Government of Canada Gouvernement du Canada

A FRAMEWORK FOR THE APPLICATION OF PRECAUTION IN SCIENCE-BASED DECISION MAKING ABOUT RISK

Canada

National Library of Canada cataloguing in publication data

Main entry under title :

A framework for the application of precaution in science-based decision making about risk

Text in English and French on inverted pages.
Title on added t.p.: Cadre d'application de la précaution dans un processus décisionnel scientifique en gestion de risque.
Issued also on the Internet.
ISBN 0-662-67486-3
Cat. no. CP22-70/2003

1. Risk management – Canada.
2. Risk assessment – Canada.
3. Decision making – Canada.
4. Science and state – Canada.
5. Technology and state – Canada.
I. Canada. Privy Council Office.
II. Title : Cadre d'application de la précaution dans un processus décisionnel scientifique en gestion de rique.

HD61.F25 2003 368 C2003-980218-1E

Table of Contents

1.0 Introduction

This Framework outlines guiding principles for the application of precaution to science-based decision making in areas of federal regulatory activity for the protection of health and safety and the environment and the conservation of natural resources.

What is the application of precaution?

The application of "precaution", "the precautionary principle" or "the precautionary approach"[1] recognizes that the absence of full scientific certainty shall not be used as a reason for postponing decisions where there is a risk of serious or irreversible harm.

The application of precaution is distinctive within science-based risk management and is characterized by three basic tenets: the need for a decision, a risk of serious or irreversible harm and a lack of full scientific certainty.

Canada has a long-standing history of applying precaution in areas of federal regulatory activities. The Government's obligations in this regard are governed by applicable provisions of federal law, binding federal-provincial agreements and international agreements to which Canada is a party.

Are guidance and assurance needed?

Given the distinctive circumstances associated with the application of precaution, notably the lack of full scientific certainty about a risk of serious or irreversible harm, guidance and assurance are required as to the conditions governing decision making. Guidance and assurance are particularly needed in circumstances when the scientific uncertainty is high.

What is the purpose of the framework?

This Framework serves to strengthen and describe existing Canadian practice. The purpose of the framework is to:

- improve the predictability, credibility and consistency of the federal government's application of precaution to ensure adequate, reasonable and cost-effective decisions;[1]

---

1 This document uses these expressions interchangeably. It focuses on the guiding principles of precautionary decision making rather than discussing distinctions that may be drawn between different expressions of precaution.

- support sound federal government decision making while minimizing crises and controversies and capitalizing on opportunities;
- increase public and stakeholder confidence, in Canada and abroad, that federal precautionary decision making is rigorous, sound and credible; and
- increase Canada's ability to positively influence international standards and the application of precaution.

Ultimately, the Framework provides a lens to assess whether precautionary decision making is in keeping with Canadians' social, environmental and economic values and priorities. It complements the Government's *Integrated Risk Management Framework* and *A Framework for Science and Technology Advice: Principles and Guidelines for the Effective Use of Science and Technology Advice in Government Decision making.*

2.0 Context

Canada has a long-standing history of applying precaution in science-based regulatory programs. Technology, globalization and the knowledge-based economy are driving tremendous changes in both the private and public sector. Risk, inherent in the activities of individuals and business, contributes to even greater uncertainty. When combined with high-profile, risk-based events, these changes highlight the need for more effective strategies to manage risk and seize the opportunities that change presents.

Governments can rarely act on the basis of full scientific certainty and cannot guarantee zero risk. Indeed, they are traditionally called upon and continue to address new or emerging risks and potential opportunities, and to manage issues where there is significant scientific uncertainty. However, the need for decision making in the face of scientific uncertainty has grown both in scope and public visibility and this has led to a growing awareness of and emphasis on the application of precaution to decision making.

While the application of precaution primarily affects the development of options and the decision phases within science-based risk management, it is clearly linked to scientific analysis (it cannot be applied without an appropriate assessment of scientific factors and consequent risks). Ultimately, it is guided by judgment, based on values and priorities but its application is complicated by the inherent dynamics of science — even though scientific information may be inconclusive, decisions will still have to be made as society expects risks to be addressed and managed and living standards enhanced.

Canada's application of precaution is flexible and responsive to particular circumstances. Moreover, rules-based approaches are employed to achieve the results required by specific legislation or international obligations (e.g., fisheries management).

3.0 Science and uncertainty in decision making

As the scientific process is often characterized by uncertainty and debate, the decision-making process for managing risks associated with scientific information requires sound judgment. The application of precaution to decision making is distinctive within traditional risk management on the basis of a higher degree of scientific uncertainty and the parameters that can establish what constitutes an adequate scientific basis and sound and rigorous judgment. As it applies here, judgment focuses on addressing:

- what is a sufficiently sound or credible scientific basis?
- what follow-up activities may be warranted?
- who should produce a credible scientific basis? and
- the inherent dynamics of science on decision making.

What is a sufficiently sound or credible scientific basis?

In traditional situations of decision making to manage risks, "sound scientific evidence" is generally interpreted as either definitive and compelling evidence that supports a scientific theory or significant empirical information that clearly establishes the seriousness of a risk.

Within the context of precaution, determining what constitutes a sufficiently sound or credible scientific basis is often challenging and can be controversial. The emphasis should be on providing a sound and credible case that a risk of serious or irreversible harm exists. "Sufficiently sound" or credible scientific basis should be interpreted as a body of scientific information — whether empirical or theoretical — that can establish reasonable evidence of a theory's validity, including its uncertainties and that indicates the potential for such a risk.

What follow-up activities may be warranted?

Given the significant scientific uncertainty implicit in the application of precaution, follow-up activities such as research and scientific monitoring are usually a key part of the application of precaution. In some cases, international agreements (e.g., World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures) require scientific monitoring and follow-up when precaution is applied. Such efforts can help reduce the scientific uncertainty associated with certain risks and allow informed follow-up decisions to be made. In other circumstances, scientific uncertainty may take a long time to resolve or, for practical purposes, never be resolved to any significant degree.

In order to capture the full diversity of scientific thought and opinion, the basis for decision making should be drawn from a variety of scientific sources and experts from many disciplines. Decision makers should give particular weight, however, to peer-reviewed science and reasonableness in their judgments. Moreover, the science function can be further supplemented by formal, structured and, where warranted, independent advisory processes that include widely recognized and credible individuals.

Who should produce a credible scientific basis?

Establishing who should be responsible for producing a credible scientific basis raises a different question: Who should be designated as having the responsibility to produce the scientific data and provide the basis for decision making? Decision makers should assess such criteria as who holds the legal responsibility or authority (e.g., the proponent who is designated as the legal agent in Canada), who would be in the best position to provide the scientific data and who has the capacity to produce timely and credible information.

While the party who is taking an action associated with potential serious harm is generally designated as the responsible party, this may best be decided on a case-by-case basis. Innovative strategies may also be introduced, such as collaborative arrangements among different levels of government and industry. As the scientific knowledge evolves, this responsibility may shift among governments, industry or another proponent (e.g., health practitioners documenting adverse effects from a product already on the market).

The inherent dynamics of science on decision making

The inherent dynamics of uncertainty in science present unique challenges. Climate change provides a good example. There is international consensus that human activities are increasing the amounts of greenhouse gases in the atmosphere and that these increases are contributing to changes in the earth's climate. However, there is scientific uncertainty regarding the sensitivity of climate to these increases, particularly the timing and regional character of climate change. There is also a degree of uncertainty in the economic costs of potential measures to reduce greenhouse gases, although the modelling suggests that these impacts are manageable, as well as the economic costs, to adapt to the expected changes in climate.

While scientific information is still inconclusive, decisions will have to be made to meet society's expectations about enhancing living standards and addressing the potential for risks. An understanding of the full potential of the products and processes arising from rapidly evolving science and technology is critical to shaping Canada's laws and regulations, as well as international agreements and guidelines. The implications are only now starting to emerge and will ultimately influence decisions.

4.0 Guiding Principles for the application of precaution to science-based decision making

As noted earlier, the application of precaution to science-based decision making to manage risk is driven by specific circumstances and factors and is characterized by three basic tenets: the need for a decision, a risk of serious or irreversible harm and a lack of full scientific certainty.

Guiding principles outlined in this Framework reflect current practices and, in their entirety, are intended to support overall consistency in application, allow for flexibility to respond to specific circumstances and factors and help to counter misuse or abuse. While they focus on those aspects of the process that are distinctive within risk management overall, they could not direct decision makers to act in a way inconsistent with their legal authority. Moreover, this Framework is not meant to create any new legal obligations to apply precaution.

General principles of application outline distinguishing features of precautionary decision making whereas principles for precautionary measures describe specific characteristics that apply once a decision has been taken that measures are warranted.

Five General Principles of Application

4.1 The application of precaution is a legitimate and distinctive decision-making approach within risk management.

- While precaution primarily affects the development of options and the decision phases, it is clearly linked to scientific analysis (it cannot be applied without an appropriate assessment of scientific factors and consequent risks). Ultimately, it is guided by judgment, based on values and priorities.

- The Government's obligations to apply precaution are governed by applicable provisions of federal law, binding federal-provincial agreements and international agreements to which Canada is a party.

- The Government does not yet consider the precautionary principle/approach to be a rule of customary international law.

4.2 It is legitimate that decisions be guided by society's chosen level of protection against risk.

- To the extent possible, the level of protection should be established in advance through domestic policy instruments such as legislation and international agreements.

- While societal values and public willingness to accept risk are key in determining the level of protection, in all cases sound scientific evidence is a fundamental prerequisite to applying the precautionary approach.

- It should be recognized that some risks are new or emerging and evolution of scientific knowledge may influence society's tolerances and its chosen level of protection. In such circumstances, public involvement mechanisms that seek the input of those most affected by decisions should help advance understanding of the level of protection against risk.

4.3 Sound scientific information and its evaluation must be the basis for applying precaution; the scientific information base and responsibility for producing it may shift as knowledge evolves.

- It is particularly relevant that sound scientific information and its evaluation be the basis for (i) the decision to act or not to act (i.e., to implement precautionary measures or not) and (ii) the measures taken once a decision is made.

- In determining what constitutes a sufficiently sound or credible scientific basis, the emphasis should be on providing a sound and credible case that a risk of serious or irreversible harm exists. "Sufficiently sound" or credible scientific basis should be interpreted as a body of scientific information — whether empirical or theoretical — that can establish reasonable evidence of a theory's validity, including its uncertainties and that indicates the potential for such a risk.

- Scientific data relevant to the risk must be evaluated through a sound, credible, transparent and inclusive mechanism leading to a conclusion that expresses the possibility of occurrence of harm and the magnitude of that harm (including the extent of possible damage, persistency, reversibility and delayed effect).

- Available scientific information must be evaluated with emphasis on securing high quality scientific evidence (not quantity). Reports should summarize the existing state of knowledge, provide scientific views on the reliability of the assessment and address remaining uncertainties and areas for further scientific research or monitoring.

- Peer review represents a concrete test for the practical application of precaution to decision making. A peer-review process can assess the soundness of the scientific evidence and its inherent credibility within the scientific community.

- Scientific advice should be drawn from a variety of sources and experts and should reflect the full diversity of scientific interpretations consistent with the evidence available. This does not preclude contributions of traditional knowledge from sources such as Aboriginal peoples or fishing communities; these have a valid role in providing both evidence and its interpretations. Scientific advisors should give weight to peer-reviewed science and aim at sound and reasonable evidence on which to base their judgments.

- In circumstances where there is a potential for imminent harm, it may be appropriate to make decisions and implement precautionary measures in the near term, with an understanding that close monitoring would occur to assess the effectiveness of the measures in addressing risk and overall impacts.

- Follow-up activities, including research and monitoring, are key to reducing scientific uncertainty and allow improved decisions to be made in the future.

- Overall, the responsibility for providing the sound scientific basis should rest with the party who is taking an action associated with a risk of serious harm (e.g., the party engaged in marketing a product, employing a process or extracting natural resources). However, when faced with a concrete scenario, there should be an assessment of who would be in the best position to provide the information base. This could depend upon which party holds the responsibility or authority, and could also be informed by such criteria as who has the capacity to produce timely and credible information.

- The responsibility for providing the sound scientific basis may best be decided on a case-by-case basis and may be collaborative. Moreover, it should be recognized that what constitutes an appropriate scientific base and responsibility for producing it may shift as the knowledge grows and roles of the public and private sectors evolve.

4.4 Mechanisms should exist for re-evaluating the basis for decisions and for providing a transparent process for further consideration.

- It is desirable that those affected by a decision have input into the re-evaluation process.

- The impact (benefits and drawbacks) of re-evaluation and consultative mechanisms in any particular situation should be assessed (i.e., in some cases, they may not be practical or productive). Given some existing re-evaluation and consultative mechanisms (e.g., fishery conservation), it should be recognized that additional mechanisms may not be appropriate.

- A re-evaluation may be triggered by the emergence of new scientific information, new technology or a change in society's tolerance for risk. Effective review of decisions requires monitoring the effectiveness of decisions on an ongoing basis with provision for regular feedback and reporting of performance measurements results.

- The decision-making hierarchy and the duties and responsibilities of participants in the process should be clearly laid out so that accountabilities can be understood, respected and communicated. This would also facilitate requests for additional re-evaluation and consultation.

- The nature, type and frequency of re-evaluation and consultation mechanisms may be related to the specific circumstances of a situation, for example whether precaution is applied within an ongoing mechanism for conservation of resources or in circumstances where there is a potential for imminent harm.

4.5 A high degree of transparency, clear accountability and meaningful public involvement are appropriate.

- An understanding of the "public's tolerance for risks" or "society's chosen level of protection" underpins the need for high transparency, clear accountability and meaningful public involvement.

- Transparency in documenting the rationale for making decisions strengthens accountability.

- Two-way sharing of information and the inclusion of a range of perspectives in the decision-making process can become the cornerstone of openness and transparency for the decision-making process and enhance credibility of and trust in the decisions that the Government makes. The Government's Communications

Policy provides principles for well co-ordinated, effectively managed and responsive communications.

- Public involvement can provide a platform to resolve conflict or engage in joint problem solving by a specific set of rules. It can bring about the recognition of ambiguities and uncertainties, and promote acceptance of different perspectives. Moreover, it can provide impetus for peer review and an opportunity to receive interpretations on uncertainty and risk from the public.

- Public involvement should be structured into the scientific review and advisory process, as well as the decision-making process. At the same time, it should be recognized that the opportunity for public involvement often depends on the specific context and timeliness of the required decision. In situations of significant uncertainty (regarding the magnitude and/or likelihood of harm or the most effective means of addressing the harm, combined with complex science), public involvement is needed to provide an opportunity to receive interpretations on uncertainty and risk.

Five Principles for Precautionary Measures

4.6 Precautionary measures should be subject to reconsideration, on the basis of the evolution of science, technology and society's chosen level of protection.

- Precautionary measures should generally be implemented on a provisional basis; that is, they should be subject to review in light of new scientific information or other relevant considerations, such as society's chosen level of protection against risk.

- Given the limitations of evolving scientific knowledge, decision makers should recognize that scientific uncertainty may not be resolved quickly and, in some cases is intrinsic to the situation (e.g., change is intrinsic to natural resources) — they should review new scientific knowledge if and as it evolves. In certain instances, setting time considerations would be counter-productive.

- Domestic or international obligations may require that some precautionary measures be deemed explicitly provisional and subject to re-evaluation; they may include obligations requiring mechanisms for ongoing monitoring and reporting.

- Regardless of whether there is a formal obligation, follow-up scientific activity (e.g., further research and monitoring) should be promoted, as it can help reduce uncertainty and allow improved decisions as the science evolves.

4.7 Precautionary measures should be proportional to the potential severity of the risk being addressed and to society's chosen level of protection.

- There is an implicit need to identify, where possible, both the level of society's tolerance for risks and potential risk-mitigating measures. This information should be the basis for deciding whether measures are proportional to the severity of the risk being addressed and whether the measures achieve the level of protection, recognizing that this level of protection may evolve.

- While judgments should be based on scientific evidence to the fullest extent, decision makers should also consider other factors such as societal values and willingness to accept risk and economic and international considerations. This would allow for a clearer assessment of the proportionality of the measure and ultimately help maintain credibility in the application of precaution.

- Generally, the assessment of whether measures are considered proportional to the severity of risk should be in relation to the magnitude and nature of the potential harm in a particular circumstance, not in comparison with measures taken in other contexts.

4.8 Precautionary measures should be non-discriminatory and consistent with measures taken in similar circumstances.

- Consistent approaches should be used for determining an appropriate level of protection against risk. Ultimately, the level of protection should be set in the public interest by weighing potential (or perceived) costs and benefits of assuming the risk in a manner that is consistent overall with societal values.

- Similar situations should not be treated substantially differently and decision makers should consider using processes used in comparable situations to ensure consistency. Except where the choice of precautionary measures is predetermined in agreements or legislation, it should be flexible and determined on a case-by-case basis.

- Domestic applications of precaution should be consistent with Canada's obligations arising from international agreements to which it is a party and where applicable, meet the requirements established by the Regulatory Policy.

4.9 Precautionary measures should be cost-effective, with the goal of generating (i) an overall net benefit for society at least cost, and (ii) efficiency in the choice of measures.

- The real and potential impacts of making a precautionary decision (whether to act or not to act), including social, economic and other relevant factors, should be assessed.

- Decision making should identify potential costs and benefits as explicitly and as soon as possible, and distinguish what risk the public is prepared to accept on the basis of sound and reasonable, albeit incomplete, scientific evidence.

- Consideration of risk–risk tradeoffs or comparative assessments of different risks would generally be appropriate, although this may not be possible in circumstances where urgent action is needed. This can ensure that society receives net benefits from decision making and that the application of precaution is inherently responsive to the potential from innovation or technological change and the overall benefits that such change can entail.

- Assessing the efficiency of precautionary measures generally involves comparing various policy instruments to determine which options could most efficiently address the risk at least overall cost. The outcome of this process should result in any measures taken imposing the least cost or other negative impact while reducing risks to an acceptable level.

- As science evolves, it is inherently appropriate that the cost-effectiveness of decisions and associated measures be assessed and taken into account at the start, in the interim and, possibly, over the longer term. For some issues, a net benefit may not be realized for a long period of time, for example, decisions associated with biodiversity. However, the emphasis should always be on ensuring that ongoing costs are assessed and minimized, so that new scientific data that alters cost-effectiveness considerations can be incorporated (including performance monitoring results), while maintaining the reduction of risks and, where appropriate, maximizing the benefits (e.g., from innovation).

- Decision makers should consider broader costs and benefits from decisions to help ensure that society receives net benefits overall (e.g., benefits associated with enhanced health status of children as a segment of the population or benefits from innovation or technological change).

4.10 Where more than one option reasonably meets the above characteristics, then the least trade-restrictive measure should be applied.

- When making a choice among different types of measures that would provide a similar level of response to the potential for harm, there should be an endeavour to select measures that would be "least trade-restrictive".

- Least trade-restrictive considerations should apply to both international and internal trade. This is especially relevant in terms of international trade where disciplines and mechanisms exist for other States to challenge the nature and impact of precautionary measures.

5.0 Conclusion

A Framework for the Application of Precaution in Science-based Decision Making About Risk sets out guiding principles to achieve coherent and cohesive application of precaution to decision making about risks of serious or irreversible harm where there is lack of full scientific certainty, with regard to federal domestic policies, laws and agreements and international agreements and guidelines in areas where science is implicated.

Departmental and agency officials are expected to consider its guiding principles in decision making and to work together in developing, in consultation with their stakeholders, guidance for the application of precaution in their particular area of responsibility.