



WORKSHOP SUMMARY

Workshop on BSE and vCJD Risks in Canada Managing Prion Disease Risks: A Canadian Perspective

**Location: Room 202, Fauteux Hall,
57 Louis Pasteur, University of Ottawa,
Ottawa, Ontario.
June 25, 2008**

Overview:

PrioNet Canada, a Network of Centres of Excellence established in 2005, has been investigating the etiology of bovine spongiform encephalopathy (BSE), variant Creutzfeldt-Jakob disease (vCJD), and other prion diseases from both a Canadian and international perspective. An important component of this work has been the development of risk management strategies for BSE and vCJD.

The purpose of this workshop was to present a new integrated risk management framework (IRMF) for BSE developed by PrioNet Canada to senior federal and provincial government officials. Comments on the framework received at the workshop will be of great value in finalizing the framework, which will serve as a guide to addressing BSE as an important international risk issue that has had considerable impact on Canada. This report provides a summary of the discussions that took place at the workshop.

Dr. William Leiss (University of Ottawa) presented an overview of the concept of risk, risk management frameworks, past management of BSE, and work completed on a new integrated risk management framework that incorporates additional factors to be considered in future decision-making. Dr. Leiss noted that back-calculation methods applied in several countries (including the U.K., France, and Japan) have demonstrated that the actual number of BSE cases has been much higher than the number detected.

Canada has experienced the highest ratio of costs per case of BSE among all countries affected by BSE. The significant socioeconomic impact of BSE in Canada was one of the main reasons why PrioNet Canada developed the integrated risk management framework presented at the workshop. Prior to developing the framework, PrioNet Canada conducted an analysis of BSE risk management practices in over 20 different countries, and how those practices evolved with the unfolding of the BSE epidemic that began in the United Kingdom in the mid-1980s. The overview of the country case studies covered a number of salient issues pertaining to BSE risk management, including:

- 1) Surveillance (active and passive, and which is appropriate for disease with a long incubation period);
- 2) Determination of the true prevalence of BSE, and its relation to timely risk-control measures;
- 3) Delayed recognition of the problem by many countries;
- 4) Delayed response of adequate risk-control measures;
- 5) Changing levels of uncertainty and risk classification systems for country risk; and
- 6) Difficulties with international standards (such as that established by the OIE) and bilateral negotiations by affected countries.

In addition, the high degree of vulnerability faced by the Canadian agricultural sector, particularly primary beef producers, with regards to BSE was the result of a high degree of dependence on the beef export trade to the U.S. While there was market integration between Canada and the U.S., the necessary complement, regulatory integration, was not in place. The lack of regulatory integration in the presence of market integration was an important factor in the Canadian BSE crisis, and needs to be addressed within any risk management framework approach adopted by Canada. The primary objective of risk management should be to anticipate and prevent or mitigate harms that may be avoidable, including market vulnerability and socio-economic impacts.

Dr. Leiss recounted the history of the development of formal risk management schemes by governments intended to represent the necessary steps in arriving at a sound risk management decision, beginning with the U.S. National Research Council's 1983 'Red Book, *Risk Assessment in the Federal Government: Managing the Process*'. A review of various risk management frameworks that have evolved since that time reveals a number of potential weaknesses. As the risk issue or decision-making process becomes more complicated (a function of the risk issue itself), the allocation of responsibilities can become blurred. Other factors such as increasing economic globalization have increased the number of agencies involved in risk management, leading a need for greater international collaboration in risk management. Outside of the U.S., there is limited use of independent external peer review for risk estimation; the development, selection, and implementation of appropriate risk management policies and strategies within existing frameworks remains somewhat obscure as a process, compared with the relative transparency of associated risk assessment procedures.

The new integrated risk management framework (IRMF) attempts to improve risk management decision-making through the incorporation of the following features.

- 1) The entire risk decision-making process should be formalized by introducing appropriate and publicly available documentation at each stage.
- 2) The framework should attempt to increase inter-agency collaboration at both the domestic and international levels.
- 3) Greater provision should be made for involving and communicating with directly affected parties and the public.
- 4) Risk assessment should be completed in a timely manner in order to facilitate anticipatory decision-making. When necessary, interim assessments of risk may be conducted to achieve this objective.
- 5) Risk assessment should be extended beyond the estimation of the likelihood of occurrence of adverse outcomes, to include an assessment of health, environmental, socioeconomic, and psychosocial consequences.
- 6) Risk assessment should be subjected to independent peer review.

Ten policy issues as challenges to risk assessment and management were discussed. The first four represent risk assessment policy issues relevant within Canada; the remaining six are of international relevance, requiring risk management integration with Canadian decision-making processes.

1. What risks should be assessed?

2. Formal consideration of psychosocial factors in risk assessment.
3. Early warnings: The importance of preliminary risk estimation.
4. Being proactive: What should be done about CWD?
5. Market/regulatory policy interaction.
6. Coordination of risk control measures.
7. Where, when, and how to implement a precautionary approach.
8. Surveillance.
9. Product labeling.
10. Product testing.

Experience with BSE, vCJD and CWD in Canada and internationally has shown that current risk management frameworks need to be strengthened to address critical risk issues of this type. If the goal of risk management is to “attempt to anticipate and prevent or mitigate harms that may be avoidable,” then there are components within the decision-making frameworks that require improvement. Notably, the processes of risk estimation itself, as well as the estimation of consequences (social, economic, and psychosocial impacts) need to be accounted for which requires 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. The integrated risk management framework includes elements that are designed to take these factors into account.

Group Discussion on the IRMF

Discussion by the workshop participants about the integrated risk management framework focused on several issues. Overall, the group appreciated the work done under the PrioNet project and considered the IRMF to be a valuable contribution with the potential to strengthen risk management practices for prion diseases. At the same time, participants felt that implementation of some aspects of the framework would be a challenging task, since the requisite infrastructure is not well developed in some areas. Four main themes were dominant in the discussion:

- 1) International and intra-jurisdictional aspects of the IRMF;
- 2) Risk perception and the IRMF;
- 3) Risk assessment and management aspects of the IRMF;
- 4) Incorporation of social and psychosocial aspects in the IRMF.

1) International and Intra-jurisdictional Aspects of the IRMF

Although the IRMF incorporates consultation and collaboration at the international level, past experience suggests that international standards supported by most countries are a good benchmark for risk management, in reality they often represent a “least common denominator” for standards based on science. While the OIE has no science expertise in the area of laboratory research, it did update standards yearly by evaluating new scientific information that became available on BSE. If the OIE produced guidelines that were too

restrictive, onerous, or costly, many countries would not continue to participate and the OIE's leadership role in risk management would be diminished. Ideally, a system that leads to enforceable standards recognized by the WTO would be best, although there would be great difficulty in making them mandatory. New, and sometimes conflicting, scientific developments can make harmonization of expert opinion difficult (prompting one participant to suggest the need for the use of consensus seeking mechanisms in the decision-making processes). In retrospect, international risk management actions on BSE should have been pursued more vigorously.

Several participants commented on the need for collaboration among agencies in multi-jurisdictional risk issues such as BSE. Collaboration among provinces on zoonotic disease issues is of particular importance. While each jurisdiction is ultimately responsible for its own risk assessment and risk management decisions, there is the need for cooperation and collaboration to share information resources in order to achieve consistency. As a template, the IRMF can be used for multiple diseases and could help to improve multi-jurisdictional coordination and cooperation. While several participants noted that interdepartmental cooperation was needed for managing the various impacts from prion disease risks, few resources were available to support this endeavor. Although precautionary approaches within domestic and international settings need to be applied in the interest of protecting public health from emerging risks, risk-based approaches also warrant consideration in terms of optimizing public health benefit.

2) Risk Perception and Potential Impacts on the IRMF

The perception of risk was an important factor for several countries (notably Japan, Germany, UK, and, more generally, the EU as a whole). A unique aspect of BSE crisis was that the Canadian consumer did not stop eating beef while many other countries experienced significant consumer aversion to beef. People seem to be more willing to accept other zoonotic disease risks than they do BSE risks. [A study of risk perception recently completed by PrioNet Canada has considerable information in this regard]. In Canada, concerns were fuelled largely by perceptions of risk originating in other countries. Thus, BSE is largely viewed as an economic risk, rather than a public health risk (BSE and vCJD are not presently indigenous public health problems). The group was reminded that many countries, not just the U.S., closed their borders to Canada when the first BSE case was diagnosed in May 2003, largely due to the perception of risk and Canada's inability to establish the true level of disease prevalence within the cattle herd.

Risk perception is important and variable in food issues. For example irradiation of beef is used in the US and the UK, but not in Canada, due to the perception of added risks, despite scientific evidence that shows irradiation kills bacteria and pathogens. Irradiation saves more lives than other treatment methods and is a cost effective intervention.

As perception can be greatly influenced by news media and frequency of reporting, one participant raised the problem of how do we deal with minor issues that receive intensive media coverage (the 'CNN effect' or social amplification effect) that can amplify or alter public perception? Recognition of the problem created by news media that results in very short timelines for response and action requires improved response. This truncation of timelines could affect the proposed IRMF timelines and activities.

Public perception has played an important role in the flow of the funding into prion research. Priorities for prion disease in relation to other health and environmental issues was mentioned, and the idea of who should determine risk acceptability/risk tolerance levels. It is likely that even a single case of domestic vCJD would quickly change public opinion and perception of BSE risks in Canada.

3) Risk Assessment and Management Aspects Related to the IRMF

Prion diseases present unique attributes of scientific uncertainty, which has changed over time as new information became available. A major problem was the changing terminology and there was a need for harmonization of terminology in risk assessment and in risk communication (for example, ‘negligible risk’ does not mean the same in all contexts). Some participants sought clarification in the definitions that were in use within the IRMF and wanted to make sure that the concept of “reasonable” was fully implemented in the definition for risk management (appropriate “reasonable” actions). The use of cost-benefit analysis can maximize benefit if risk management resources are allocated where they can do the most good. The group discussed the issue of when should a (usually expensive) risk assessment be done, and how this work should be funded? It was suggested that the Council of Canadian Academies could play a role here, and has mandate to do so in Canada. Moreover, the group discussed how such government-wide risk assessments were to be coordinated? The Treasury Board of Canada could take leadership role here, as regulatory impact analysis statements (RIAS) are now required government-wide.

Discussion focused on several barriers related to risk assessments: 1) not all countries have equal capacities in risk assessment and risk management; 2) there is a need to consider

the effectiveness of risk communication practices in advance of the events themselves; and 3) there is a need to inform the public about new developments on an ongoing basis. Blood safety and surveillance was considered as an example: the four documented cases of transfusion transmitted vCJD highlights the need to consider secondary routes of transmission, risk assessments, surveillance capacity, testing capacity, options and knowledge transfer to the public. This has been done in an anticipatory manner through deferral policies in Canada for vCJD (and other blood borne diseases), but has not been implemented to such a degree in many other countries. Canadian Blood Services (CBS) confirmed that blood risk assessments changed with time. CBS is under continuous scrutiny: perhaps their work best signifies the IRMF goal of, “anticipating and preventing or mitigating harms that may be avoidable.”

While the Treasury Board of Canada (TBC) is not responsible for the conduct of risk assessments within the federal government, it could play a leadership role in the development of risk assessment guidelines to be used government-wide. TBC was also involved in transatlantic dialogue with the EU and intends to collaborate with other external stakeholders as well. Independent reviews of the risk assessments should be conducted by academia for unbiased opinions to warrant transparency in the whole process.

Risk management actions should be cost-effective [This will help to maximize the benefit of limited risk management resources]. One example of cost effectiveness was the example of meat irradiation, a highly cost-effective public health measure that has been implemented elsewhere. Participants also questioned how do managers allocate risk management resources among different risk issues all competing for attention?

Of all the issues managed by government departments, many are not problematic; however, a few can be of critical importance, such as the need to forecast the evolution of a risk issue to find cost-effective and proactive interventions. Canadian officials did meet with UK Foresight Group, and discussed the problem of dealing with obesity which will become prohibitively costly over time. Foresight exercises are important as it is difficult for governments to fund risk issues with considerable uncertainty or long time lines. Resources are usually allocated to deal with crises of immediate concern, rather than for issues that will or may require attention 20 or more years in the future. In the UK, the Foresight Group receives public funds and reports directly to the chief scientist in government. The group looks at infectious disease, natural disasters (floods), and other risks and their impacts some 20-50 years in the future. There is a need for improved central capacity for such foresight in Canada.

Despite the difficulties in forecasting for complex issues, ‘What if?’ scenarios are very useful in guiding risk management policy development. The European ‘foresight’ process focuses on major high impact risk issues, such as obesity (minor issues are already well managed). [This is similar in spirit to the IRMF’s ‘anticipate and prevent’ philosophy].

Dr. Cashman, Scientific Director of PrionNet Canada indicated that the network has become a valuable resource on prion diseases, comprising over 60 diverse scientific members and three international collaborators, along with students and young professionals working in partnership with governments, non-government organizations, and industry. Governmental agencies like the Canadian Food Inspection Agency, Health Canada, and the Public Health Agency of Canada could make use of this pool of expertise in addressing future outbreaks of prion diseases, such as chronic wasting disease, atypical bovine spongiform encephalopathy, or atypical scrapie. It is important to leverage and share the expertise through collaborations.

Risk priorities need to be set (as was recently done with the 22,000 chemicals on the Domestic Substances List).

Strengths of the framework were highlighted. The IRMF is ‘nonlinear’ and can be used in a modular fashion: risk issue can be addressed at different levels from different perspectives at any time. Improved tools for risk assessment such as the IRMF are of interest to industry (if used appropriately) to help put risks into perspective. As a template for risk management, a well developed operational tool for risk management decision-making, such as that provided by the IRMF, is essential.

4) Integration of Social and Psychosocial Aspects in the IRMF

Mental health (psychosocial impacts) can be very important, and turned out to be the main public health problem for affected farm communities in Canada. BSE in Canada resulted in increased family violence, suicides, depression and other social effects. Attention to psychosocial impacts needs to be developed more fully in existing frameworks and participants confirmed that it was good to see this aspect incorporated into the IRMF. Social impacts have not been adequately dealt with in the past. Consideration might be given to segregating the socioeconomic impacts into social and economic impacts so that neither impact is overlooked. One solution offered as an improvement for the IRMF was to consider the “one health” concept: integrate public health and animal health and build this into the framework.

Next Steps:

Further comment on draft paper “Managing Prion Disease Risks: A Canadian Perspective”:

- Canada/US/Mexico workshop to be held at PAHO in Washington, D.C. on July 10, 2008
- Final version of the IRMF
- Publication of special issue of IJRAM describing international experiences in BSE risk management

Re-orientation of PrioNet Canada towards risk management:

- Develop prion disease risk models for Canada
 - Develop measures of psychosocial impacts of prion diseases
 - Examine lessons learned from BSE for other prion diseases, such as CWD
- (‘anticipate and prevent’)

Workshop Attendees

Name	Position	Affiliation
Hélène Bergeron	Directrice adjointe par intérim	Institut National de Santé animale
Judith Bossé	Vice President, Science	Canadian Food Inspection Agency
Neil Cashman	Scientific Director	PrioNet Canada
Robert C. Clarke	Assistant Deputy Minister	Public Health Agency of Canada
Shalu Darshan	Research Coordinator	McLaughlin Center, University of Ottawa
Gavin Downing	Manager, Food Safety Science Unit	Ontario Ministry of Agriculture, Food and Rural Affairs
Brian Evans	Executive Vice President	Canadian Food Inspection Agency
John Giraldez	Policy Analyst	Treasury Board of Canada
Bob Hills	Manager, TSE Secretariat	TSE Secretariat, Health Canada
Mark Klassen	Director, Technical Services	Canadian Cattlemen's Association
Daniel Krewski	Director	McLaughlin Center, University of Ottawa
Dennis Laycraft	Vice President	Canadian Cattlemen's Association
Ron Lewis	Chief Veterinary Officer and Director of the Animal Health Branch	British Columbia Ministry of Agriculture and Lands
Judie Leach-Bennett	Assistant General Counsel	Canadian Blood Services
William Leiss	Scientist	McLaughlin Center, University of Ottawa
Stephen Moore	Scientific Director	Alberta Prion Research Institute
Noel Murray	Senior Advisor, Policy and Programs Branch	Canadian Food Inspection Agency
Maura Ricketts	Director, Office for Public Health	Canadian Medical Association
Ron Rogers	Senior Scientific Advisor, Health Products and Food Branch	Health Products & Food Branch, Health Canada
Janie Toth	Executive Director	PrioNet Canada
Michael Tyshenko	Research Associate	McLaughlin Center, University of Ottawa

Maria Nazorowec-White	Coordinator, Food Safety and Quality, National Science Program	Agriculture and Agri-Foods Canada
Norm Willis	Consultant, International Animal Health; Honorary President (Lifetime), OIE	World Organisation for Animal Health