

# Information Brief on International Risk Management Standards

To support the discussion on the Government Directive on Regulating

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# 1. Purpose, Scope and Approach

The purpose of this brief is to support the discussion on risk management within the current development of a Government Directive on Regulating. More precisely, this brief presents some of the most interesting aspects of key international standards – aspects that are of interest to Canada because they are novel, different from Canadian traditions, or because they represent particularly well-developed international approaches to risk management systems.

This brief has been written for a broad audience, including non-experts on risk management. However, to ensure brevity, it does neither include an introduction to the theory of risk management nor a detailed account of current Canadian practices.

Risk management is a discipline that has developed rapidly in recent years and this development is truly international. This means that important contributions have been made by a number of different nations. Some of the most important standards and concepts have come from Australia and New Zealand (AUS/NZ), the United States (US) and the United Kingdom (UK). I have selected these three jurisdictions as the most promising sources of ideas to support the discussion in Canada. The selected documents are either national standards or documents of equivalent stature (as opposed to departmental guidelines).

In addition, two new initiatives, one by the International Standards Organization (ISO) and one by a small and new group, the International Risk Governance Council (IRGC) are briefly discussed. The former is particularly important to the future of risk management standards and the latter is, arguably, breaking new ground.

The judgment of what is novel, different or advanced requires a reference point. Since Canada has its own national standard, *Risk Management: Guideline for Decision-Makers – A National Standard for Canada*, issued by the Canadian Standards Association (CSA),<sup>1</sup> it makes sense to use it as the main reference point. However, this brief is neither an analysis of the CSA Guideline, nor should the description of an important contribution from another standard included in this brief imply that this point has been forgotten in the CSA Guideline (instead, it may simply be different, less explicit, or less detailed).

The key to a successful discussion on risk management is the careful handling of terminology – one should neither ignore the importance of semantics nor be paralysed by it. The next, brief section on terminology should help.

# 2. Terminology

I do not know of a single debate that is more hampered by semantic confusion than that on risk management. One major problem is the conception of the term "risk management" itself. Fortunately, central bodies of the Government of Canada (namely, Privy Council Office, Treasury Board Secretariat, and the Canadian School of the Public Service) use the concept consistently. It largely conforms to the following definition by the CSA (1997) where "risk management" is conceived of broadly by covering the full range of risk-related activities.

Risk management – the systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling, and communicating about risk issues [p. 3].

In broad agreement with CSA (1997), the External Advisory Committee on Smart Regulation, EACSR defines risk management as follows in *Smart Regulation* – *A Regulatory Strategy for Canada* (2004):

Risk management is a systematic approach to setting the best course of action under uncertainty by identifying, understanding, assessing, prioritizing, acting on and communicating about potential threats, whether they affect the public's social, financial or economic well-being, health and safety, or the environment.

Managing the related risk involves allocating limited national resources where they can do the most good for the greatest number of people. It includes the following steps: identification of the issue; assessment of the level and severity of risk; development of the options; decision; implementation of the decision; and evaluation and review of the decision. At each step of the process, communications and consultation activities, legal considerations and ongoing operational activities must also be taken into account in effective risk management strategies. [p.36]

However, a narrow concept of "risk management," that excludes the analysis and communication activities, has had an impact on Canadian regulatory practice and legislation. The narrow concept originates from a framework issued by the United States National Research Council in 1983, has been used by the World Health Organization and the Food and Agricultural Organization of the United Nations, and is referred to in the General Agreement on Tariffs and Trade (GATT) of the World Trade Organization and in the North American Free Trade Agreement (NAFTA).

We are faced with the following:<sup>2</sup>

- (1) The Canadian Standards Association uses a <u>broad concept</u> of risk management and the following key terms this largely corresponds to usage by central agencies of the Government of Canada and modern texts on risk management:<sup>3</sup>
  - Risk *management* = the overall enterprise
  - Risk *analysis* = the scientific work within that enterprise (further separated into "preliminary analysis" and "risk estimation")
  - Risk *evaluation* = the key decision-making step within that enterprise
  - Risk *assessment* = the combination of risk analysis and risk evaluation
  - Risk *control* = the management of an acceptable risk

(2) Some important international bodies that impact on the regulation of products in Canada use a <u>narrow concept</u> of risk management as the following illustrates:

- Risk *analysis* = the overall enterprise
- Risk *assessment* = the scientific work within that enterprise
- Risk *management* = the key decision-making step within that enterprise and the management of an acceptable risk

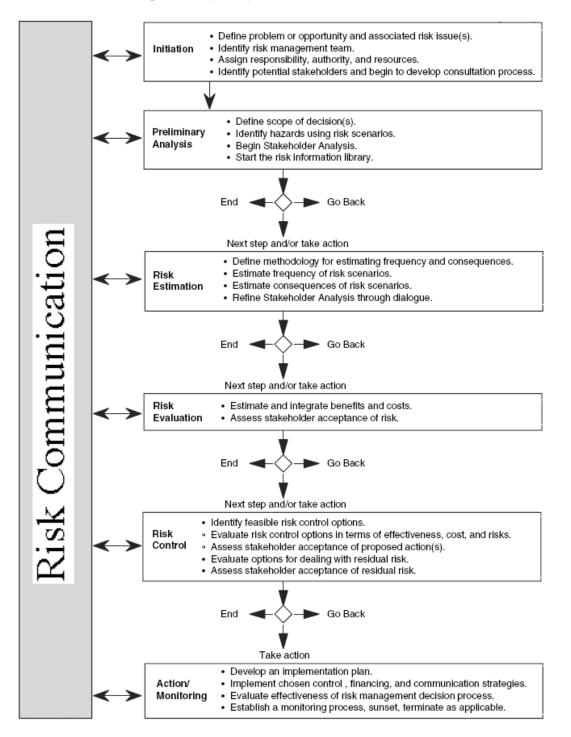
Therefore, comparing (1) and (2) we can observe:

- Risk management may be synonymous to risk analysis
- Risk *management* may be synonymous to risk *evaluation* + *control*
- Risk analysis may be synonymous to risk assessment
- Risk analysis may be synonymous with risk management
- Risk *analysis* may be a sub-component of risk *management*
- Risk *management* may be a sub-component of risk *analysis*

The situation gets even worse if one includes additional standards into the comparison. Semantic disagreement of this magnitude can become a serious obstacle to effective analysis and communication. See also **Appendix C** on this point. It becomes essential to be precise about meaning at all times (and especially when comparing frameworks or when communicating interdepartmentally). Note also that the term "risk" is sometimes substituted with "safety" or "hazard."

It is common practice in guidance documents on risk management to enhance the meaning of definitions, and to illustrate logical flows, by means of graphical charts. **Chart 1** on the following page shows the CSA (1997) concept in this graphical form.

**Chart 1**: The Risk Management Decision-Making Process According to CSA (1997). Note: The combination of "preliminary analysis" and "risk estimation" is called "risk assessment"



Source: CSA (1997), p. 7

For the purpose of this brief, it is necessary to use clear and precise terminology. A simple risk management framework can be built on the following five activities named in a way that avoids the confusion shown above. The following terminology will be used throughout this brief (except when quoting from other texts, of course) as "neutral language" – it represents terminology that deliberately avoids overlap with the various current terminologies.<sup>4</sup> Note, I do <u>not</u> recommend that the following terminology should replace the CSA and ISO Standards.

## Five Key Activities within a Risk Management Framework ("the overall enterprise"):

- Set goals and focus: identifying context, prioritizing objectives, and setting the scope and focus of the overall exercise. The choices made within this activity are based on a judgment about interests (whose interests count?) and entities (which entities have value?). This is sometimes called "endpoint selection" which risk are we considering?
- **Describe:** arriving at an objective understanding of the likelihood and the magnitude of an impact (in qualitative or, better, quantitative terms). As such it is largely a technical or scientific activity.
- **Prescribe:** evaluating the quality of forecasts provided within the descriptive step, the balancing of positive and negative effects, the decisions on how to mitigate and otherwise manage the risk and the implementation of measures. As such it is evidence and judgement-based activity that requires the consideration of the big picture. It represents the key decision-making step within the risk management framework (which should not imply that decisions of another nature are not taken elsewhere).
- **Communicate:** communicating among the key actors in the process as well as with the intended beneficiaries and other stakeholders. Communication can be broadly understood as to include public information, consultation, engagement or even partnership. Public designates "the regulated" and other stakeholders.
- **Monitor and learn:** an activity that describes the monitoring of the effects of decisions and activities that cause changes to the environmental conditions and the emergence of new evidence. Decisions on the need for re-evaluations and the implementation of lessons learned are part of this outcome-oriented activity. These activities are components of performance measurement and results-based management.

# 3. Selected International Initiatives

# 3.1 Current Work of the International Standards Organization (ISO)

The International Standards Organization  $(ISO)^5$  has produced a very valuable guide on terminology in 2002, the *Guide 73 Risk management – Vocabulary – Guidelines for use in standards*. In this guide approximately 40 terms are defined in order to support the more ambitious project of creating an international standard on risk management (currently underway, see below).

ISO's terminology compares as follows to the options outlined above:

- Risk *management* = the overall enterprise
- Risk *analysis* = the scientific work within that enterprise
- Risk *evaluation* = the key decision-making step within that enterprise
- Risk *assessment* = the combination of risk analysis and risk evaluation
- Risk *treatment* = the management of an acceptable risk

At this general level, ISO (2002) and CSA (1997) name the basic elements of a risk management system identically except for the substitution of "risk control" (CSA) with "risk treatment" (ISO). We can note in this context that CSA reaffirmed its guideline in 2002.

Despite this overall agreement, it is valuable for policy makers to consider the ISO guide alongside our Canadian standard because some differences in vocabulary become apparent when examining the guidelines in detail.

ISO members are currently working on an international standard on risk management. The current discussion draft is entitled *Risk Management – General Guidelines for Principles and Implementation of Risk Management*. Canada has joined the effort through its own working group. The standard will target senior management and assist decision makers to deal with any type of risk (e.g., financial, security, public health risks) in any type of organization.

The first international meeting of working groups took place in Japan in the autumn of 2005. As a result a revised draft standard is being produced. The next meeting is scheduled for February 20-22, 2006 in Australia. It is expected that the standard will be completed by the end of 2008, which corresponds to a three-year working period. A revision of the ISO (2002) guide on vocabulary will be part of these developments.<sup>6</sup>

The efforts of this group could become very important to the design of risk management frameworks. It is, however, too early to judge what types of innovation will ultimately emerge.

Take-home Points – ISO Initiatives

- ISO is planning to release an International Risk Management Standard in 2008
- The existing ISO Standard on Risk Management Vocabulary will be revised
- A Canadian working group is involved in the effort

3.2 Current Work of the International Risk Governance Council (IRGC)

The International Risk Governance Council (IRGC) was created in 2004.<sup>7</sup> This not-for-profit organization is independent, located in Switzerland, and supported by an international scientific and technical council. The founders were the World Business Council for Sustainable Development, the President of Hoseo University in Korea, a former Senator of the United States, the President of ETH University in Switzerland, and a prominent former Federal Councilor of the Swiss Confederation.

The most recent IRGC conference, *Implementing a Global Approach to Risk Governance*, took place in September 2005 in Beijing. Current interests of IRGC are international risks such as epidemiology and nanotechnology.

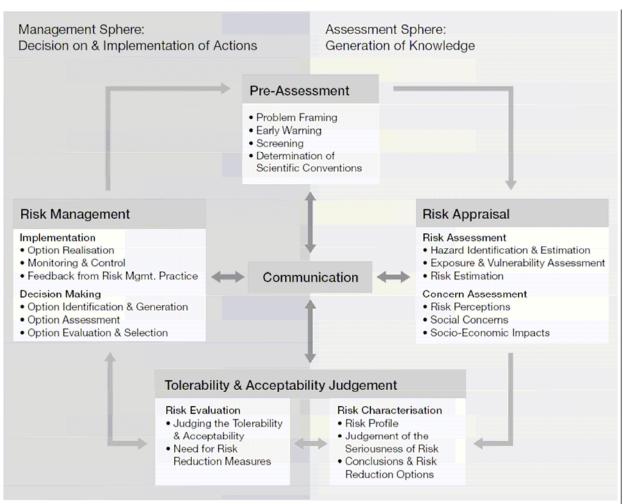
It is too early to tell if this organization is going to be influential - it is included here because it is a source of innovative thinking and because it is relevant in the context of the development of a Government Directive on Regulating.

In its detailed *White paper on Risk Governance: Towards an Integrative Approach*, "Risk governance" is defined by IRGC (2005) as follows:<sup>8</sup>

Risk Governance: Includes the totality of actors, rules, conventions, processes, and mechanisms concerned with how relevant risk information is collected, analysed and communicated and management decisions are taken. Encompassing the combined risk-relevant decisions and actions of both governmental and private actors, risk governance is of particular importance in, but not restricted to, situations where there is no single authority to take a binding risk management decision but where instead the nature of the risk requires the collaboration and co-ordination between a range of different stakeholders. Risk governance however not only includes a multifaceted, multifactor risk process but also calls for the consideration of contextual factors such as institutional arrangements (e.g. the regulatory and legal framework that determines the relationship, roles and responsibilities of the actors and co-ordination mechanisms such as markets, incentives or self-imposed norms) and political culture including different perceptions of risk. [p. 80] <sup>9</sup>

Unfortunately, IRGC does not refer to the CSA (1997) Guideline and does not follow the ISO (2002) terminology. Instead, the terminology used represents a narrow conception of "risk

management" as illustrated in the following **Chart 2**. IRGC (2005) produced a useful comparison of terminologies of different international standards – it is included here as **Appendix C** (which also illustrates the types of standards used to supports IRGC's Framework).





Source: IRGC (2005), p. 65.

Despite the differences in terminologies, there is no fundamental disagreement between the CSA (1997) and IRGC (2005) frameworks. The noteworthy aspect of the work of IRGC is an emphasis on a systemic approach that emphasizes the role of people and power-relationships. In their view, it is necessary to consider how risk-related decision-making unfolds when a range of actors are involved, requiring co-ordination and possibly reconciliation between a profusion of roles, perspectives, goals and activities. In IRGC's view, risk governance illuminates a risk's context by taking account of such factors as the historical and legal background, guiding principles, value systems and perceptions as well as organisational imperatives.

IRGC (2005) claims that their framework offers two major innovations to the risk field: the inclusion of the societal context and a new categorisation of risk-related knowledge:

Inclusion of the societal context: Besides the generic elements of risk assessment, risk management and risk communication, the framework gives equal importance to contextual aspects which, either, are directly integrated in a model risk process comprising of the above as well as additional elements or, otherwise, form the basic conditions for making any risk-related decision. Contextual aspects of the first category include the structure and interplay of the different actors dealing with risks, how these actors may differently perceive the risks and what concerns they have regarding their likely consequences. Examples of the second category include the policy-making or regulatory style as well as the sociopolitical impacts prevalent within the entities and institutions having a role in the risk governance. Linking the context with risk governance, the framework reflects the important role of risk-benefit evaluation and the need for resolving risk-risk trade-offs.

*Categorisation of risk-related knowledge:* The framework also proposes a categorisation of risk which is based on the different states of knowledge about each particular risk, distinguishing between 'simple', 'complex', 'uncertain' and 'ambiguous' risk problems. The characterisation of a particular risk depends on the degree of difficulty of establishing the cause-effect relationship between a risk agent and its potential consequences, the reliability of this relationship and the degree of controversy with regard to both what a risk actually means for those affected and the values to be applied when judging whether or not something needs to be done about it. Examples of each risk category include, respectively, known health risks such as those related to smoking, the failure risk of interconnected technical systems such as the electricity transmission grid, atrocities such as those resulting from the changed nature and scale of international terrorism and the long-term effects and ethical acceptability of controversial technologies such as nanotechnologies. For each category, a strategy is then derived for risk assessment, risk management as well as the level and form of stakeholder participation, supported by proposals for appropriate methods and tools. [p. 11-12, from the Executive Summary]

It is indeed correct that these two points are not emphasized in CSA (1997) and other frameworks currently used in Canada. While acknowledging my bias towards an interest in governance issues, I believe it is difficult to argue against the utility of the "risk governance" concept because it is the natural endpoint of the following progression towards greater inclusion of outsiders to which Canada seems increasing committed:

Risk expertise  $\rightarrow$  Risk communication  $\rightarrow$  Risk consultation  $\rightarrow$  Risk governance.

Take-home Points – IRGC Initiative

- IRGC is a relatively new body that carries out conceptual thinking on risk governance and that applies these concept to current international risk issues
- The recently released White Paper covers novel thinking on the systematic inclusion of societal contexts and on the categorization of risk-related knowledge (differentiating simple, complex, uncertain, and ambiguous risks)

# 4. Selected National Standards

## 4.1. Australia and New Zealand

Standards Australia & Standards New Zealand (AS/NZS) were the first out of the gate with a National Risk Management Standard in 1995. The current third version, AS/NZS (2004) comes in two parts: a short standard and very detailed *Risk Management Guidelines Companion*, which provides a wealth of information in clear language.

ISO has approved this national standard. Furthermore, the basic concepts in the Australian / New Zealand Standard are an important foundation of the first discussion draft of the current international ISO project discussed above. Finally, the standard has been adopted by a number of multi-national enterprises and has been translated into French, Spanish, Chinese, Japanese, and Korean. For these reasons, this national standard is an influential set of documents.<sup>10</sup>

We should also note that in 2001, the Government of British Columbia has favoured the second (1999) version of the Australian / New Zealand Standard over the Canadian Standards Association 1997 Guidelines and adopted it throughout its departments and Crown corporations.<sup>11</sup>

An example from Australia shows that legal obstacles can impede the full adoption of the standard. The 2005 *Risk Analysis Framework* of the Office of the Gene Regulator of the Australian Government follows, by-in-large, the Australian / New Zealand Standard. However, the Office of the Gene Regulator is legally bound to use the terminology of the WHO, WTO, FAO and the Codex Alimentarius Commission. As a result it uses a narrow concept of "risk management" in its new framework (risk assessment, risk management and risk communication are separate steps). In my opinion, the fact that this reality is explained in detail is a very valuable service to the reader,.<sup>12</sup>

I want to highlight three features of the Australian / New Zealand Standard. The first feature is its *holistic approach* that covers risks <u>and</u> benefits and is applicable to all risk contexts and all organizations. The second feature is the emphasis on establishing a *context for risk management*. Finally, the third feature is the emphasis on *consultation* (rather than just communication).

First, however, I provide a summary of the framework used in the Australian / New Zealand Standard in **Chart 3**. This model corresponds by-in-large to that of the Canadian Standards Association. Most of the terminology is identical except for the use of "risk treatment" that is called "risk control" in the Canadian Standard. Another difference is that the Australian / New Zealand Standard places the monitoring and review activity very explicitly alongside the entire process, instead of highlighting its place only at the end of the process.

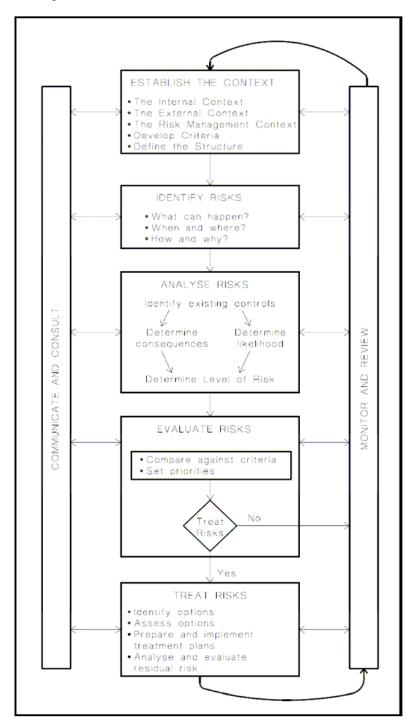


Chart 3: The Risk Management Process in the Australia/New Zealand Standard (AS/NZS 2004)

Source: AS/NZS (2004), p. 13

## Holistic Approach

Several aspects of the holistic approach used in AS/NZS (2004) are already visible in its definition of risk management:

Risk management: the culture, processes and structures that are directed towards realizing potential opportunities whilst managing adverse effects [p. 4]

Unlike the Canadian Standard (CSA 1997), the consideration of opportunities and benefits is interwoven with the entire process. The Canadian Standard, and many other standards, do not emphasize benefits to the same extent and confine it to the key decision making step (called "risk evaluation" in the Canadian Standard).

We should note that cost-benefit analysis is a well-established activity in many management contexts. However, some risk management contexts stay away from an early consideration of benefits in order not to inhibit a complete estimation of risks. A good example is product registration that is considered a privilege and not a right. In this model a proponent has to convince regulators that the product is "safe". In absence of convincing evidence the product will not be considered "safe" and, thus, will not be eligible for registration, regardless of the potential benefits of the product. Because of this existing tradition, it is noteworthy that Australian / New Zealand Standard makes a strong commitment to the consideration of benefits and opportunities.

In addition to risks, benefits are also actively managed in the Australian / New Zealand Standard. It incorporates the following options to treat the positive outcomes from hazards:

- Actively seeking an opportunity by deciding to start or continue with an activity likely to create or maintain it (where this is practicable). [...]
- Changing the likelihood of the opportunity, to enhance the likelihood of beneficial outcomes.
- Changing the consequences, to increase the extent of the gains.
- Sharing the opportunity. [...] Retaining the residual opportunity. [...] [p 20]

Another aspect of the holistic approach is the incorporation of risk management thinking into the culture of an organization, into its business practices and everyday activities:

To be most effective, risk management should become part of an organization's culture. It should be embedded into the organization's philosophy, practices and business processes rather than be viewed or practiced as a separate activity. When this is achieved, everyone in the organization becomes involved in the management of risk. [p. V, Foreword]

Yet another aspect of the holistic approach is that the Standard is designed to be applicable to organizations in public, private and voluntary sectors and that it can cover the evaluation of any type of risk, including financial, health and environmental risks – the Canadian Standard is comparatively more focused on public policy and less on financial and operational risks.

#### Risk Management Context

Another important part of Australian / New Zealand Standard is the thinking behind the first step of "establishing the context". It corresponds to the "initiation" step in Canadian Standard and provides considerable detail on the following three types of contexts:

#### Establish the external context

[...] It is particularly important to take into account the perceptions and values of external stakeholders and establish policies for communication with these parties. Establishing the external context is important to ensure that stakeholders and their objectives are considered when developing risk management criteria and that externally generated threats and opportunities are properly taken into account.

#### Establish the internal context

[...] Establishing the internal context is important because:

- risk management takes place in the context of the goals and objectives of the organization;
- the major risk for most organizations is that they fail to achieve their strategic, business or project objectives, or are perceived to have failed by stakeholders;
- the organizational policy and goals and interests help define the organization's risk policy; and
- specific objectives and criteria of a project or activity must be considered in the light of objectives of the organization as a whole.

#### Establish the risk management context

The goals, objectives, strategies, scope and parameters of the activity, or part of the organization to which the risk management process is being applied, should be established. The process should be undertaken with full consideration of the need to balance costs, benefits and opportunities. The resources required and the records to be kept should also be specified. ... [p. 14-15]

#### Risk Consultation Rather Than Communication

The Canadian Standard uses the term "risk communication" but not "risk consultation." Nevertheless, it is specified in the Canadian Standard that communication must be a two-way street, which amounts to a form of consultation. In the Australian / New Zealand Standard the term "communication and consultation" is used to emphasize that the idea of dialogue among stakeholders – as opposed to strategic communication by an organization.

The Australian / New Zealand Standard makes it clear that consultation impacts on decisions through influence rather than power. In other words, consultation leads to the collection of views and advice from stakeholders but does not amount to shared decision-making.

## Handbook and Tools

The *Risk Management Guidelines Companion to AS/NZS 4360:2004* provides useful tools such as examples on how to tabulate risks of different kinds, how to write a risk treatment plan and a form to build a Risk Register (called Risk Information Library in the Canadian Standard).

#### Commentaries on the AS/NZS Standard

The following quote by Michael Tarrant, Assistant Director, Research Management, Emergency Management Australia, made at the occasion of a 2002 workshop, illustrates some of the benefits of the Australia / New Zealand model:<sup>13</sup>

Risk management based the Australian Standard AS/NZS 4360 is now a foundation for management both in the private and public sectors. At a recent seminar in early 2002 for Chief Executive Officers a number of the most senior managers in the Australian Public Service described how they were using and integrating risk management into the culture and management practices of their organisations.

They developed a number of key themes:

- Support from senior management is critical
- Developing a risk management across the whole organisation is vital.
- Risk management is a core element of good management practice
- Risk management needs to have a holistic approach
- Risk management helps break down silos and divisions in organisations
- Better understanding of objectives.
- Risk management integrates a systematic way to make informed decisions. [p. 1]

The analysis in the White Paper of the International Risk Governance Council (IRGC 2005) is somewhat critical, however:

Comment: A very general and generic approach. Valuable as an overall structure but does not address in any detail issues such as uncertainty, different characteristics of risk such as ubiquity or persistence. Nor does it cover societal aspects of risk in any detail – although it refers to perceptions of risk and the fact that these need to be detailed and understood. [p. 119].

#### Take-home Points – Australian / New Zealand Standard

- Risk and benefits (or opportunities) are included under "risk management"
- Emphasis on the context of risk managements; uses the term risk *consultations*
- The Standard addresses all types of risk in all types of organizations
- Legal constraints can prevent full implementation even by Australian Government
- Contains a very useful and detailed handbook to supplement the standard
- Internationally influential and adopted by the Province of British Columbia
- Represents a high-level standard more detail is needed for specific applications

## 4.2. United States

The United States does not have a National Risk Management Standard but much of the early conceptual work on risk management was carried out in the U.S. and a number of internationally influential reports were created through this early research. I will explain the development of risk management thinking in the United States by discussing the so-called Red, Blue, White, and Orange Books. Some of the books are still commonly cited in the international literature.

#### The Red Book and The Blue Book

The National Research Council (NRC) of the National Academy of Sciences (NAS) produced the report *Risk Assessment in the Federal Government: Managing the Process* in 1983 (the so-called "Red Book")<sup>14</sup>. In this ground-breaking study, a clear conceptual distinction between risk assessment (the descriptive step) and risk management (the prescriptive step) was advocated. The purpose of this distinction was to ensure that risk assessments (i.e., scientists) are protected form inappropriate policy influences. This report is the origin of what I have called the "narrow conception" of risk management. However, the NRC also recognized that the choice of risk assessment techniques could not be isolated from society's risk management goals and stressed the importance of integrating the risk assessment and risk management steps.

Approximately 10 years later, in 1994, the NRC produced a second report entitled *Science and Judgment in Risk Assessment* (the "Blue Book").<sup>15</sup> In the Blue Book, NRC explains that the Red Book's separation of risk assessment (descriptive step) and risk management (prescriptive step) should neither imply that there should be no policy judgment when evaluating science nor that risk assessors may not be guided when it comes to the type of information collected, analyzed, or presented. The Blue Book concluded further that organizations' priorities and goals should be used to make the science policy judgments during the course of a risk assessment to build more productive linkages between science and policy.<sup>16</sup>

## The Orange Book

Two years later, in 1996, the National Research Council produced the report *Understanding Risk: Informing Decisions in a Democratic Society* (the so-called "Orange Book").<sup>17</sup> The goal of this report was to improve the characterization of risk, which is thought to be at the heart of many risk controversies. Dealing with risk controversies requires not only addressing technical aspects but also incorporate social, economic, behavioral, and ethical aspects. A key feature of the report is its emphasis on a process in which the characterization of risk emerges from a combination of analysis and deliberation. To this end seven principles are set out in the Orange Book:

1. Risk characterization should be a decision-driven activity, directed towards informing choices and solving problems. [This implies that all those involved in risk decisions, and not just the decision makers, should carry out the risk characterization]

2. Coping with a risk situation requires a broad understanding of the relevant losses, harms, or consequences to the interested and affected parties. [This means that risk characterizations should, where appropriate, address socio-economic, ecological and ethical outcomes. If needed they should address particular populations rather than just the whole population. Perspectives of interested and affected parties should be brought in.]

3. Risk characterization is the outcome of an analytical-deliberative process. [This principle goes on to describe features of that process, e.g. appropriate systematic analysis, responding to the needs of affected parties, treatment of uncertainties, deliberations that focus on the problem and on improving understanding and participation.]

4. Those responsible for a risk characterization should begin by developing a provisional diagnosis of the decision situation so that they can better match the analytic-deliberative process leading to the characterization to the needs of the decision [...]. [The Report notes that the level of effort that should go into the process is situation dependent, as is the breadth of participation. But it also notes that using the wrong process can undermine the decision-making process.]

5. The analytical-deliberative process leading to a risk characterization should include early and explicit attention to problem formulation; representation of [...] interested and affected parties at this stage is imperative.

6. The analytical-deliberative process should be mutual and recursive. [In other words, it should be iterative between analysis and deliberation].

7. Each organization responsible for making risk decisions should work to build organizational capability to conform to the principles of sound risk characterization. [The application of this principle may involve staff training, the recruitment or engagement of specific expertise, and possible organizational change. Evaluation of current activities can inform future work on risk characterization.]<sup>18</sup>

The concept of stakeholder consultation is important in this report and an appendix is devoted to "Common Approaches to Deliberation and Public Participation." This report is often characterized as a "paradigm shift." Under the new paradigm, the framing of the risk analysis is not done by the analysts – the science function – but, instead, by the policy function in the system. Instead of a paradigm shift, it could also be interpreted as the final instance of a continuous development to interpret, and perhaps weaken, the strict separation of science and policy advocated in the Red Book.<sup>19</sup>

#### Presidential/Congressional Commission (White Book)

The final key text of national stature in the United States is the two-volume 1997 report by the Presidential/Congressional Commission on Risk Assessment and Risk Management entitled *Framework for Environmental Health Risk Management* and *Risk Assessment*, and *Risk Management In Regulatory Decision-Making* (the two-volume "White Book").<sup>20</sup> As before in the Blue Book, the full integration between risk assessment and risk management is emphasized. Furthermore, the following text shows that a broad conception of risk management is now being advocated.

Risk management is the process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health and to ecosystems. The goal of risk management is scientifically sound, cost-effective, integrated actions that reduce or prevent risks while taking into account social, cultural, ethical, political, and legal considerations. Our definition of risk management is broader than the traditional definition, which is restricted to the process of evaluating alternative regulatory actions and selecting among them. In recent years, the scope and tools of risk management have broadened considerably beyond regulatory actions taken by federal, state, and local government agencies, for two reasons:

• Government risk managers now often consider both regulatory and voluntary approaches to reducing risk. This is particularly important as our society is challenged to solve more complex risk problems, especially those that cut across environmental media, with limited resources.

• Increasingly, risk management is being conducted outside of government arenas, by individual citizens, local businesses, workers, industries, farmers, and fishers. This decentralization has resulted in part from the growing recognition that decision-making is improved by the involvement of those affected by risk problems ("stakeholders").

The Commission developed an integrated framework for environmental health risk management that can also be applied to other types of risk management – it is shown in **Chart 4** (next page).

The framework shown in **Chart 4** is based on the following six steps. Note also the key position of stakeholder engagement.

- 1. Define the problem and put it in context
- 2. Analyze the risks associated with the problem in context
- 3. Examine options for addressing the risks
- 4. Make decisions about which options to implement
- 5. Take actions to implement the decisions; and
- 6. Conduct an evaluation of the action's results.

This terminology corresponds fairly well with the Canadian Standard (CSA 1997) and the ISO Vocabulary (ISO 2002) except for the word "evaluation" in Step 6, above, that would be called "monitoring" in the Canadian Standard.<sup>21</sup>

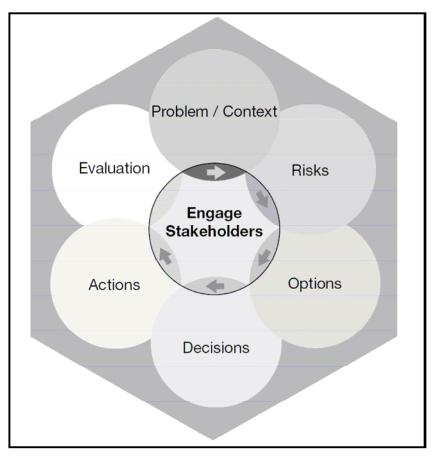


Chart 4: Framework for Environmental Health Risk Management

Source: Presidential / Congressional Commission on Risk Assessment and Risk Management (1997), front page

## Additional Frameworks Available from the United States

The lack of a National Standard in the United States should not be interpreted as a lack of information. The United States National Academies of Science have over 150 books and reports available under the keyword "risk" and departments such as the United Stated Environmental Protection Agency have produced numerous advanced risk assessment and management frameworks. However, no report or books of similar overarching importance, as those discussed above have been issued in the United States in recent years.

There are many specialized reports that could be useful to Canadian regulators among current U.S. documents. To name just two examples, the United States Environmental Protection Agency (EPA) has taken on the very difficult project to produce a *Framework for Cumulative Risk Assessment*<sup>22</sup> and the United States Department of Homeland Security has issued a series of new guidelines related to risk management.<sup>23</sup>

Some individual departments also provide sophisticated risk tools. One example is the *Integrated Risk Information System* (IRIS) by the U.S. Environmental Protection Agency that provides an electronic database on the human health effects that may result from exposure to various chemicals in the environment. The IRIS System does not only provide detailed risk data on hundreds of commercial chemicals but also functions as a gateway to risk management information, including links to more than 20 specialized risk guidance documents.<sup>24</sup> It may be a model of interest in the design of public information gateways.

Take-home Points – Frameworks from the United States

- No National Standard on Risk Management exists
- The United States provides much of the original thinking on the benefits and perils of separating the scientific and decision-making steps within risk management
  - Two schools of thought explain the current co-existence of the narrow and broad concepts of risk management
- Many advanced departmental frameworks exist they are tailored to specific contexts and mandates
- Canadian regulators may benefit from considering risk-related tools (for example, the Integrated Risk Information System of the U.S. Environmental Protection Agency)

## 4.3. United Kingdom

BSI British Standards has issued a National Standard on *Project Management: Guide to the Management of Business Related Risk* in 2000.<sup>25</sup> This Standard is not significantly different to the Canadian Standard but is focused on financial and business risks. It is not a key document in the context of a Canadian Government Directive on Regulating.

The British Government, however, has issued a number of important documents on risk management. The National Audit Office issued the report Supporting Innovation – Managing Risk in Government Departments in 2000 and the HM Treasury issued the short Management of *Risk – A Strategic Overview* (the so-called "Orange Book," not to be confused with the Orange Book of the United States) in 2001. The British Prime Minister announced the creation of a Strategy Unit on Risk and Uncertainty in 2001. The Strategy Unit published the report *Risk*: Improving Government's Capability to Handle Risk and Uncertainty in 2002. One of the recommendations made by the Strategy Unit, that was later implemented, was the creation of the Risk Programme that focused on improving the capacity of government to handle risk. The final report of The Risk Programme was issued to the Prime Minister at the end of 2004. The HM Treasury is continuing the work on risk and has issued several important documents including an updated Orange Book: Management of Risk – Principles and Concepts (2004) and Managing Risks to the Public: Appraisal Guidance (2005). As a whole, these reports contain many innovative concepts and tools for risk management. The following is only an introduction to some of the novel or important elements in these documents – most of it is drawn from the 2002 Report by the Strategy Unit that contains most of the novel thinking on risk management.

#### Strategy Unit

The very comprehensive report *Improving Government's Capability to Handle Risk and Uncertainty* <sup>26</sup> (Strategy Unit 2002) introduced a number of ideas that go beyond the information contained in the Canadian Standard (CSA 1997). The authors of the report offer three definitions related to risk management – the following is the slightly updated version currently posted on a dedicated webpage of the HM Treasury:<sup>27</sup>

**Risk** is most commonly held to mean "hazard" and something to be avoided. But it has another face - that of opportunity. Improving public services requires innovation - seizing new opportunities and managing the risks involved. In this context risk is defined as uncertainty of outcome, whether positive opportunity or negative threat, of actions and events. It is the combination of likelihood and impact, including perceived importance. **Risk management** covers all the processes involved in identifying, assessing and judging risks, assigning ownership, taking actions to mitigate or anticipate them, and monitoring and reviewing progress. Good risk management helps reduce hazard, and builds confidence to innovate.

**Risk handling** is used as a broader term including the processes of risk management, but also embracing wider issues of government's roles and responsibilities, and organisational culture.

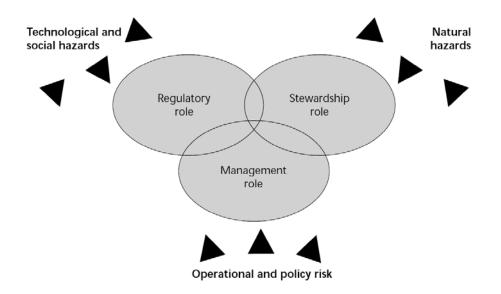
These definitions show that benefits (or opportunities) are part of the risk management framework, as it is the case in the Australian / New Zealand Standard but unlike the Canadian Standard. Of interest in the context of regulation is how the Strategy Unit conceived of Government's roles and responsibilities:

Government is responsible for dealing with two broad categories of risk: risks to the public and the wider UK interest, and risks to delivering its own business. In discharging these responsibilities, governments have three overlapping roles (see Figure below).

• **Regulatory**: where individuals or businesses impose risks on others, government's role is mainly as regulator, setting the rules of the game.

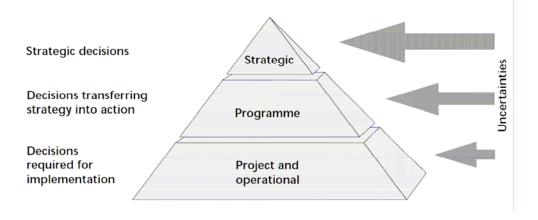
• **Stewardship**: where risks cannot be attributed to any specific individual or body, governments may take on a stewardship role to provide protection or mitigate the consequences.

• **Management**: in relation to their own business, including provision of services to citizens, governments are responsible for the identification and management of risks. [p. 6 of Strategy Unit 2002, Summary Report]



A further distinction is the classification of risks and hazards in terms of a hierarchy of strategic, programme and operational levels. These three levels need to be integrated. In this model, the risk management strategy of the organization will be led from the top and embedded in the normal working routines and activities of the organization. **Chart 5**, on the next page, illustrates this organisational view of risk classification.

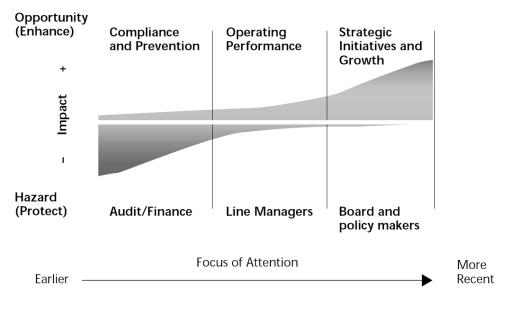
## Chart 5: Hierarchy of Risk



Source: Strategy Unit (2002), p. 15

Another insightful element in the report of the Strategy Unity is the relationship between the focus on risk within the finance and policy domains, respectively. The Strategy Unit argues that this focus shifts over time with more mature organizations moving from the left to the right in **Chart 6** below.

Chart 6: Typical Development of Risk Management Within an Organization



Source: Strategy Unit (2002), p. 40

A final noteworthy element of the Strategy Unit (2002) report is the listing of five *Principles of Managing Risks to the Public:*<sup>28</sup>

#### • Openness and transparency:

Government will make available its assessments of risks that affect the public, how it has reached its decisions, and how it will handle the risk. It will also do so where the development of new policies poses a potential risk to the public. When information has to be kept private, or where the approach departs from existing practice, it will explain why. Where facts are uncertain or unknown, government will seek to make clear what the gaps in its knowledge are and, where relevant, what is being done to address them. It will be open about where it has made mistakes, and what it is doing to rectify them.

#### • Involvement

Government will actively involve significant stakeholders, including members of the public, throughout the risk identification, assessment and management process. This will support timely and targeted action. Two-way communication will be used in all stages of policy development, risk assessment and risk management. Where there are differences in interpretation it will aim to clarify these through open discussion, and it will seek to balance conflicting views in a way that best serves the wider public interest. It will explain how views obtained through consultation have been reflected in its decisions.

#### Proportionality and consistency

Government will seek to apply a consistent approach to its assessment of risks and opportunities and to its evaluation of the costs and benefits of options for handling them, and will ensure that these are clearly articulated. It will apply the precautionary principle where there is good reason to believe that irreversible harm may occur and where it is impossible to assess the risk with confidence, and will plan to revisit decisions as knowledge changes.

#### Evidence

Government will aim to ensure that all relevant evidence has been considered and, where possible, quantified before it takes decisions on risk. It will seek impartial and informed advice that can be independently verified wherever possible, and seek to build a shared understanding of the risks and options for action. It will consider evidence from a range of perspectives, including the public as well as experts.

#### Responsibility

Government, where possible, will ensure that those who impose risks on others also bear responsibility for controlling those risks and for any consequences of inadequate control. It will aim to give individuals a choice in how to manage risks that affect them, where it is feasible and in their interest to do so and where this does not expose others to disproportionate risk or cost.

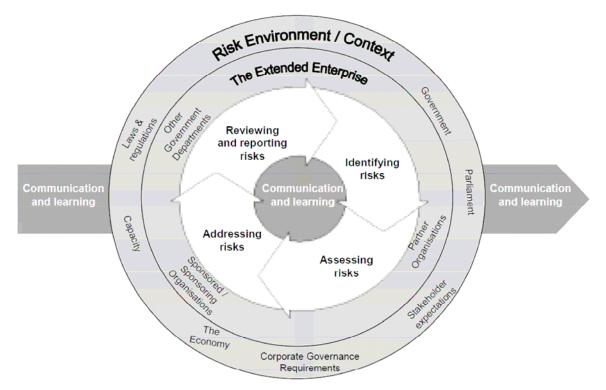
#### Risk Programme

The Risk Programme had a strong capacity building focus. Risk Improvement Managers were appointed in all departments and a Risk Improvement Managers Network was created. The Risk Programme also released a *Risk Management Assessment Framework: A Tool for Departments* in 2004.<sup>29</sup> This tool allows departments to evaluate their capacity and performance in risk management.

## Continuing Work by the HM Treasury

HM Treasury released *The Orange Book: Management of Risk – Principles and Concepts* in 2004. This detailed guide draws heavily from the work of the Strategy Unit. The Risk Management Model by the Strategy Unit, however, was amended. **Chart 7** is taken from the U.K. Orange Book and shows an emphasis on viewing risk management as embedded in a larger context. It also emphasizes that risk communication and risk learning (monitoring) is taking place within a broader communication and learning activity.





Source: HM Treasury (2004), p. 13

The risk terminology used in **Chart** 7 and the rest of the U.K. Orange Book is not identical to that of the Canadian Standard or the ISO. For example, the word "assessing" (U.K.) is used instead of "analysis" (Canada) and "addressing risks" (U.K.) is used instead of "risk evaluation" and "risk control" (Canada). The Orange Book also makes central use of the unusual term "risk appetite" to express the idea of the acceptability of a risk or the acceptability of the cost to achieve an opportunity. However, the underlying logic is identical to that of the Canadian Standard.

The newest report by the HM Treasury, *Managing Risks to the Public: Appraisal Guidance* (2005)<sup>30</sup> is designed for policy makers and decision-makers. One objective is to achieve greater consistency and transparency in government decision-making. Two key tools are cost-benefit analyses (CBA) and cost effectiveness analyses.

Access to these tools is facilitated through a government "Risk Portal" – a website that facilitates the finding of resources related to risk management.<sup>31</sup>

I want to conclude this section by pointing out that the U.K. has a Better Regulation Action Plan and is currently consulting on a Better Regulation Bill.<sup>32</sup>

Take-home Points – Frameworks from the United Kingdom

- Significant innovation in risk management thinking was achieved by the Strategy Unit of the U.K. Government between 2001 and 2002
- Government has three overlapping roles: *regulation* (for technical and social risks), *stewardship* (for natural risks) and *management* (for internal risks). These require somewhat different risk management thinking and processes.
- The integration of strategic, program and operational risks is important for an organization's capacity to manage risk effectively
- Over time, organizations may move their attention from internal risk (audit and finances) to strategic risks (policy decisions)
- The U.K. appointed "Risk Improvement Managers" in all departments
- The five principles of managing risks to the public are (1) Openness and Transparency, (2) Involvement, (3) Proportionality and Consistency, (4) Evidence, and (5) Responsibility

# 5. Discussion and Conclusion

Key points were already provided in boxes at the end of the chapter – I shall not repeat these here. Instead, I shall offer a few overarching observations.

- (1) The field of risk management is still in rapid development, with the project to develop an International Risk Management Framework well underway and with new concepts and ideas emerging on a regular basis. This field, therefore, requires on-going monitoring.
- (2) Vocabularies differ more than one would expect in a technical discipline but the underlying logic models of different frameworks do not differ substantially. Perhaps this is an indication that risk management, at a basic level, is very simple and intuitive to the point that it is inviting for organization to "reinvent the wheel" over and over again. Or, perhaps, it is an indication of the important practical consequences small changes in language and models may produce. In any case, one of the biggest obstacles to a productive analysis and dialogue is semantic confusion. Semantics, therefore, should be a serious topic of reflection and, perhaps, attention.
- (3) An important conceptual difference among frameworks lies in the choice of scope. The exclusion or inclusion of benefits and opportunities is an important example. The separation of an internal focus ("management risk" in the U.K. model) and outward focus ("regulatory risks" or "stewardship risks") is another, equally important example. This requires consideration of the trade-off between having one overarching model that may necessarily be vague in some parts and may face difficult semantic problems and several tailored systems that can be more specific and face fewer semantic problems.
- (4) An aside: Neither the Canadian Standard, the Australian / New Zealand Standard, nor the U.K. Orange Book contain the words "caution" or "precaution." The exception, in the context of this paper, is the U.K. Strategy Unity Report. It is difficult to avoid the precautionary approach or precautionary principle in the domain of product risk assessment (and environmental risk assessment in particular). Perhaps this point needs to be considered if a role for the Canadian or Australian / New Zealand standards were to be considered within a Government Directive on Regulating.
- (5) Another aspect of scope has to do with instrument choice. According to William Leiss' paper to EACSR, there are variety of policy instruments that can be used to influence public risks.<sup>33</sup> Examples include explicit statutory authority, regulation, compensation for injury or accidental death, voluntary standards, market-based instruments, social-welfare support structures, legal liability, insurance, international conventions, and information dissemination. A discussion on the scope of risk management within *regulation* should be guided by an awareness of these instruments.

- (6) Obstacles towards greater consistency are definitions of key concepts anchored in legislation. For example, although the Office of the Gene Regulator of the Australian Government wanted to use modern language in its risk management framework, they were constrained by the different terms used in the Australian food legislation. A question arises is it more important to achieve clarity and consistency, or is it more important to avoid the costs and risks to adjust domestic and international legislation and trade agreements? In other words, the goal setting when it comes to working towards greater clarity and consistency in risk management requires its own cost-benefit analysis.
- (7) In this context, it is interesting to observe that the United States did not develop a National Standard on Risk Management.
- (8) A lesson from the United States is how difficult it is to design the "science-policy interface" within a risk management framework. There are good reasons for the strict separation of science and policy, namely the concern over the integrity of science hence the approach chosen in the Red Book. There are also good reasons for giving policy makers (including stakeholders) influence over the agenda-setting of a risk management exercise and also the power to make decision that are science-*based* rather than directly driven by a scientific result without regard to a broader context hence the approach chosen in the U.S. Orange Book. Designing the science-policy interface (the interface between facts and politics, scientists and policy-makers) is difficult and requires attention. It is not clear, however, that the experience in the United States provides an answer to this difficult issue.
- (9) A similar problem is the design of the interface between experts and stakeholders. There is a steady trend towards greater inclusion of stakeholders in the jurisdictions discussed above and in Canada. In other words, governments are moving from a government risk management framework to a governance risk management model. Designing the stakeholder involvement system requires much thought because extensive consultations can delay risk management decision which competes with the goal of efficient and timely regulatory decision-making a goal that is in the interest of both the regulated industries and consumers that are waiting for new products.

# Appendix A: Key Reports Cited in this Brief

AS/NZS (2004): Australia and New Zealand Standard: Risk Management, issued by Standards Australia, Guideline 4360

- a) *Standard* available for purchase at <u>http://www.riskmanagement.com.au/Default.aspx?tabid=148</u> 116 pp.
- b) *Risk Management Guidelines Companion to* AS/NZS 4360:2004 available for purchase at <u>http://www.riskmanagement.com.au/Default.aspx?tabid=157</u> 28 pp.

CSA (1997) *Risk Management: Guideline for Decision-Makers – A National Standard of Canada*. Canadian Standards Association (1997 reaffirmed 2002) CAN/CSA-Q850-97 <a href="http://www.csa-intl.org/onlinestore/GetCatalogItemDetails.asp?mat=00000000002005912">http://www.csa-intl.org/onlinestore/GetCatalogItemDetails.asp?mat=00000000002005912</a>

EACSR (2004): External Advisory Committee on Smart Regulations, *Smart Regulation – A Regulatory Strategy for Canada*. Available at <u>http://www.pco-bcp.gc.ca/smartreg-regint/en/index.html</u>

HM Treasury (2004) *The Orange Book. Management of Risk: Principles and Concepts.* Available at <u>http://www.hm-treasury.gov.uk./media/FE6/60/FE66035B-BCDC-D4B3-11057A7707D2521F.pdf</u>

HM Treasury (2005) *Managing Risks to the Public: Appraisal Guidance*. Available at <u>http://www.hm-treasury.gov.uk/media/8AB/54/Managing\_risks\_to\_the\_public.pdf</u>

IRGC (2005) *White Paper on Risk Governance: towards an integrated app*roach. International Risk Governance Council (IRGC), Switzerland. Available at <a href="http://www.irgc.org/\_cgidata/mhscms/\_images/12326-3-2.pdf">http://www.irgc.org/\_cgidata/mhscms/\_images/12326-3-2.pdf</a>

ISO (2002) *Risk Management Vocabulary: Guidelines for use in Standards*. International Standards Organization (ISO). Available for purchase at <a href="http://www.iso.org/iso/en/CatalogueDetailPage.CatalogueDetail?CSNUMBER=34998&scopelist=ALL">http://www.iso.org/iso/en/CatalogueDetailPage.CatalogueDetail?CSNUMBER=34998&scopelist=ALL</a>

NRC (1983) *Risk Assessment in the Federal Government: Managing the Process*. U.S. National Research Council ("Red Book"). Available for purchase (and single-page viewing) at <a href="http://www.nap.edu/openbook/0309033497/html/">http://www.nap.edu/openbook/0309033497/html/</a>

NRC (1994) *Science and Judgement in Risk Management*. U.S. National Research Council ("Blue Book"). Available for purchase (and single-page viewing) at <a href="http://www.nap.edu/books/030904894X/html/">http://www.nap.edu/books/030904894X/html/</a>

NRC (1996) Understanding Risk: Informing Risk in a Democratic Society. U.S. National Research Council ("Orange Book"). Available for purchase (and single-page viewing) at http://www.nap.edu/books/030905396X/html/

Presidential / Congressional Commission (1997) *Risk Assessment and Risk Management Framework for Environmental Health Risk Assessment* ("White Book"). Available at:

- vol. 1: http://www.riskworld.com/Nreports/1997/risk-rpt/pdf/EPAJAN.PDF
- vol 2: http://www.riskworld.com/Nreports/1997/risk-rpt/volume2/pdf/v2epa.PDF

Strategy Unit (2002) *Risk: Improving government's capacity to handle risk and uncertainty*. Strategy Unit of the UK. Available at <u>http://www.strategy.gov.uk/downloads/su/RISK/REPORT/01.HTM</u>

## Appendix B: Ten Selected Books on the Big Picture

The following books provide viewpoints on the intersection of risk management and society that likely would enrich a discussion on risk management in the context of a Government Directive on Regulating (arranged chronologically).

- Shrader-Frechette, K.S. (1991), *Risk and Rationality Philosophical Foundations for Populist Reforms*, Berkeley: University of California Press.
- Hood, Christopher & David K.C. Jones, Eds. (1996), Accident and Design Contemporary Debates in Risk Management, London: UCL Press.
- von Schomberg, Rene, Ed. (1999), *Democratising Technology Theory and Practice of a Deliberative Technology Policy*, Hengelo/Buenos Aires: International Centre for Human and Public Affairs.
- Jones, Laura, Ed. (2000) Safe Enough? Managing Risk and Regulation, Vancouver: The Fraser Institute.
- Doern, Bruce G. & Ted Reed, Eds. (2000) *Risky Business Canada's Changing Science-Based Policy and Regulatory Regime*, Toronto: University of Toronto Press.
- Robertson, David & Aynsley Kellow, Eds. (2001), *Globalization and the Environment Risk* Assessment and the WTO, Cheltenham, UK: Edward Elgar.
- Leiss, William (2001) In the Chamber of Risks Understanding Risk Controversies, Montreal & Kingston: McGill-Queen's University Press.
- Hood, Christopher, Henry Rothstein & Robert Baldwin (2001) *The Government of Risk Understanding Risk Regulation Regimes*, Oxford: Oxford University Press.
- Beierle, Thomas C. & Jerry Cayford (2002) *Democracy in Practice Public Participation in Environmental Decisions*, Washington: Resources for the Future.
- McDaniels, Timothy & Mitchell J. Small, Eds. (2004) *Risk Analysis and Society An Interdisciplinary Characterization of the Field*, Cambridge: Cambridge University Press.

# Appendix C: Comparison of International Terminologies

The following is a copy of "Annex D" in IRGC (2005) [with editorial notes in square brackets]

#### Australia/New Zealand Risk Management Standard

Risk assessment = Risk Analysis + Risk Evaluation

#### **Codex Alimentarius**

Risk Analysis = Risk Assessment + Risk Management + Risk Communication Risk Assessment = Hazard Identification + Hazard Characterization + Exposure Assessment + Risk Characterization

#### EMPRES [FAO]

Risk Analysis = Hazard Identification + Risk Assessment + Risk Management with Risk Communication involved in all three components

Risk Assessment = Release Assessment + Exposure Assessment + Consequence Assessment + Risk Estimation Risk Management = Risk Evaluation + Option Evaluation + Implementation + Monitoring and Review

#### FERMA [Federation of European Risk Management Associations]

Risk Analysis = Risk Identification + Risk Description + Risk Estimation

Risk Management = Risk Assessment + Risk Analysis + Risk Evaluation + Reporting + Decision + Risk Treatment + Residual Risk Reporting + Monitoring

#### International Programme on Chemical Safety

Risk Analysis = Risk Assessment + Risk Management + Risk Communication Risk Assessment = Hazard Identification + Hazard Characterisation + Exposure Assessment + Risk Characterisation Risk Management = Risk Evaluation + Emission and Exposure Control + Risk Monitoring

#### ISO/IEC Risk management vocabulary guidance (ISO/IEC Guide 73)

Risk Assessment = Risk Analysis + Risk Evaluation

#### Nuclear Safety (from HSE Tolerability of Risk)

Risk assessment = risk from normal operations + risk from accidents Risk from accidents = risks from plant failure + risks from natural events + human factor risks

#### **UK Cabinet Office Report on Risk**

Risk Management = Identifying and Judging Risks + Assigning Ownership + Taking action to anticipate or mitigate the risks + Monitoring and Reviewing

#### USA Presidential/Congressional Commission on Risk Assessment and Risk Management

Risk Characterization = Organising information on risk + Evaluating that information + Communication the information and evaluation

Risk Management = Analysing possible actions to reduce risk + Selecting preferred option + Implementing + Evaluation

#### US Red Book [NRC 1983]

Risk Assessment = Hazard Identification + Dose-Response Assessment + Exposure Assessment + Risk Characterization

# Endnotes

<sup>1</sup> Canadian Standards Association (1997, reaffirmed 2002) CAN/CSA-Q850-97 Risk Management: Guideline for Decision-Makers – A National Standard of Canada http://www.csa-intl.org/onlinestore/GetCatalogItemDetails.asp?mat=00000000002005912

<sup>2</sup> See also Appendix E of CSA (1997) on this point.

<sup>3</sup> Note that EACSR (2004) uses the term "risk assessment" to describe what CSA (1997) calls "risk analysis". Although EACSR follows by-in-large the CSA model, in this case it uses terminology that is more commonly used in the second, narrow conception of risk management.

<sup>4</sup> This concept is similar to the one used by the Canada School of the Public Service (e.g., <u>http://www.myschool-monecole.gc.ca/Research/publications/html/risk\_mgnt\_rt/risk\_mgnt\_rt\_7\_e.html#10</u>) which seems to be originating from the background paper authored by Stephen Hill (undated) "A Primer on Risk Management in the Public Service – A Background Document for CCMD's Action-Research Roundtable on Risk Management". Our concept, however, avoids terminology that will lead to confusion in the context of a broad review and also does not draw arrows to describe an information flow for which no clear consensus exists.

<sup>5</sup> International Standards Organization: <u>www.iso.org</u>

<sup>6</sup> This information is from the CAC/ISO/Risk Management Forum of the Canadian Standards Council and, in particular, John Shortreed's summary of the Japan meeting.

<sup>7</sup> International Risk Governance Council: <u>www.irgc.org</u>

<sup>8</sup> The White Paper of the IRGC (2005) is available at http://www.irgc.org/\_cgidata/mhscms/\_images/12326-3-2.pdf

<sup>9</sup> Based on our own work, we would propose the short definition:

Risk governance is the process whereby societies or organisations make important decisions about risk, determine whom they involve, and how they render account.

<sup>10</sup> From the website of Standards Australia at http://www.riskmanagement.com.au/News/AgloballyacceptedStandardforRiskManagement/tabid/149/Default.aspx <sup>11</sup> See the article by Graham Fisher, Minstry of Finance, British Columbia: <u>http://www.riskmanagement.com.au/News/CanadaputsAustralianStandardtoworkinthepu/tabid/151/Default.aspx</u>

The decision made in B.C. may not be flattering for the Canadian Standards Association, but one should note that Standards Australia acknowledges that the emphasis on risk communication in CSA (1997) had a strong influence on the development of the second (1999) and third version (2004) of the AS/NZS standard.

<sup>12</sup> Office of the Gene Technology Regulator, Government of Australia (2005) *Risk Analysis Framework*. <u>http://www.ogtr.gov.au/pdf/public/raffinal2.2.pdf</u> - see page 20.

<sup>13</sup> The text by Michael Tarrant is posted on the website of the United Nations Online Network in Public Administration and Finance. Quote is from page 1. http://unpan1.un.org/intradoc/groups/public/documents/APCITY/UNPAN009853.pdf

<sup>14</sup> U.S. National Research Council (1983) "Red Book": <u>http://www.nap.edu/openbook/0309033497/html/</u>

<sup>15</sup> U.S. National Research Council (1994) "Blue Book": <u>http://www.nap.edu/books/030904894X/html/</u>

<sup>16</sup> This follows closely the explanation given in <u>www.epa.gov/ttn/fera/data/risk/vol\_1/chapter\_27.pdf</u> on pages 27-1 to 27-4.

<sup>17</sup> U.S. National Research Council (1996) "Orange Book": <u>http://www.nap.edu/books/030905396X/html/</u>

<sup>18</sup> This an abbreviated phrasing of the text in the Orange Book (NRC 1996) – it has been obtained from IRGC (2005).

<sup>19</sup> The difference between the Red Book (NRC 1983) and the Orange Book (NRC 1996), both influential documents, explains why the different conceptions of "risk management" exist that are now sometimes enshrined in legislation and actively used in Canada and elsewhere:

- a narrow concept representing only the prescriptive step (Red Book)
- a broad concept representing the entire enterprise (Orange Book; White Book)

<sup>20</sup> Presidential/Congressional Commission (1997) "White Book": <u>http://www.riskworld.com/Nreports/1997/risk-rpt/pdf/EPAJAN.PDF</u> <u>http://www.riskworld.com/Nreports/1997/risk-rpt/volume2/pdf/v2epa.PDF</u>

<sup>21</sup> **Chart 4** has been used – in improved form – as the framework for Health Canada's *Decision-making Framework for Identifying, Assessing, and Managing Health Risk* (2000). See <a href="http://www.hc-sc.gc.ca/ahc-asc/alt\_formats/hpfb-dgpsa/pdf/pubs/risk-risques\_e.pdf">http://www.hc-sc.gc.ca/ahc-asc/alt\_formats/hpfb-dgpsa/pdf/pubs/risk-risques\_e.pdf</a>

<sup>22</sup> <u>http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=54944</u>

<sup>23</sup> <u>http://www.fema.gov/fima/rmsp.shtm</u>

<sup>24</sup> Integrated Risk Information System of the U.S. Environmental Protection Agency (IRIS): <u>http://www.epa.gov/iris/intro.htm</u>

<sup>25</sup> Available at <u>http://www.bsi-global.com/Quality\_management/Project/bs6079-3.xalter</u>

<sup>26</sup> Full Report of the Strategy Unit:

http://www.strategy.gov.uk/downloads/su/RISK/REPORT/downloads/su-risk.pdf Summary Report: http://www.strategy.gov.uk/downloads/su/RISK/REPORT/downloads/su-risk-summary.pdf

27 http://www.hm-treasury.gov.uk/Documents/Public\_Spending\_and\_Services/Risk/Risk\_Improvement/pss\_risk\_defin.cfm

<sup>28</sup> Original text on page 91 of Strategy Unit (2002). This updated text is available as a separate pamphlet at <u>http://www.hm-treasury.gov.uk/media/C87/A1/risk\_principles\_180903.pdf</u>

<sup>29</sup> <u>http://www.hm-treasury.gov.uk./media/17A/81/17A8166B-BCDC-D4B3-16668DC702198931.pdf</u>

<sup>30</sup> http://www.hm-treasury.gov.uk./media/3E3/EE/managingrisks\_appraisal220705.pdf

<sup>31</sup> Risk Portal:

http://www.hm-treasury.gov.uk./documents/public\_spending\_and\_services/risk/pss\_risk\_portal.cfm

<sup>32</sup> Better Regulation Action Plan:

http://www.hm-treasury.gov.uk./newsroom\_and\_speeches/press/2005/press\_50\_05.cfm

<sup>33</sup> William Leiss (2003) *Smart Regulation and Risk Management*, Report for EACSR. Available at <u>http://www.leiss.ca/articles/137</u>