



A Canadian Perspective on the Precautionary Approach/Principle

Proposed Guiding Principles

September 2001

The principles expressed in this document should not be considered to be the official position of the Government of Canada or of federal departments and agencies.

They are for discussion purposes only.

FOREWORD

Governments are often called upon to address new or emerging risks of serious or irreversible harm and to manage issues where there is a lack of scientific certainty. Within the changing context for managing risk, there has been a growing awareness of and increased emphasis on adopting precautionary approaches.

This discussion paper outlines broad guiding principles to support consistent, credible and predictable policy and regulatory decision making when applying the precautionary approach/principle. These principles would also increase Canada's ability to contribute to and have an influence on international discussions.

The objective of this discussion paper is to inform stakeholders about the precautionary approach/principle and solicit reaction to some concepts; and determine if the proposed "guiding principles" for applying the precautionary approach/principle will:

- < increase coherence and consistency of the process;
- < provide an appropriate balance of flexibility and predictability;
- < be adaptable to various functional areas; and
- < be value-added as a complement to tools for risk management.

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1.0 Introduction

1.1 *The Changing Context for Managing Risk and Increased Emphasis on Precautionary Approaches*

The rapid evolution of technology, globalization and the knowledge-based economy offers tremendous opportunities to improve Canadians' quality of life, but it is sometimes accompanied by scientific uncertainty and the potential for serious or irreversible harm. When combined with high-profile events, these changes highlight the need for more effective strategies to manage risk and seize the opportunities that change presents.

Public opinion surveys show that Canadians want to reap the benefits of change (e.g., biotechnology), but they also want their governments to protect them from the risks. As a result, governments are often called upon to balance new or emerging risks and potential opportunities, and to manage issues where there is significant scientific uncertainty. The decisions they make can have profound effects on societies, trade and economies.

In this context, governments face increased responsibility to demonstrate sound decision making. While governments cannot guarantee zero-risk, Canadians expect that risk-management decisions will be based on “scientific evidence”. Governments often turn to the scientific community for advice, but the scientific information they receive is sometimes characterized by uncertainty or disagreement, or both. Consequently, governments are finding that managing risks under these circumstances can be particularly challenging, especially when the environment or the physical, social and economic well-being of Canadians are involved.

The need for governments to make decisions in these situations has grown both in scope and public visibility and has led to a growing emphasis on the precautionary approach. The precautionary approach/precautionary principle¹ is a distinctive approach within risk management² that primarily affects the development of options and the decision phases. It is ultimately guided by judgment, based on values and priorities.

Canada supports the statement in Principle 15 of the “1992 Rio Declaration on Environment and Development”:
“In order to protect the environment, the precautionary approach shall be widely applied by States according to their capability. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”

1

While there may be distinctions to be drawn between them, the terms “precautionary approach” and “precautionary principle” are used interchangeably in this document.

2

The *Oceans Act* requires the government to promote a wide application of the precautionary approach to the conservation, management and exploitation of marine resources.

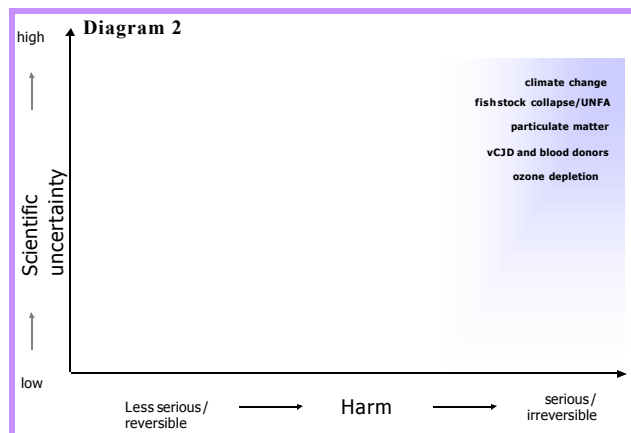
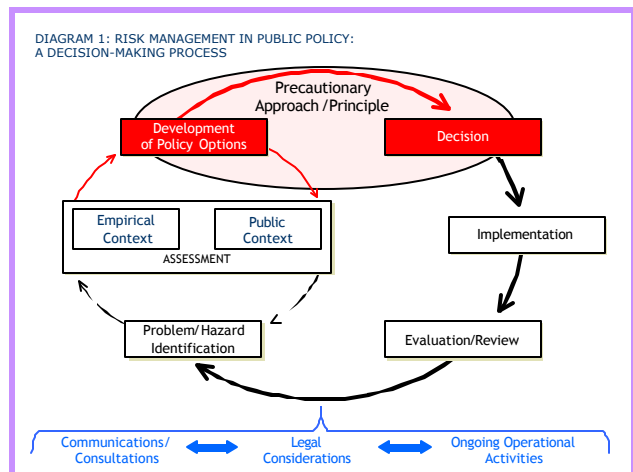
This approach is consistent with Canadian practice in environmental protection and is increasingly reflected in Canadian environmental legislation, such as the *Canadian Environmental Protection Act*. Canada also has a long-standing history of implementing the precautionary approach in science-based programs of health and safety and natural resources conservation. This reflects an impetus towards decisions with the greatest net benefit for Canadians.

The precautionary approach recognizes that the absence of full scientific certainty shall not be used as a reason to postpone decisions in the presence of serious or irreversible harm. However, guidance and assurance are required as to the conditions governing the actions that will be taken, particularly when there is a risk of serious or irreversible harm, the scientific uncertainty is significant and a decision must be made (represented for illustrative purposes in Diagram 2).

Applying the precautionary approach is complicated by the inherent dynamics of science. Even though scientific information may be inconclusive, decisions will still have to be made because society expects risks to be addressed and living standards maintained.

Since 1992, the precautionary approach has generated significant debate and differences of opinion in Canada and around the world. Some stakeholders are concerned that it may be misused or abused. They fear, for example, that it could be applied to perceived risks for which there is no sound scientific basis; unnecessarily stifle innovation or impose unfair costs on sectors of society; or prevent existing risks from being curtailed by, for instance, impeding the development of new therapeutic products and technologies. Other stakeholders, such as consumers and their advocacy groups, may view the precautionary approach as a new approach, or an “extra measure” of care, that can lead to more rigorous and responsive decision making. The precautionary approach can also be seen as a government’s tangible commitment to the importance of balancing science with social values such as health, safety, the environment and natural resources conservation.

At the domestic and international levels, the debate is vigorous, as the stakes are high. Decisions are associated with significant risks to health and safety, the environment or natural



resources and may result in crucial economic repercussions. Nations' decisions that purport to protect human health and have disruptive economic repercussions on trading partners are most open to contention and often lead to allegations of trade protectionism.

Decision makers, then, are often faced with the need to address potentially serious or irreversible harm, characterized by a significant scientific uncertainty, while maintaining credibility and trust in the process they have followed and the decision they have made. That is, it must be clear that the decision addresses the potential harm and is in keeping with all public interests.

1.2 The Need for a Federal Framework on the Precautionary Approach

Canada has been flexible and responsive to the needs of particular circumstances when applying the precautionary approach. However, rules-based approaches are used where necessary to achieve the results required by specific legislation or international obligations.

There are, however, broad principles that apply to all situations. This paper outlines proposed "guiding principles" (Section 3) to support overall consistency in how the precautionary approach is used in science-based risk decision making in government. These principles could not direct decision makers to act in a way inconsistent with their legal authority. In fact, they would complement the federal government's "Integrated Risk Management Framework"³ and support department-specific initiatives.

These principles would constitute the key elements of a federal framework for the precautionary approach. The framework would have four purposes: improve the predictability, credibility and consistency of Canadian federal precautionary approaches to ensure they are adequate, reasonable and cost-effective; support sound federal government decision making while minimizing crises and unnecessary controversies, and capitalizing on opportunities; increase the confidence of public and private stakeholders, 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 applications of the precautionary approach.

This document describes the guiding principles inherent to practices and policies of the federal government's application of the precautionary approach within risk management. It does not, however, provide a checklist for risk assessors or decision makers. Nevertheless, it can help ensure that the decision-making process and the decision itself are appropriate, reasonable and cost-effective, and in keeping with Canadians' social and economic values and priorities.

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The Government of Canada's "Integrated Risk Management Framework" can be found on the following Web site: http://www.tbs-sct.gc.ca/pubs_pol/dccpubs/RiskManagement/rmf-cgr_e.html

2.0 Overarching Considerations

There are several overarching considerations relevant to the precautionary approach. These include the scientific basis for application, legal issues and the international context.

The decision-making process for managing risks always requires sound and rigorous judgment. When it comes to the precautionary approach, however, determining what constitutes a *sufficiently* sound scientific basis is difficult and often controversial⁴. The scientific process is almost always characterized by uncertainty and debate. The precautionary approach differs from traditional risk management in three ways: the higher degree of uncertainty; the parameters for establishing an adequate scientific basis; and the distinctive aspects of sound and rigorous judgment. Judgment means determining what is a *sufficiently* sound or credible scientific basis, what *follow-up* activities may be warranted, and *who* should produce a credible scientific basis.

What is a sufficiently sound or credible scientific basis? Sound scientific evidence traditionally means definitive and compelling evidence supporting a scientific theory or significant empirical information that a risk of serious or irreversible harm exists beyond reasonable doubt. Such evidence can come from empirical, theoretical or “traditional knowledge”. Decision makers should use a variety of scientific sources and experts from many disciplines in their judgments, giving particular weight to peer-reviewed science and reasonableness.

What follow-up activities may be warranted? To reduce significant scientific uncertainty and improve decision making, the precautionary approach usually includes follow-up activities such as research and scientific monitoring. In fact, some international agreements require it.

Who should be responsible for producing the scientific data that serve as the basis for decision making? Or who should be assigned the “burden of proof”? This should be determined by who has legal responsibility or authority, who would be in the best position to provide the scientific data, and who can produce timely and credible information. The party taking an action associated with potential serious harm is usually the one responsible, but this may best be decided on a case-by-case basis. Different levels of government and industry may even share the burden of proof. Also, as the scientific knowledge evolves, this responsibility may shift among governments, industry or another proponent.

The inherent dynamics of uncertainty in science also present unique challenges. For example, there is broad international scientific consensus that the amounts of greenhouse gases in the atmosphere are increasing, that these increases are caused by human activities, and that they are likely to affect climate change. However, there is scientific uncertainty in *when* and *where* climate change occurs and in the *economic costs* to reduce greenhouse gases and to adapt to the expected changes in climate. Nevertheless, decisions will have to be made to meet society’s expectations about living standards and to address risks.

Many of the key challenges associated with the application of the precautionary approach relate to the legal issues that are raised in both domestic and international contexts. From an international perspective, legal issues include the status of the precautionary approach/principle in international law. From a domestic perspective, they include whether the inclusion of the precautionary approach in Canadian law creates a positive legal duty to act.

Rules of customary international law are developed by the common consent of States. Due to an absence of clear evidence of uniform State practice and *opinio juris*, Canada does not yet consider the precautionary principle to be a rule of customary international law.

Interestingly, a majority of judges, in a recent decision of the Supreme Court of Canada on the use of pesticides, referred to the precautionary principle for the purpose of supporting its interpretation of a municipal by-law⁵. Although the majority did not pronounce conclusively as to whether the precautionary principle is a rule of customary international law, it stated that “there may be ‘currently sufficient state practice to allow a good argument that the precautionary principle is a principle of customary international law.’”⁶ It is too early to assess fully the impact of this judgment.

From a domestic perspective, government-wide guidelines on precaution would have to be applied in a flexible way, taking into account the various statutory regimes already in place. Such guidelines could support overall consistency in applying the precautionary approach to science-based risk decision making in government. They could not, however, direct decision makers to act in a way inconsistent with their statutory authority.

A number of international environmental and resource management agreements illustrate the evolution of the issue internationally. Health and safety concerns are also driving the current international debate. Debate about the precautionary approach is also playing out in various international fora. At the same time, stakeholder interest in these debates and their outcomes is broadening and has, on several occasions, pitted different stakeholders or philosophies against one another.

A clear and consistent framework for applying the precautionary approach would help Canadian officials more actively engage in international discussions in a clear, coherent and consistent manner. It would also help to ensure that international rules are shaped in a way that respects Canadian interests. A number of existing agreements (including the Agreement on the Application of Sanitary and Phytosanitary measures (SPS)) may offer models for principles that could be applied more generally. Some examples include, acknowledging the right of States to set their own acceptable “level of protection”; setting out clearly the thresholds of harm that would trigger precautionary measures; establishing and assigning the

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114957 Canada Ltée (Spraytech, Société d'arrosage) v. Hudson (Town), 2001 SCC 40. In a separate concurring judgment, a minority of judges expressed the view that references to international sources had “little relevance” for the case in question and did not discuss precaution (para. 48).

6

Supra, para. 32.

burden of proof; and imposing an obligation on States taking precautionary measures to continue gathering further information to decrease the scientific uncertainty.

3.0 Guiding Principles

As noted earlier, the precautionary approach is distinctive within risk management and primarily affects the development of options and the decision phases. It is ultimately guided by judgment, based on values and priorities. Canada implements the precautionary approach in science-based programs of health and safety, the environment and natural resources conservation, both domestically and internationally. This reflects an impetus towards decisions with the greatest net benefits for Canadians.

The application of the precautionary approach to science-based risk decision making is often driven by specific circumstances and factors. However, a review of regulatory practices and policies indicates that there are eleven (11) broad “guiding principles” that would apply to all situations. These principles would support overall consistency in application and can 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.

General Principles of Application

General principles of application suggest distinguishing features of decision making within the context of a precautionary approach. The precautionary approach 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 guiding principles enunciated in this document are particularly applicable to circumstances of a risk of serious or irreversible harm about which there is significant scientific uncertainty. They also help guide the broader application of precautionary approaches to manage risks.

3.1 *The precautionary approach is a legitimate and distinctive decision-making tool within risk management.*

3.2 *It is legitimate for decisions to be guided by society’s chosen level of protection against risk.*

, The chosen level of protection should be established in advance. It should be recognized that some risks are new or emerging, and evolution of scientific knowledge may influence societal tolerances and its chosen level of protection.

, While societal values are key in determining a chosen level of protection against risk, in all cases sound scientific evidence is a fundamental prerequisite to applying the precautionary approach.

, Situations where there is no threat of serious or irreversible harm to human health, safety, the environment or resource conservation should not be considered to be related to the precautionary approach.

3.3 *Sound scientific information and its evaluation must be the basis for applying the precautionary approach, particularly with regard to (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.*

A valid and reasonable scientific information base underpins the application of the precautionary approach.

Before the precautionary approach can be applied, 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).

Urgent situations may require different approaches to assess whether sound scientific evidence has been attained. Imminency of risk may dictate the choice of the best “probably successful option” in view of the available scientific information, with an understanding that implementation of the option will include close monitoring to assess the effectiveness of the measure in addressing risk and positive/negative impacts.

Evaluation of all available scientific information must be completed. The emphasis need not be on securing a high quantity of scientific evidence but, rather, on high quality. 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 the precautionary approach. A peer-review process can demonstrate the soundness of the scientific evidence and its inherent credibility within the scientific population.

Scientific advice should be drawn from a variety of sources and from experts in relevant disciplines in order to capture the full diversity of scientific schools of thought and opinion. Scientific advisors should give weight to peer-reviewed science and aim at sound and reasonable evidence on which to base their judgments.

While judgments on scientific evidence must guide decisions to the fullest possible extent, societal values, public willingness to accept risk, and economic considerations must also be weighed.

3.4 *The scientific evidence required should be established relative to the chosen level of protection. Further, the responsibility for producing the information base (burden of proof) may be assigned. It is recognized that the scientific information base and responsibility for producing it may shift as the knowledge evolves.*

Follow-up scientific activities, including further research and scientific monitoring, are a key part of the application of the precautionary approach. Such follow-up should reduce scientific uncertainty and allow improved decisions to be made in the future.

“Sufficiently sound information base” should be interpreted as sound and reasonable scientific information, including uncertainties that, through evaluation, indicate

unacceptable risk of serious negative consequences. That is, while scientific information would not need to demonstrate definitively the cause-and-effect relationship between risk and serious harm, it would demonstrate that such a risk exists.

Generally, the responsibility for providing the scientific information base (the burden of proof) should rest with the party who is taking an action associated with potential or serious harm. 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 assessment 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. Assignment may best be decided on a case-by-case basis and may introduce innovative strategies such as collaborative arrangements. The responsibility for providing information may shift as the scientific knowledge evolves.

It should be recognized that it is impossible to prove a negative (e.g., to prove categorically that something will cause no harm, or to prove with absolute certainty that something bad might not happen or to prove that something is not harmful), but possible to demonstrate that “reasonable testing” was done with no evidence of harm.

3.5 *Mechanisms should exist for reevaluating the basis for the decisions and for providing a transparent process for further consultation.*

Stakeholders significantly affected by a decision should have some input into the reevaluation process. There should be an assessment of what impact (benefits and drawbacks) reevaluation and consultative mechanisms may have in any particular situation (i.e., in some cases, they may not be practical or productive). Further, given some existing reevaluation and consultative mechanisms or legislated authorities (e.g., fishery conservation), it should be recognized that additional mechanisms may not be appropriate.

A reevaluation may be triggered by the emergence of new scientific information or a change in society’s tolerance for risk. Effective review of decisions made using the precautionary approach would require 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 and respected. This would also facilitate requests for additional reevaluation and consultation, domestically and internationally.

The nature, type and frequency of requests for reevaluation and consultation may be related to whether the precautionary approach is being used as a continuous management tool (i.e., as a mechanism for conservation) or in situations where decisions are made about specific risks.

3.6 *A greater degree of transparency, clearer accountability and increased public involvement are appropriate.*

- , Transparency in documenting the rationale for making decisions strengthens accountability while demonstrating due diligence.
- , Openness and transparency are essential to support precautionary decisions. In fact, continuous communication of risk is necessary at every stage of the process. Failure to document and communicate can undermine the credibility of and trust in sound decisions.
- , 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.
- , It is recognized that the opportunity for public involvement and the degree of transparency depend on the specific context and immediacy of the decision, and that urgent decisions often require a different approach than issues that do not present immediate risks. However, these decisions should be developed as impacts become evident.

Principles for Precautionary Measures

Principles for precautionary measures propose specific characteristics that apply once a decision to implement such measures has been taken.

3.7 *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.
- , Due consideration for the limitations of evolving scientific knowledge means that decision makers should recognize that scientific uncertainty may last for years (i.e., quasi-permanent) and that they should review new scientific knowledge if and when it evolves. In many instances, setting any time considerations would be counter-productive.
- , Domestic or international obligations may require that some precautionary measures be deemed explicitly provisional and subject to reevaluation. Such instances may include obligations requiring mechanisms for ongoing monitoring and reporting.

Follow-up scientific activity (e.g., further research and monitoring) should be undertaken, as it can help reduce uncertainty and allow improved decisions as the science evolves.

3.8 *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 obligation 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 chosen level of protection, recognizing that this level of protection may evolve.

While judgments should be based on scientific evidence to the fullest possible extent, decision makers should also consider other factors such as societal values, the public's 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 the precautionary approach.

Generally, proportionality with respect to severity of risk should be applied in the broadest sense and based on the magnitude of the negative effect rather than any specific comparisons.

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

Consistent approaches should be used for judging acceptable levels of risk. Ultimately, the chosen 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.

Comparable situations should not be treated substantially differently and should consider using previous approaches to ensure internal consistency. Except where the choice of precautionary measures is predetermined in agreements or legislation, the choice of measures to be implemented should be flexible and determined on a case-by-case basis.

The precautionary approach should not be used to legitimize decisions that are unrelated to a threat or the presence of scientific uncertainty (but determined by other factors). In addition, domestic applications should be consistent with Canada's international obligations and with the policy requirements of the federal regulatory policy.

3.10 *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. Moreover, 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 precautionary approach is not used as an unnecessary or unintentional barrier to innovation or technological change.

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 the precautionary approach is, by definition, an evolutionary process, precautionary measures should be monitored on an ongoing basis so that new scientific data that alters cost-effectiveness considerations can be incorporated (including performance monitoring results).

3.11 *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 risk, there should be an endeavour to select measures that would be “least trade-restrictive”.

Particular care should be taken when selecting the measure that will have the least trade-restrictive effect on an activity. This is because regulatory actions almost always have an economic impact on that activity and precautionary decisions will almost always have a selective impact on it.

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

4.0 Closing Comment

This paper is an important step in the establishment of a Canadian federal framework for the coherent and consistent application of the precautionary approach. Consultations within Canada and abroad are intended to help define and address key issues and build consensus on the broad principles that should guide decision making in the use of the precautionary approach.

5.0 Proposed Questions

The following questions, while not comprehensive, may help begin the dialogue. Readers are encouraged to consider them in domestic and international contexts. While there may be a tendency to see regulatory activity as basically domestic, current discussions also have a large international dimension, either because the issues are by their nature international or because they have significant implications on international trade.

Is this discussion paper clear in describing the precautionary approach and the guiding principles? Does it provide the right level of guidance? If not, what changes would you suggest to ensure that it captures the “right” principles?

1. How do the principles address your particular concerns, interests and field of work in the application of the precautionary approach? How or when might the guidelines affect your area of interest?
2. Would the principles achieve the goal of preventing misuse or abuse (misinterpretation, misapplication) when implementing the precautionary approach?
3. What effect would the guidelines have on your level of acceptance or trust in the decision-making processes—positive, neutral or negative? Why (clarity, understandability, etc.)? If needed, how would you address this?
4. Does this discussion paper adequately balance the various needs of Canadians? If not, how could it establish the right balance?

6.0 Web Sites

In addition to this one, two other documents are available: the first is a more detailed discussion document, “A Canadian Perspective on the Precautionary Approach/Principle — Discussion Document”, September 2001; the second is a backgrounder on the precautionary approach/principle, both of which may be obtained through the departments listed below or their Web sites. If you wish to provide feedback, the Web sites will provide advice in this regard.

Agriculture and Agri-Food Canada: www.agr.ca

Canadian Food Inspection Agency: www.inspection.gc.ca

Department of Fisheries and Oceans: www.dfo-mpo.gc.ca

Department of Foreign Affairs and International Trade: www.dfait-maeci.gc.ca

Environment Canada: www.ec.gc.ca

Health Canada: www.hc-sc.gc.ca

Industry Canada: www.ic.gc.ca

Natural Resources Canada: www.nrcan.gc.ca