested to satisfy the statistical condition used by the US (i.e., 99% confidence level)” (Koizumi et al., 2005). Of course, actual testing in the US and some other countries comprised only a small fraction of that percentage.<sup>40</sup>

Countries which assumed there was good reason to think they could expect to find relatively few cases of indigenous BSE, for whatever reason, have found an abundance of reasons not to embark on broad surveillance programs. Some of them have, instead, resorted to rhetorical appeals to a vague, unspecified, and ever-changing justification for their choices that is claimed to be rooted in “science” (and which are in fact based on some version of the OIE requirements, which is not quite the same thing). The end result has been, at times, a conflicting set of politically-driven rationalizations on an important technical issue—disease surveillance policy—that ought to be clarified using mechanisms such as consensus science conferences.

## B5. Product Labeling

A 2005 report by the US General Accounting Office, in a section dealing with the animal feed labeling requirement, noted: “Animal feed and feed ingredients containing

prohibited material (including material from rendered cattle) are not required to be labeled with the cautionary statement, 'Do not feed to cattle or other ruminants,' when that material is intended for export" (US, GAO, 2005, p. 22). This is a highly relevant concern, given the role of exported MBM in the BSE epidemic. More generally, it also raises issues about the integration of national policies with the attempted coordination of zoonotic disease risk management through agencies such as WHO and WOA. H.

#### B6. Product Testing.

Among all the contentious aspects of the policy responses to BSE, none is more contentious, perhaps, than the issue of testing. The initial driver for this controversy were the decisions taken by Japan and, to a lesser extent, by the European Union, to undertake massive testing programs for slaughtered cattle, up to 100% of all animals. In the case of Japan, the main objective was to reassure a public which blamed their government for egregious mistakes and deceitful communication around the time of the initial BSE cases. In the case of Europe, a primary consideration was the convincing evidence of systematic under-reporting of BSE cases, as demonstrated by the back-calculation studies, and a subsequent resolve to bring the epidemic under control as quickly as possible and to provide convincing evidence to the public that this mission was succeeding.

The situation has been far different in North America, where governments have firmly resisted calls from elements of the public for a similar large-scale program, as well as efforts by some producers to embark voluntarily on such a program in order to re-enter some of their traditional export markets. (Current costs of testing have been

estimated for the US at somewhere between \$25-50 per animal, including all overhead: US, CRS, 2007, pp. 41-42.<sup>41</sup>) The main battles have been fought in the US. In 2004 a law to this effect was introduced in the California legislature, but was never enacted. In the same year, USDA rejected a proposal by Creekstone Farms, a large Kansas-based operation, to be allowed to test all the cattle it slaughters, and Creekstone sued. The company, now supported by the industry lobby group R-CALF, won its case in front of a federal district court judge in 2007, whereupon USDA appealed (US, District Court for the District of Columbia, 2007). By May 2008 the case was before a three-judge panel at the US Court of Appeals for the Washington, DC circuit.

As quoted in press reports, one of the federal lawyers argued, “They want to create false assurances”; and the USDA undersecretary alleged: “The use of the test as proposed by Creekstone would have implied a consumer safety aspect that is not scientifically warranted.”<sup>42</sup> The company rejects these allegations, arguing that this is what many of their customers demand, and that they should be entitled to satisfy that demand using the best available testing technologies.

## **10 Conclusions from the integrated framework and component projects.**

To date, bovine spongiform encephalopathy has affected twenty-five countries, and more than a quarter-century has passed since it entered the scene as a zoonotic disease that was not characterized until well after the epidemic had begun. The toll imposed on beef producers and farm communities around the world, calculated in both in human and economic terms, has been enormous. The costs imposed on national governments as a result of the trade disruptions, the risk control measures,

and the compensation schemes that have been undertaken, are nothing short of staggering. Almost certainly it is fair to say that no other zoonotic disease has had, at least up to the present time, a comparable level of total impact.

Both the challenge posed by BSE itself, as well as the efforts made by national governments and international organizations to respond to it, have raised serious questions about the adequacy of current risk management frameworks. If we accept the view that risk management is “the attempt to anticipate and prevent or mitigate harms that may be avoidable,” then we must acknowledge that there are components in those frameworks that require substantial fine-tuning. In particular, the processes of risk estimation itself, as well as the estimation of consequences, notably social, economic, and psychosocial factors, are in need of the development of new tools, methodologies, and algorithms. These are needed in order to better anticipate both the likelihood and consequences of risks, especially those that involve novel types of hazards. For only an ability to improve the calculus of anticipation will enable us to make robust decisions about how much we are justified in investing in precautionary measures that can prevent or mitigate serious harms.

## Appendix I

### International Journal of Risk Assessment and Management (IJRAM)

Special Issue: International Risk Management and Policy for Bovine Spongiform Encephalopathy

Guest Editors: Dr. Mark Raizenne, Dr. Maura Ricketts, Dr. Shalu Darshan

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## Endnotes.

<sup>1</sup> Vol. 27, no. 5 (October 2007), pp. 1091-1202. The introductory article (pp. 1091-3) is the source for points 2-6 in the following list.

<sup>2</sup> Heres et al., 2007, note 2, pp. 1119-20.

<sup>3</sup> As of the mid-December tally, total European cases were 119 for all of 2007 (see note 14); adding Canada (2) and Japan (3), the 2007 world total is 124.

<sup>4</sup> As of June 2008, the total number of UK cases is 167, comprising 115 pathologically confirmed cases, 49 probable cases with no post mortem, and 3 probable living cases.

<sup>5</sup> de Koeijer and Havelaar, 2007, p. 1092. Since the number of BSE cases was underreported over a long period of time prior to 2001, and almost certainly significantly so, the actual ratio of vCJD to BSE cases should be quite a bit lower as well, perhaps even well under 1 to 1000.

<sup>6</sup> Calavas et al., 2007, note 2, p. 1144.

<sup>7</sup> The country tables published by the Office International des Epizooties (OIE) do not necessarily give the most recent figures for BSE cases; the numbers shown in the text reflect both OIE and other sources, including EU and individual country data.

<sup>8</sup> The countries and regions listed here are those which have been investigated by the case study team based at the McLaughlin Centre, University of Ottawa.

<sup>9</sup> Another issue entirely, and a serious one, has to do with the effectiveness of the initial MBM feed ban. In expert testimony given to the BSE Inquiry, Professor Roy Anderson argued that British authorities did not make use of available scientific methods that would have alerted them to the existence of serious deficiencies in the 1988 MBM ban (Anderson 1998a, 1998b): “To put the failure to apply appropriate scientific methods in perspective—if these ‘back calculation’ techniques had been applied in the period 1989-91, they would have revealed that the meat and bone meal (MBM) feed ban was not fully effective since new infections via this route continued through the early 1990s. If this had been known at that time, and if measures to stop the continued use of contaminated feed had been put in place, the size of the epidemic would have been significantly smaller...”

<sup>10</sup> D. MacKenzie, *New Scientist*, 10 February 2001; A. Barnett, “Feed banned in Britain dumped on third world,” *The Observer*, 29 October 2000. Accessed on: February 1, 2008: <http://observer.guardian.co.uk/focus/story/0,6903,389559,00.html>

<sup>11</sup> Tyshenko and Krewski, “Continued management of the diminishing BSE outbreak in the United Kingdom” (2008: Appendix I, #1), p. 2, note that the first veterinary report of a “novel progressive spongiform encephalopathy in cattle” (cow 133) was made in April 1985; this is the case described more than two years later in the first technical publication (see note 25 below). The UK government website gives a date that is a full nineteen months later: “BSE was first diagnosed in November 1986 at the Central Veterinary Laboratory, Weybridge.” <http://www.defra.gov.uk/animalh/bse/controls-eradication/index.html>. The “BSE Chronology” in volume 16 of Phillips et al., *The BSE Inquiry: The Report*, explains the difference by saying that the November 1986 date is the one “given by the *Southwood Report* as being ‘when BSE was first identified as an entity.’” The chronology also indicates that research

into transmissibility (using mice) was begun in November 1987; the positive results of this study were published in October 1988 in *Veterinary Record*. The first suggestion that ruminant-derived MBM may be a factor in BSE was made one month later. The UK ruminant feed ban had come into force on 18 July 1988, indicating that it was clear to MAFF officials already by early 1988 that BSE was a transmissible type of SE.

<sup>12</sup> <http://www.defra.gov.uk/animalh/bse/controls-eradication/index.html>: “The average incubation period of BSE is five years, and only very rarely indeed do animals under three years of age display symptoms.”

<sup>13</sup> “Clinical” surveillance—looking for animals displaying clinical symptoms of a disease—is also known as “passive” surveillance and is contrasted with “active” [or pre-clinical] surveillance; since the beginning of 2001, in the EU, the latter policy has required the testing of all animals over 30 months of age: [http://ec.europa.eu/food/fs/bse/bse21\\_en.html](http://ec.europa.eu/food/fs/bse/bse21_en.html). For the UK detailed statistics, see: <http://www.defra.gov.uk/animalh/bse/statistics/incidence.html> (where there is a comparison of active vs. passive surveillance results).

<sup>14</sup> The EU has later figures than does OIE. As of mid-December 2007, in the 26 countries of the EU, for 2007 there were 119 positives (.00001) out of 8,178,011 tests for BSE (of which 87% were accounted for by only three countries – the UK (61), Spain (24), and Ireland (18): [http://ec.europa.eu/food/food/biosafety/bse/mthly\\_reps\\_bse2007\\_en.pdf](http://ec.europa.eu/food/food/biosafety/bse/mthly_reps_bse2007_en.pdf). The comparable figures for 2006 were 320 (.00003) positives out of 10,131,360 tests, where those same three countries accounted for 73% of the positives: [http://ec.europa.eu/food/food/biosafety/bse/mthly\\_reps\\_bse2006\\_en.pdf](http://ec.europa.eu/food/food/biosafety/bse/mthly_reps_bse2006_en.pdf)

<sup>15</sup> [http://ec.europa.eu/food/food/biosafety/bse/mthly\\_reps\\_bse2001\\_en.pdf](http://ec.europa.eu/food/food/biosafety/bse/mthly_reps_bse2001_en.pdf).

<sup>16</sup> [http://ec.europa.eu/food/fs/bse/bse21\\_en.html](http://ec.europa.eu/food/fs/bse/bse21_en.html)

<sup>17</sup> <http://www.vegsource.com/talk/madcow/messages/1001204.html>

<sup>18</sup> Numbers reflecting imported cases are designated as “(b)” in the OIE tables: [http://www.oie.int/eng/info/en\\_esb.htm](http://www.oie.int/eng/info/en_esb.htm); the numbers for Italy and Spain for 2001 follow the EU table (note 14).

<sup>19</sup> N. Farhat et al., “Portugal BSE Case Study” (2008: Appendix I, #9), p. 15.

<sup>20</sup> N. Shilnikova et al., “BSE and vCJD in Spain” (2008: Appendix I, #10), pp. 18-20.

<sup>21</sup> N. Farhat et al., “Portugal BSE Case Study” (2008: Appendix I, #9), p. 35.

<sup>22</sup> R. Lewis et al., “Germany and BSE Management” (2008: Appendix I, #8), pp. 14-18.

<sup>23</sup> See Leiss, 2004, pp. 235-9 and 246-8, for a discussion of the unfounded outrage expressed by Canadian politicians over the actions taken by other countries in response to Canada’s BSE cases, including the element of hypocrisy, since Canada had earlier taken exactly the same actions against others in similar circumstances.

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<sup>24</sup> M. Tyshenko (2008, pp. 8-13), “The Office International des Epizooties Policy for Bovine Spongiform Encephalopathy Risk Management and Its Use by Member Countries” (Appendix I, #23).

<sup>25</sup> Wells et al., 1987.

<sup>26</sup> The issue is discussed in volume 3, chapter 6, of Phillips et al., 2000.

<sup>27</sup> M. G. Tyshenko (2008, p. 23), “Comparative Country Case Study Analysis Using Relative Time Anchors to Determine Policy Drivers for Bovine Spongiform Encephalopathy Risk Management” (Appendix I, #21, Table 1).

<sup>28</sup> [http://www.oie.int/eng/normes/Mcode/en\\_chapitre\\_2.3.13.htm](http://www.oie.int/eng/normes/Mcode/en_chapitre_2.3.13.htm)

<sup>29</sup> [http://www.oie.int/eng/info/en\\_statesb.htm?e1d6](http://www.oie.int/eng/info/en_statesb.htm?e1d6) (accessed February 1, 2008). The “missing” countries—that is, countries with 2006 confirmed cases of BSE but not shown in *any* current OIE category—are: Austria, Belgium, Czech Republic, France, Germany, Ireland, Italy, Japan, Netherlands, Poland, Portugal, Slovenia, Spain, and Sweden. There are also two countries which had at least one case in 2005, and none in 2006, but had not yet reported for 2007: Denmark and Slovakia. This list comprises 16 countries, more than are actually categorized by OIE. However, there is an easy solution to this apparent paradox: Among the eleven countries which have achieved a OIE “certification” (either negligible or controlled risk) are all of the largest beef-exporting nations on the planet. Facilitation of international trade in animal products is clearly one of the highest imperatives for the organization. Perhaps also the neglect in assigning a broader range of risk categories reflects the belief that the international epidemic of BSE is definitely and rapidly waning at this point.

<sup>30</sup> The puzzling absence of the entire EU from the new OIE scheme reflects the insistence of the EU on being treated as a “bloc,” rather than having the status of its 27 member states evaluated separately. The Commission of the European Communities simply announced on 29 June 2007 that, so far as the EU is concerned: “Pending a final conclusion (by OIE) on the BSE risk status of the Member States and taking into account the harmonized stringent BSE protective measures applied within the Community, the Member States should be provisionally recognized as countries with a controlled BSE risk”. The Annex to the decision proceeds to list the names of all 27 member states (European Union, 2007).

<sup>31</sup> M. Tyshenko (2008, pp. 6-16), “The Office International des Epizooties Policy for Bovine Spongiform Encephalopathy Risk Management and Policy Use by Member Countries” (Appendix I, #23). Canada in particular experienced severe adverse consequences as a result. However, as noted above (note 23), we were equally guilty of first doing unto others exactly what was later done to us, especially in the case of the sanctions imposed on Brazil in 2001 .

<sup>32</sup> Canada, CFIA (2002), “Risk Assessment on Bovine Spongiform Encephalopathy in Cattle in Canada,” Part A: Evaluation of Risk Factors, pp. 32, 84. Google searches using the title of the 1994 report appear to indicate that there is no other public reference to this document.

<sup>33</sup> This is a highly unusual case, where an important concluding statement appears in the abstract, but *nowhere in the text*, of an article. Furthermore, the statement in the text that is closest in meaning to it says something different (p. 172): “[T]he amplification and establishment of BSE in Canada, before the 1997 feed ban and after the 1997 feed ban, are

negligible.” The words “introduction” and “amplification” clearly do not have the same meaning; but more importantly, it is difficult to understand how the phrase in the quoted passage, “before the 1997 feed ban,” could be justified on the basis of the CFIA risk estimation. Note also that the concluding words in this same abstract, “the economic consequences would have been extreme [if BSE were to be introduced and established in Canada],” also does not occur anywhere in the text. These words also change the verb tense, used in the risk estimation document itself (see the main text, p. 21), in an interesting way.

<sup>34</sup> To be sure, failures in risk communication during the BSE episode were not limited to Canada; among European countries, similar deficiencies were a major factor in undermining public confidence in risk governance in the UK, Germany, Italy and other countries (World Health Organization, 2006).

<sup>35</sup> Ted Haney of the Canadian Beef Export Federation, commenting on the accumulated financial impact of BSE in Canada, said: “We stopped counting at \$20 billion,” and he noted that those impacts have not yet ended. Quoted in “Mad-cow disease ‘controlled’ in Canada,” *The Globe and Mail*, 23 May 2007, p. B8.

<sup>36</sup> We acknowledge the important contribution of Professor Tim McDaniels, University of British Columbia, in formulating this statement of objectives.

<sup>37</sup> <http://en.wikipedia.org/wiki/Risk>

<sup>38</sup> CWD prions from both deer and elk are indistinguishable, so these researchers believe that their findings about transmissibility are equally applicable to both.

<sup>39</sup> M. G. Tyshenko (2008, p. 19), “Comparative Country Case Study Analysis Using Relative Time Anchors to Determine Policy Drivers for Bovine Spongiform Encephalopathy Risk Management” (Appendix I, #21).

<sup>40</sup> With reference to the “enhanced” surveillance program announced by USDA on 15 March 2004, “[US] officials stated that if 268,500 high-risk animals were to be sampled, APHIS could detect BSE at the rate of 1 positive in 10 million adult cattle with a 99 percent confidence level” (US, CRS, 2007, pp. 34-35). Or perhaps fewer: “Ron Dehaven, the US’s chief veterinary officer,... said testing between 201,000 and 268,000 cattle would allow the prevalence of BSE to be determined with 95 to 99 percent accuracy, but otherwise refused to specify any specific target for the tests” (D. MacKenzie, *New Scientist*, 16 March 2004); see also Leiss, 2004, p. 256, for a statement of prior US policy.

<sup>41</sup> This report, by staff of the US Congressional Research Service, provides an excellent overview of the key aspects of US policy on BSE.

<sup>42</sup> A full account of the legal dispute may be found at: *High Plains/Midwest AG Journal*, “Federal judge rules that Creekstone can test for BSE,” 09 April 2007: <http://www.hpj.com/archives/2007/apr07/apr9/FederaljudgerulesCreekstone.cfm>; Tom Johnston, “Creekstone Farms defends right to test for BSE,” 12 May 2008: <http://foodsafetyinfo.org/phpbb/viewtopic.php?t=17867>