



## Theme 5

### McLaughlin Centre Project

# Managing Prion Disease Risks: A Canadian Perspective William Leiss

Washington, D.C.

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# Workshop Paper

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## “Managing Prion Disease Risks: A Canadian Perspective”

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“International Risk Management and Policy  
for Bovine Spongiform Encephalopathy”



# Special Journal Issue

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- Twenty case study papers on countries and regions: Europe, North and South America, Australia—New Zealand, Latin America, Russia, Israel—Middle East, India, Japan, and China;
- Special papers on OIE, policy drivers, compensation programs in Canada, impacts on the farm level, and the risk management paper under discussion here.
- Thanks to Shalu Darshan and Michael Tyshenko for assembling this set of papers.



# Overview

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1. The situation at present.
2. Case study overview.
3. The Canadian situation.
4. Challenges to the risk management framework.
5. Renewal of the risk management framework in Canada.
6. Policy challenges going forward.



# 1. The situation at present: BSE

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- Incidence of BSE in Europe peaked in Europe in 1992 (37,316) [2007 total: Europe 119, World 124].
- World totals to date, OIE tables: UK 184,643; ROW, 5,714; total 190,357.
- UK, back-calculation: 900,000 – 1, 130,000 infected cattle, approx. 470,000 slaughtered for human consumption (Ferguson et al., 1997).
- France (1987-97): OIE, 31 cases; Back-calculation: 51,300 [24,300-84,700] (Calavas et al., 2007)



# 1. The situation at present: vCJD

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1. 202 cases worldwide, 167 in UK.
2. De Koeijer & Havelaar, 2007: ratio, vCJD to OIE confirmed BSE cases; as of now: 1:942
3. If we were to assume, based very roughly on the back-calculation totals, that some 600,000 infected cattle entered the human food system, that ratio would be closer to 1:3,000, depending, of course, on the number of potential new cases now incubating.



# 1. The situation at present: Impact

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- ❑ Arguably, BSE has been the most costly zoonotic disease to affect the world to date.
- ❑ As a very rough guess, total economic direct and indirect costs, plus government expenditures, to respond to BSE, could total \$30 billion or more worldwide (better estimates are welcome!);
- ❑ Almost certainly, among all countries affected by BSE, Canada has the highest ratio of costs per case of BSE.
- ❑ This is why we must re-examine both policy options and risk management frameworks.



## 2. Case study overview.

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### Issues:

1. Surveillance, active and passive, in the case of a disease with a long incubation period.
2. The problem of true prevalence and its relation to timely risk-control measures.
3. Delayed recognition of the problem by many countries.
4. Delayed implementation of risk-control measures.
5. Ever-changing classification systems for country risk.
6. Lack of enforceable international standards (OIE).



## 2a: Surveillance

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- The set of case studies shows that countries have openly fought over the adequacy of particular surveillance strategies throughout the BSE episode, without reaching any definitive common standard they could all agree on.
- The European experience demonstrates beyond the shadow of a doubt that only active surveillance and large-scale testing indicated the true scope of BSE in the most seriously-affected countries.



## 2b: True Prevalence

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- The back-calculation studies for the UK and France give an astonishing picture of the possible true prevalence of the epidemic in the worst-affected countries.
- In expert testimony before the UK BSE Inquiry, Prof. Roy Anderson argued that the back-calculation method, if applied promptly, could have shown the flaws in the original feed ban and thus could have limited the scope of the UK epidemic.



## 2c: Delays in recognition

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- The set of case studies documents the delays in many countries in imposing the necessary risk control measures, while they argued with others over the possibility that indigenous cases of BSE were incubating in their national herds.



## 2d: Delays in risk control

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- A paper by Michael Tyshenko (Special Issue) examines these delays carefully and systematically, over the critical decade 1988-1998 and beyond.
- For example, the two-year delay in France (1988-1990) in following the UK MBM ban occurred at a time when the epidemic was surging toward its peak in both countries.



## 2e: Changing risk categories

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- The case studies show that, over a period of many years, both the EU and the OIE struggled to find an adequate and defensible hierarchy of country risk categories that could help to get agreement on risk control measures and to “normalize” trade relations.



## 2f: International anarchy

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- In the end, the international agencies lost control over the actions of individual countries which were responding to others' discoveries of the index and succeeding cases of indigenous BSE.
- The very public “sniping” between politicians, lobbyists, and officials of various countries (e.g., in Europe, and involving Japan vs. both Canada and the U.S.) certainly, in my view, undermined public confidence in the “rationality” of our risk assessment and risk management frameworks.



## 2. Conclusion: Policy Drivers

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Important paper by Michael Tyshenko (Special Issue):

- Knowledge of the UK BSE outbreak was not a significant driver for BSE policy in any other country that later reported BSE. (But the occurrence of imported BSE acted as a driver for policies to reduce both external and internal challenge.)
- 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.



## 3a. The Canadian situation

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- As mentioned, of all nations affected by BSE, our own country may have had the worst impacts, if calculated on a per case basis.
- The “shock and awe” of the instantaneous U.S. border closure—and the sheer magnitude of the resulting impacts—had not been anticipated, so far as we can tell, in any formal risk assessments.



## 3b. The Canadian situation

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- An important paper by U.S. academics (Sparling & Caswell, 2006) retrospectively analyzes the excess risk Canada faced with BSE, in relation to our dependence on the beef export trade to the U.S., in terms of our having *market integration* without having its necessary complement, *regulatory integration*.
- This and other aspects of our experience with BSE should be sufficient incentive for us to re-examine our risk management framework.

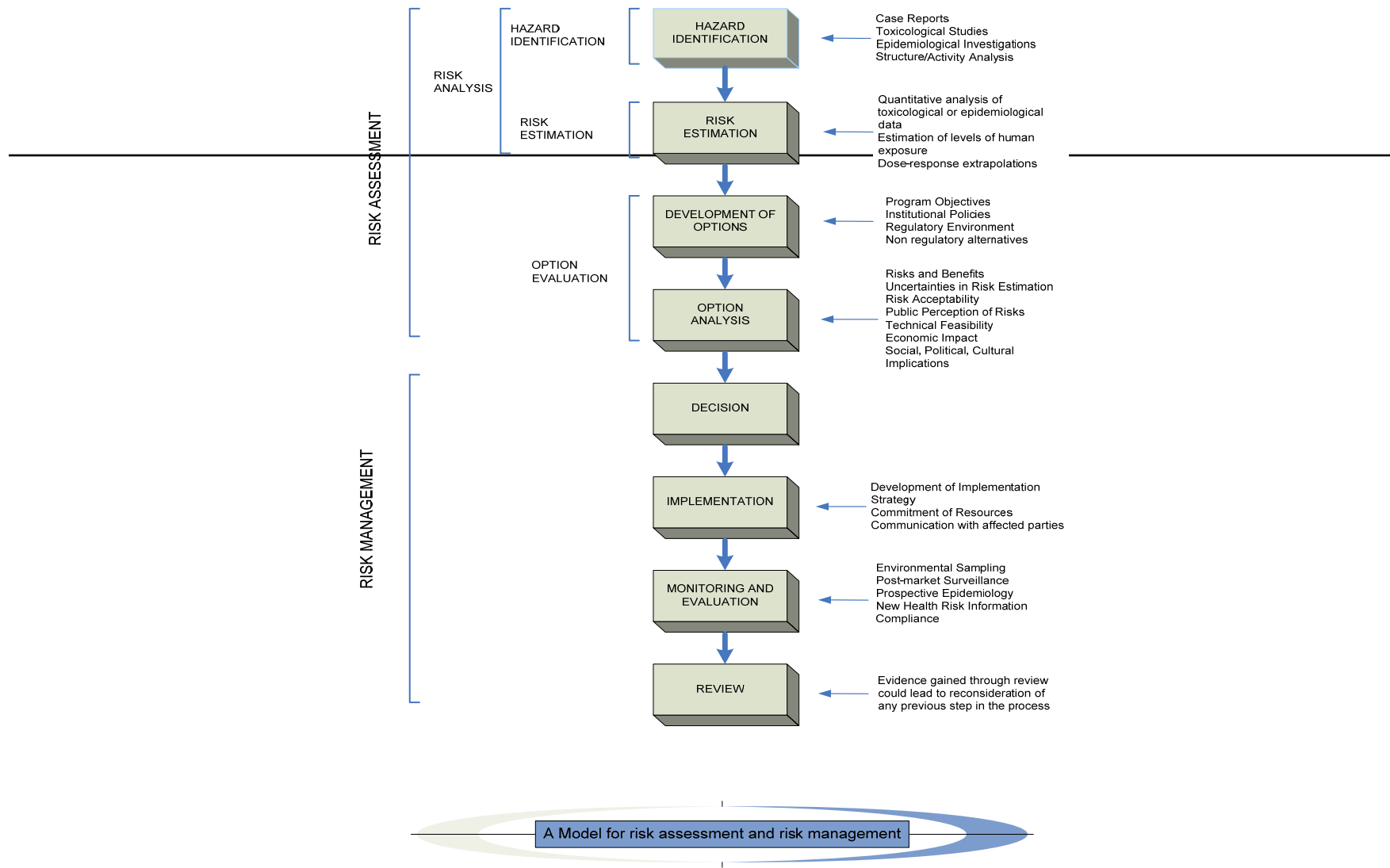
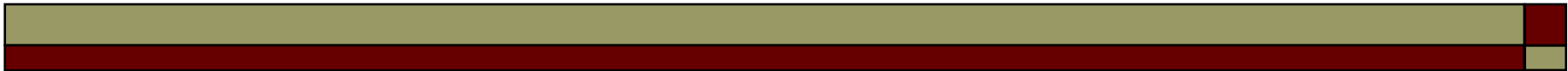


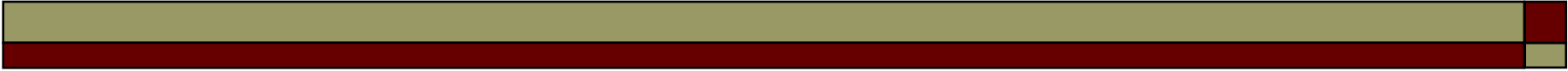
# The primary objective of risk management

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To anticipate and prevent or mitigate harms that may be avoidable.

(This definition incorporates the precautionary approach *within* good risk management.)





## 4. Challenges to the risk management framework (models).

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### Purposes of the Models:

- Indicate the major components of the process leading to a risk management decision;
- Indicate a logical sequence for the components and sub-components within the process;
- Standardize the terminology;
- Illustrate the difference between risk assessment and risk management (the “scientific” vs. the policy/values dimensions)
- First presented in the U. S. “red book” 1984.



# Integrated Risk Management Framework

## Recurring Deficiencies:

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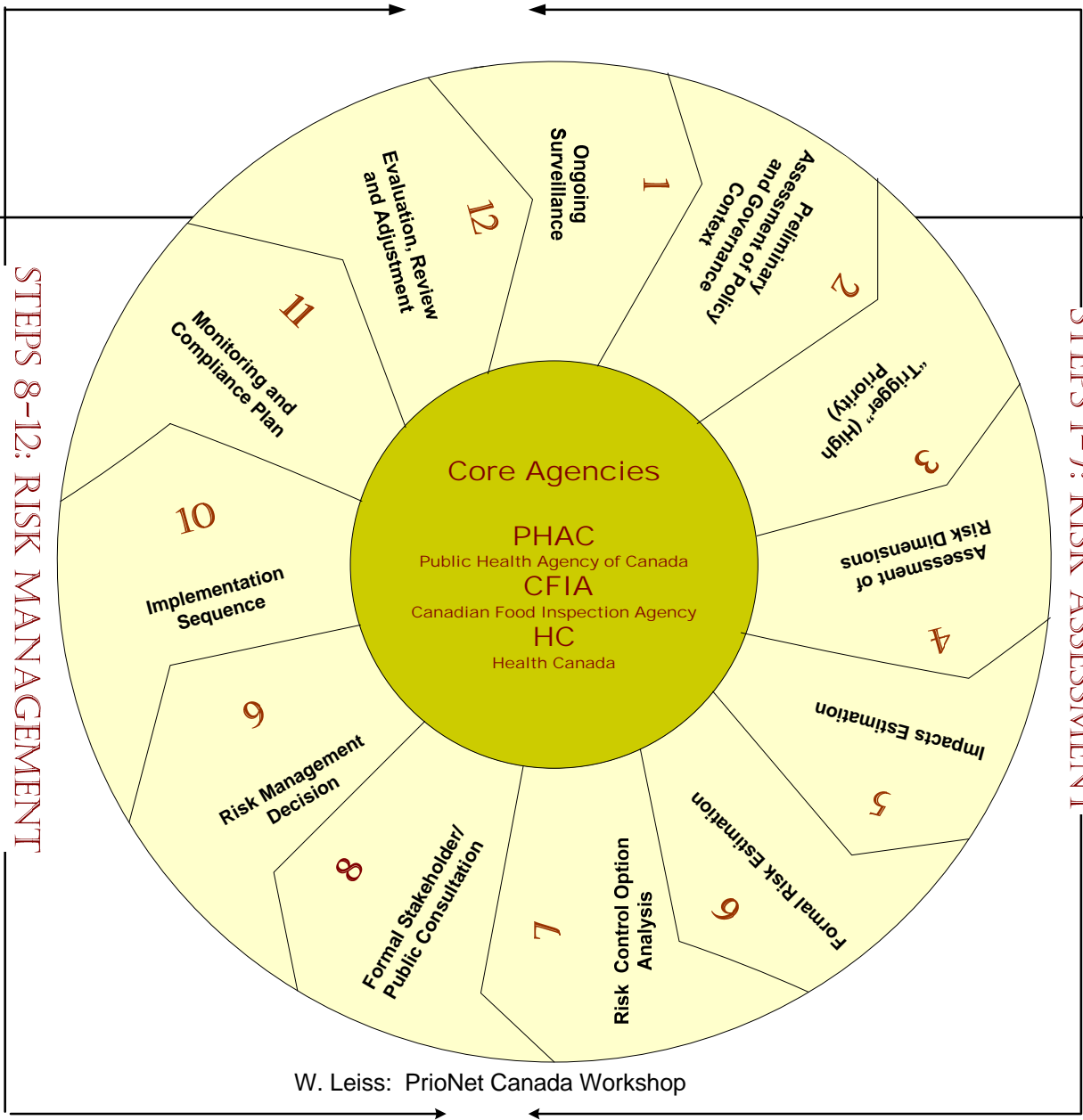
- As the process becomes more complex, the allocation of responsibilities becomes blurred, except for very well defined risk issues;
- With increasing globalization and other factors, the number of agencies potentially involved, and the need for international coordination, has grown;
- Outside the U.S., there is very limited use of independent external peer review for risk estimation;
- “Options Analysis” and “Decision” stages are still, largely, “black boxes” in contrast to the relative transparency of the risk estimation procedures.



## 5. Renewal of the risk management framework in Canada—new steps.

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- New graphical representations of the process (next two slides).



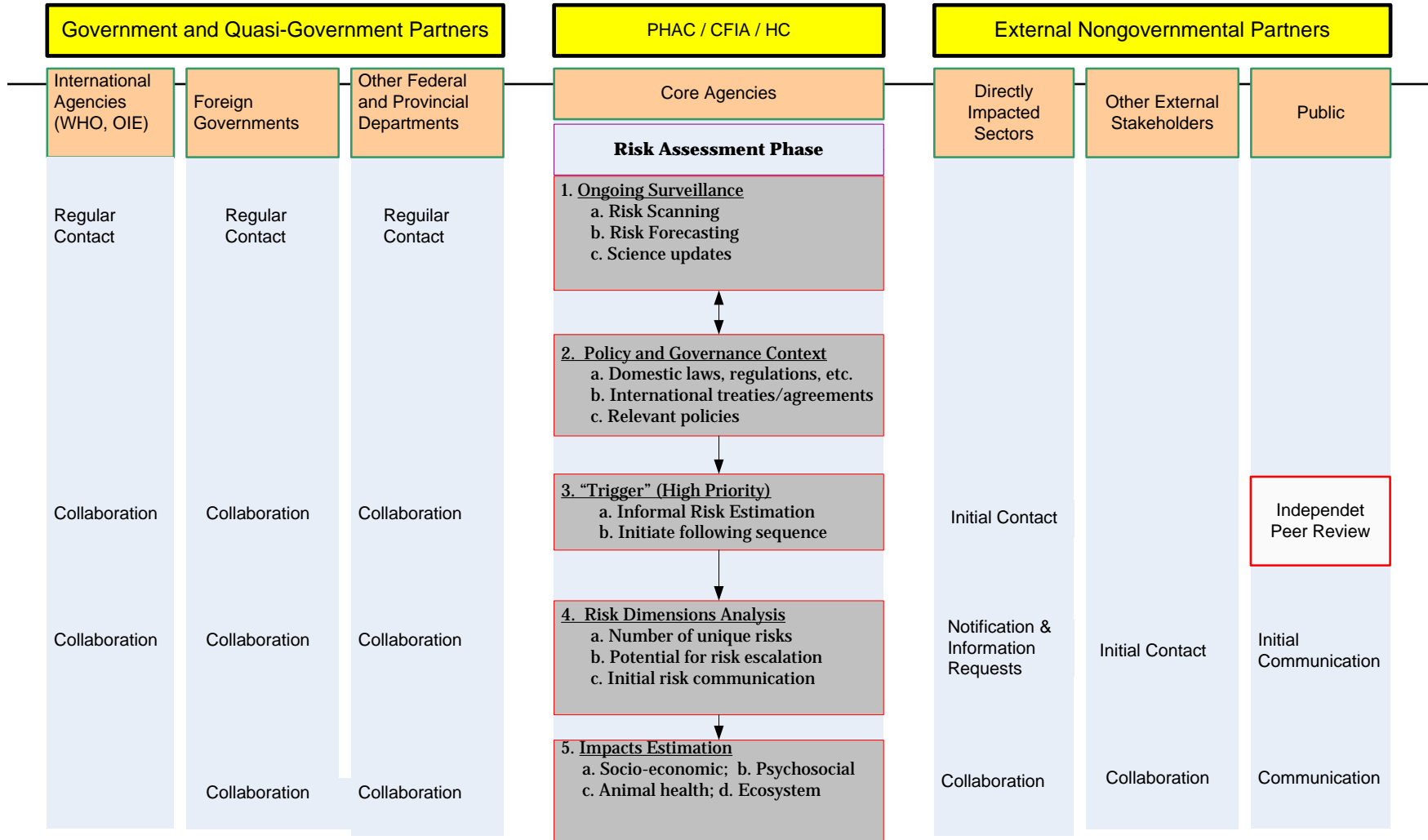
STEPS 1-7: RISK ASSESSMENT

STEPS 8-12: RISK MANAGEMENT

# Integrated Risk Management: Structure, Components, Process

PrioNet: McLaughlin Centre Project (W. Leiss: January 2007)

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## Key proposed changes to IRMF (1)

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- “Formalize” the entire process by introducing mandatory documentation at each stage, in line with the “accountability” ethic.
- The “flaps” on either side of the core process show the specific needs for international and domestic inter-agency collaboration, and the needs for involvement of, and communication with, domestic partners (directly affected parties and the public).



## Key proposed changes to IRMF (2)

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- Perform a timely, preliminary risk estimation (“back of the envelope” if necessary) to facilitate the “*anticipate and prevent or mitigate*” theme.
- Develop more formal methods, including perhaps a quantitative algorithm, for better consequences estimation, especially for psychosocial factors.
- Always use independent peer review for the formal risk estimation.



## 6. Policy challenges going forward

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- The workshop paper discusses 10 policy issues. We would very much like to have your feedback on them, both today and over the next two months.
- On the following, concluding slides are some of the questions about policy issues that we hope you will help us with, starting perhaps in today's discussion and feedback session.
- Please also provide us with documentary evidence, which we might have missed, that is relevant to any and all of the issues we have presented.

# Policy challenges – List (Paper, p. 56)

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- 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



# Policy challenges - Questions (1)

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- In what forums can the attempt to better coordinate risk control measures across international borders take place?
- In what forums can the attempt to better align regulatory and market integration take place?



# Policy challenges - Questions (2)

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- How can a robust protocol be developed, through which the feasibility, costs, and benefits of precautionary action in particular cases can be fairly assessed?
- How can policy choices about disease surveillance strategies be more adequately defined on the basis of accepted scientific principles?



# Policy challenges - Questions (3)

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- What type of protocols are needed in order to facilitate the proper assessment of psychosocial factors in risk assessments?
- On what basis in principles of good public policy should choices about product testing by governments or industry, in response to BSE and vCJD concerns, be made?



# Thank you.

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- Thanks for attending this session, and thanks in advance for helping us to revise, refine, and amplify the analysis presented in the workshop paper.