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A Canadian Perspective on the Precautionary Approach/Principle

Discussion Document

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They are for discussion purposes only.

Canada

FOREWORD

Governments have often been called upon to address new or emerging risks of harm and to manage issues where there is a lack of full scientific certainty. Moreover, within the changing context for managing risk, there has been an increased occurrence of such circumstances. Indeed, Canada has a long-standing history of implementing the precautionary approach/principle in science-based programs of health and safety, environmental protection and natural resources conservation.

The precautionary approach/principle is a distinctive approach within science-based risk management. It recognizes that the absence of full scientific certainty shall not be used as a reason to postpone decisions where there is a threat of serious or irreversible harm. While guidance and assurance are required as to conditions governing decisions, it is particularly important that this guidance and assurance be clearly conveyed and applied when a decision must be made about a risk of serious or irreversible harm and the scientific uncertainty is significant.

This discussion paper, “A Canadian Perspective on the Precautionary Approach/Principle”, outlines broad guiding principles to support consistent, credible and predictable policy and regulatory decision making when applying the precautionary approach/principle. These principles reflect current Canadian practices. An enunciation of the principles would clarify how Canada makes decisions in such circumstances and give Canada a firm basis to more actively engage in international discussions in a clear, coherent and consistent manner. The focus is on those sectors with the greatest need for guidance and clarity—science-based areas of public health and safety, the environment, and natural resources management.

This paper reflects the efforts of a multi-departmental approach, comprising Agriculture and Agri-Food Canada, Canadian Environmental Assessment Agency, Canadian Food Inspection Agency, Department of Fisheries and Oceans, Department of Foreign Affairs and International Trade, Environment Canada, Finance Canada, Health Canada, Industry Canada, Justice Canada, Natural Resources Canada, Privy Council Office, Transport Canada and Treasury Board Secretariat.

The initiative was guided by the Government of Canada’s “Framework for Science and Technology Advice: Principles and Guidelines for the Effective Use of Science and Technology Advice in Government” and the Government of Canada’s “Integrated Risk Management Framework”. Readers are encouraged to consult these documents for a more complete understanding of the challenges of managing risk.

The objective of this discussion paper is to:

- , inform and raise awareness among stakeholder groups about the precautionary approach/principle and the draft framework;
- , gauge the reaction of stakeholders to the concepts, principles and guidance reflected in the framework, as a basis for the application of the precautionary approach/principle by Canada; and
- , test the guiding principles and, in particular, obtain feedback on whether they are perceived as adequate to:
 - 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 more generally.

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Executive Summary

Science and technology have evolved rapidly in recent decades, and an ever-increasing and far-reaching explosion of complex scientific knowledge and discoveries is expected. As related issues also become increasingly complex and at times associated with risks of great harm, they require decisions to be made, decisions that can profoundly affect societies, trade and economies.

While decision making on complex issues with the potential for harm is not new, this environment has heightened public concern and generated debates about the ability of governments to effectively respond to the potential for serious or irreversible harm and address scientific uncertainty. At the same time, the public is looking to governments to maximize the benefits of scientific discoveries and new technologies for the overall good of society. They expect governments to do this through a solid regulatory framework guided by society's level of tolerance for risk.

Governments have traditionally been called upon to address new or emerging risks and to manage issues where there is a lack of full scientific certainty. However, within the changing context for managing risk, there has been an increased emphasis on adopting precautionary approaches.

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."* This language, and the approach it represents, is consistent with Canadian practice in the field of environmental protection and the approach 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.

The precautionary approach recognizes that the absence of full scientific certainty shall not be used as a reason to postpone decisions where there is a risk of serious or irreversible harm. However, guidance and assurance are required as to the conditions governing the actions that will be taken. Guidance and assurance are particularly needed when a decision must be made regarding a risk of serious or irreversible harm about which there is significant scientific uncertainty. The precautionary approach/precautionary principle¹ is a distinctive approach within risk management² that primarily

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

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

affects the development of options and the decision phases, and is ultimately guided by judgment, based on values and priorities.

Since 1992, the increasing frequency of references to the precautionary approach, both in Canada and abroad, has generated significant debate, differences of opinion and highlighted the possibilities for its misuse or abuse. Countries throughout the world are grappling with these challenges. There are concerns 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.

Decision making about risks in the context of a precautionary approach is further complicated by the inherent dynamics of science. Even though scientific information may be inconclusive, decisions will still have to be made to meet society's expectations that risks be addressed and living standards maintained.

Canada's application of precautionary approaches has been flexible and responsive to the needs of particular circumstances. Individual applications, however, do employ rules-based approaches to achieve the results required by specific legislation or international obligations (e.g., fisheries management). While the application of a precautionary approach is often driven by specific circumstances and factors, there are broad principles that apply to all situations. The proposed "guiding principles" that follow are consistent with current Canadian practices. They support overall consistency in applying a precautionary approach to science-based risk decision making in government; however, 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.

1. The precautionary approach is a legitimate and distinctive decision-making tool within risk management.
2. It is legitimate for decisions to be guided by society's chosen level of protection against risk.
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.

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.
5. Mechanisms should exist for reevaluating the basis for the decisions and for providing a transparent process for further consultation.
6. A greater degree of transparency, clearer accountability and increased public involvement are appropriate.

Principles for Precautionary Measures

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

7. Precautionary measures should be subject to reconsideration, on the basis of the evolution of science, technology and society's chosen level of protection.
8. Precautionary measures should be proportional to the potential severity of the risk being addressed and to society's chosen level of protection.
9. Precautionary measures should be non-discriminatory and consistent with measures taken in similar circumstances.
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.
11. Where more than one option reasonably meets the above characteristics, then the least trade-restrictive measure should be applied.

The paper first reviews the changing context for managing risks and discusses the overarching considerations pertaining to the precautionary approach. It then outlines guiding principles for interpreting and applying the precautionary approach. Finally, it proposes a set of questions to stimulate dialogue with the general public and stakeholders, and to help build a better understanding and some consensus on the key issues that must be defined and addressed in Canada's ongoing implementation of a precautionary approach.

1.0 Introduction

1.1 The Changing Context for Managing Risk

Technology, globalization and the knowledge-based economy are driving tremendous changes in both the private and public sectors. The concerns of citizens and business are evolving alongside these changes. Risk, already inherent in the activities of individuals and business, accompanies such change and 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.

While government has traditionally been responsible for decision making in such circumstances, the current environment results in the government facing increased responsibility to demonstrate sound decision making particularly in its mandate to protect the environment or the physical, social and economic well-being of citizens. Several factors contribute to this, including expectations of due diligence, more intense public and media awareness, increased scrutiny of Canada's investment climate due to rapidly evolving globalization and competitiveness, and initiatives for transparency and openness. Scientific information and advice is often used in decision making, but it is also frequently characterized by uncertainty or disagreement, or both.

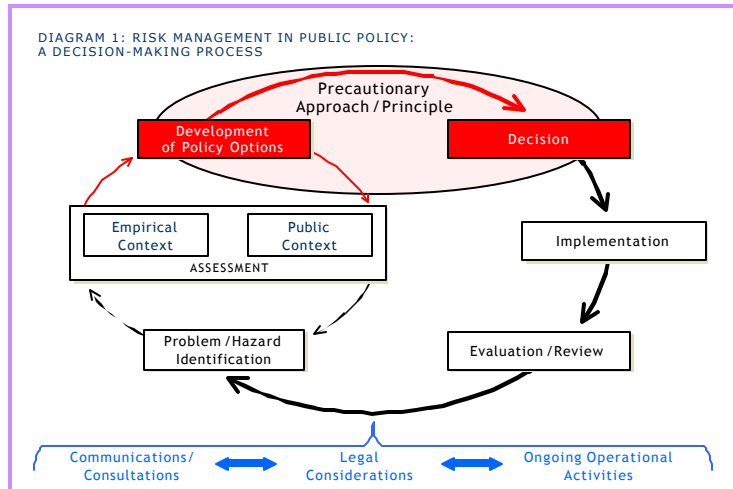
The government continues to face a major balancing act between supporting science and technology, and monitoring and assessing its risks. For example, government-commissioned polls suggest that while Canadians believe biotechnology is critical to the country's future and growth, they also expect the government to be vigilant in ensuring that it is safe.

Finally, the government continues to wrestle with how to integrate science and policy-making. When science is characterized by a significant level of uncertainty, debates and differences of opinion can be expected to erupt.

1.2 Increased Emphasis on Approaches to Deal with Scientific Uncertainty and Risks of Serious or Irreversible Harm

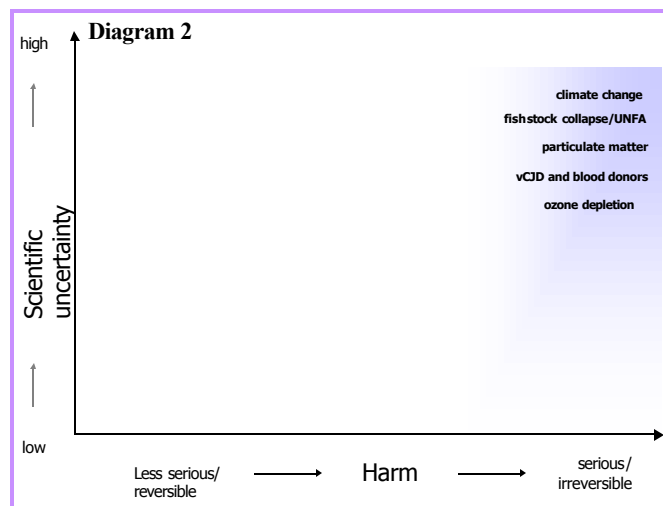
Governments can rarely act on the basis of full scientific certainty and cannot guarantee zero-risk. Indeed, they are traditionally called upon and continue to address new or emerging risks and potential opportunities, and to manage issues where there is significant scientific uncertainty. However, this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

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.” This language, and the approach it represents, is consistent with Canadian practice in the field of environmental protection, and the approach 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.

The precautionary approach recognizes that the absence of full scientific certainty shall not be used as a reason to postpone decisions where there is a risk of serious or irreversible harm. However, guidance and assurance are required as to the conditions governing the actions that will be taken. Guidance and assurance are particularly needed 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). 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.

Applying the precautionary approach to make decisions about risks 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 increasing frequency of references to the precautionary approach, both in Canada and abroad, has generated significant debate and differences of opinion, and has highlighted the possibilities for its misuse or abuse. Countries throughout the world are grappling with these challenges. There are concerns that the precautionary approach 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 (e.g., by requiring proof of absolute safety before approval is given for use), or prevent existing risks from being curtailed by, for instance, impeding the development of new therapeutic products and technologies.

On the other hand, many stakeholders, such as consumers and their advocacy groups, may view the precautionary principle as a new approach that can lead to more responsive decision making. They may interpret it as an “extra measure” of care, one that forces rigour into the decision-making process at times when, because of scientific uncertainty and the rapid evolution of the science, there would be a natural tendency to delay decisions (until more is known). The precautionary principle/approach can also be seen as a government’s tangible commitment to the importance of social values such as health, safety, the environment and natural resources conservation.

At the international level, 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. Several mechanisms to resolve disputes and appeals do exist;

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

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The *Oceans Act* requires the government to promote the wide application of the precautionary approach to the conservation, management and exploitation of marine resources in order to protect these resources and preserve the marine environment.

where there are none, however, nations can enter into protracted debates that lead to trade retaliation strategies. On the other hand, citizens of these countries are generally mindful of maintaining national economic positions and investment climates, but they also focus on ensuring that social values and priorities are respected and maintained.

Hence, decision makers 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 evident that the decision addresses the risk and is in keeping with all public interests, social and economic.

1.3 The Need for a Federal Framework on the Precautionary Approach/Principle

Canada's application of the precautionary approach has been flexible and responsive to the needs of particular circumstances. Individual applications, however, do employ rules-based approaches to achieve the results required by specific legislation or international obligations (e.g., fisheries management). While the application of the precautionary approach is often driven by specific circumstances and factors, there are broad principles that have applied to all situations. This paper outlines these as proposed “guiding principles” to 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 legal authority.

Further, it is recognized that a principles-based framework for applying the precautionary approach would complement the federal government’s “Integrated Risk Management Framework”³ and support department-specific initiatives.

This discussion paper proposes, for consultation purposes, guiding principles which would constitute the key elements of a federal framework for the precautionary approach. The four purposes of a framework would be to:

- , improve the predictability, credibility and consistency of Canadian federal precautionary approaches to ensure adequate, reasonable and cost-effective application;
- , support sound federal government decision making while minimizing crises and unnecessary controversies, and capitalizing on opportunities;

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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/dcqpubs/RiskManagement/rmf-cgr_e.html

- , 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 applications of the precautionary approach.

While a framework would describe the guiding principles inherent to practices and policies of the federal government, it would not, however, provide a checklist for risk assessors or decision makers. It could help gauge the appropriateness, reasonableness and cost-effectiveness of the decision-making process and the decision itself. Ultimately, the framework should be a lens through which decision makers and affected parties can assess whether the decision-making process is in keeping with the guiding principles and whether the decision is in keeping with Canadians’ social and economic values and priorities.

2.0 Overarching Considerations

The following sections discuss overarching considerations relevant to the precautionary approach. These include the scientific basis for application, transparency, accountability and public involvement, cost-effectiveness, legal issues and international considerations. An analysis of these considerations can help ensure that needs or criteria that emerge are consistent with and reflected by guiding principles for applying the precautionary approach.

2.1 Scientific Basis for Application

The scientific process is almost always characterized by uncertainty and debate. Hence, the decision-making process for managing risks always requires sound and rigorous judgment. The precautionary approach is unique within traditional risk management because of the higher degree of uncertainty, the parameters that can establish what constitutes an adequate scientific basis, and the distinctive aspects of sound and rigorous judgment. As it applies here, judgment focuses on 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.

In traditional situations of managing risks, “sound scientific evidence” is generally interpreted as either definitive and compelling evidence that supports a scientific theory or significant empirical information that establishes the seriousness of a risk beyond reasonable doubt.

Within the context of the precautionary approach, determining what constitutes a *sufficiently* sound or credible scientific basis is always challenging and often controversial. The emphasis is on providing a sound and credible case that a risk of serious or irreversible harm exists. “*Sufficiently* sound scientific information” is interpreted as a base of scientific data—whether empirical,

theoretical or from “traditional knowledge”—that can establish reasonable evidence of a theory’s validity, including its uncertainties, and that indicates the potential for such a risk.

Given the significant scientific uncertainty, follow-up activities such as research and scientific monitoring are usually a key part of the application of precautionary approaches. In some cases, international agreements require scientific monitoring and follow-up. Such efforts can help reduce the scientific uncertainty associated with certain risks and allow improved follow-up decisions to be made. In some risk-management areas, however, scientific uncertainty may take a long time to resolve or may never, for practical purposes, be resolved to any significant degree.

Moreover, in order to capture the full diversity of scientific thought and opinion, the scientific 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.⁴ The science function can be further supplemented by advisory processes that include widely recognized and credible individuals.

Establishing who should be responsible for producing a “*sufficiently* sound scientific basis” (also referred to as who should be assigned the “burden of proof”) often 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, 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 marketed product). Ultimately, the responsible party may be determined only by the courts.

Finally, the inherent dynamics of uncertainty in science also present unique challenges. For example, some segments of society will object to the introduction of genetically modified foods until sound evidence from longitudinal studies demonstrates both the lack of negative effects (e.g., genetic mutations affecting humans or “contamination” of global food production) *and* the existence of positive effects (e.g., that they are as or more nutritious than traditional foods). Longitudinal studies, however, cannot be undertaken until such products have been consumed over a significant period

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“The Framework for Science and Technology Advice: Principles and Guidelines for the Effective Use of Science and Technology Advice in Government Decision Making” provides guidance in this regard. http://csta-cest.gc.ca/csta/website/home_e.html

of time. As a result, such an evidence base may not evolve until alternative strategies emerge to address societal concerns.

Climate change is another good 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 change the earth's climate. However, there is scientific uncertainty in 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 and 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 living standards and to address 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 treaties. The implications are only now starting to emerge, and will ultimately influence decisions.

2.2 Transparency, Accountability and Public Involvement

Experience shows that where the public⁵ has low tolerance for serious or irreversible harm characterized by scientific uncertainty, a different approach to public engagement is required. Specifically, these situations necessitate a greater degree of transparency, clearer accountability and increased public involvement in decision making to minimize controversy and confusion and help maintain public trust.

In practical terms, an understanding of the “public's tolerance for risks” or “society's chosen level of protection” underpins the need for greater transparency, clearer accountability and increased public involvement. Precautionary decision making is often associated with disputes and, eventually, balancing of values, high economic stakes and urgency. Decision makers recognize that the public generally has a lower tolerance for health and safety risks, the loss of Canada's international reputation or trade position, or the unknown, where impacts are new, unobservable or delayed. On the other hand, the public may have a higher tolerance for risk when there is a sense of more control or more understanding about the nature of the uncertainty and the limitations of science. And such tolerances may change over time, as new information becomes available and as societal values and expectations evolve. In such circumstances, developing workable and socially acceptable solutions becomes extremely complex and challenging.

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Unless otherwise specified, “public” includes the general public, industry, consumer groups, and environmental and other special interest groups, domestically and internationally.

To promote understanding of and trust in the precautionary approach and the scientific basis for its application, stakeholders should be provided with clear, open and transparent information sources about the uncertainties surrounding risk. Moreover, the evolution of risk communication into a two-way sharing of information and the inclusion of both expert and lay perspectives in the decision-making process can become the cornerstone of transparent and effective decisions. A lack of transparency in the information age can eventually undermine the credibility of sound decisions and lead to missed opportunities to counter misinformation.

Where transparency may imply a two-way exchange of information and perspectives, public involvement is evolving towards more interactive, multi-stakeholder engagement of diverse forms of knowledge and experience. Public involvement can provide a platform to resolve conflict or engage in joint problem-solving by a specific set of rules. Importantly, it can bring about the recognition of ambiguities and uncertainties, and promote acceptance that, ultimately, both expert and lay knowledge are relevant. Moreover, it can provide impetus for peer review and an opportunity to receive interpretations on uncertainty and risk from the public.

Precautionary decisions may impose costs on certain segments of society to achieve net benefits for the public good. Public and stakeholder involvement in decision making may lead to consensual outcomes in some cases; however, it can also help reinforce differences of opinion on whether, and how, precaution should be applied to a particular risk. Transparency and openness throughout the process contribute significantly to the eventual success of public involvement strategies.

As regards clearer accountability, the public can gain confidence in both the decision-making process and a resulting decision through ongoing, open and transparent monitoring of the decision's effectiveness, and by receiving regular feedback and being informed of performance measurement results.

2.3 Cost-Effectiveness

There are two distinct issues to consider in relation to cost, both with economic components and broader implications: (i) cost-benefit and the decision as to whether or not to take action, and (ii) the efficiency of potential precautionary measures once a decision to act has been made.

First, when deciding to act or not, a cost-benefit assessment involves identifying and weighing the real and potential impacts of making a decision. However, scientific uncertainty and complex interrelationships (i.e., limited information) may not allow for an extensive cost-benefit analysis. Further, situations of potential serious or irreversible harm often arise unexpectedly, with limited scientific evidence at hand and yet requiring an urgent response. Initially, decision makers will often focus on responding quickly, particularly in situations dealing with health and safety, instead of undertaking an extensive cost-benefit analysis. At a practical level, however, 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.

Second, assessing the efficiency of potential precautionary measures generally involves comparing various policy instruments to determine which options could most efficiently achieve a well-informed and balanced chosen risk tolerance at the least overall cost (considering both long- and short-term costs, as appropriate). This process assumes that there are two or more equally effective proposed measures that could address the risk of serious or irreversible harm. In the end, this process should lead to the selection of measures that would produce an overall lower cost while reducing risks to the chosen level of protection.

Moreover, as the science will evolve, 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, while maintaining the reduction of risks and, where appropriate, maximizing the benefits (e.g., from innovation).

Since there could be numerous potential threats of serious or irreversible harm, decision makers should consider how best to distribute resources efficiently and effectively. They should also consider broader costs and benefits to help ensure that society receives net benefits from decisions (e.g., benefits associated with enhanced health status of children as a segment of the population) and that barriers to innovation or technological change are not unnecessarily introduced.

2.4 Legal Issues

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, these issues include the status of the precautionary approach/principle in international law and the remedies available under international law to promote compliance with it. From a domestic perspective, legal issues include whether the inclusion of the precautionary approach in law automatically creates a positive legal duty to act in the face of a serious threat and how codification affects Crown liability.

In Canada, treaty obligations are implemented through enactments or executive action, while customary rules of international law are automatically a part of the law of the land unless qualified by a contrary enactment. The nature of a treaty obligation will determine the method of implementation, but it is possible to implement international legal obligations in a wide variety of ways. These can range from administrative implementation under previously existing legislative or

policy mandates, to the enactment of regulations or legislation. Ultimately, Canada needs to resort to legislation and regulations only where it is required in order to give effect to the new obligations.

Rules of customary international law are developed by the common consent of States. To establish that a rule has become customary law, a number of factors must be present, including evidence of uniform State practice and evidence that States apply the concept in the belief that they are legally bound to do so under customary international law.

The precautionary principle/approach appears in a large number of international instruments, and Canada's obligations in that regard are governed by its expression in those instruments. 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.

Domestic law can make some contribution to customary international law as an element of State practice. Thus Canada can, through its own State practice, have some influence on whether or not the precautionary principle becomes a rule of customary international law. If the precautionary principle were to attain such a status, it would automatically become part of Canadian domestic law, unless a contrary domestic statute exists. To what extent this would significantly affect current Canadian law, either as a substantive and/or an interpretive rule, is unclear and should be considered further.

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-law.⁶ 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.’”⁷ It is too early to assess fully the impact of this judgment, but the brief discussion of this issue by the majority is likely to be relied on by those who argue that the precautionary principle is already part of customary international law.

If Canada wishes to promote compliance by other States with their obligations to exercise precaution, and to prevent their abuse of this principle, it can make use of various international dispute resolution mechanisms and compliance procedures. Many multilateral environmental

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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).

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Supra, para. 32.

agreements, and most international trade agreements, contain specific recourse mechanisms that allow Canada to promote compliance by other States.

In Canada, two federal statutes, two provincial statutes and several proposed laws make specific reference to the precautionary principle. Several observations are noteworthy in this regard.

First, codification of the precautionary principle in statute will not necessarily create a positive duty on the government to take precautionary action; this will depend on the way in which the principle is codified in the particular statute. If the precautionary approach is to override all other considerations, this will need to be made explicit in the statutory language.

Second, an effect of codifying the precautionary approach in statute is to shift the burden of proof from an intervener, who opposes a proposal because it may threaten serious environmental harm, to the applicant of the proposal, who must then prove that the proposed action or activity will not in fact result in the alleged harm.

Third, where the precautionary principle is codified in statute, its impact on the government's liability will depend on the statute's specific provisions and, in particular, on whether an independent duty of care already exists under that statute. Where a duty of care does exist, the precautionary principle may then impose a higher standard of care on the decision maker, if precaution has not in fact been applied. It should also be noted that any domestic decisions of a regulatory nature, including those based on applying or failing to apply precaution, may give rise to international "liability" if such decisions result in the breach by Canada of one or more of its international obligations.

Fourth, any 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.

Finally, while the use of the expressions "principle" or "approach" to describe the concept of precaution is unlikely to have any significance in domestic law, the choice to use one or the other of these terms could have some influence on the status of precaution as a rule of customary international law.⁸

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In this regard, the majority in the Supreme Court's recent pesticides decision referred to the "precautionary principle" in international law.

2.5 International Considerations

Debate about the precautionary approach is 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 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. Publicity surrounding genetically modified (GM) foods and food safety controversies have led to a significant increase in calls for the application of precaution in food safety and related health regulations. Food safety has been discussed by leaders in the G8 in each of the last three years, and a process for management of the issue through appropriate international bodies (Food and Agriculture Organization (FAO) /World Health Organization (WHO), Codex Alimentarius Commission (CODEX), Organization for Economic Co-operation and Development (OECD), World Trade Organization (WTO) / Sanitary and Phytosanitary (SPS) Agreement) has been established.

In trade, environmental and other international fora, the common denominator in the discussion and development of precautionary approaches is the need to take into account both the imperative that governments retain the ability to regulate in the public interest, and the commercial and economic interests of both domestic and foreign entities.

The application of the precautionary approach by nations or groups of nations has important commercial dimensions. For example, WTO panels on the import of U.S. fruit into Japan and hormone-treated beef into the European Union have raised awareness among nations that abuse of the approach has real trade consequences. At another level, benchmark approaches are emerging as powerful tools to help nations be alert to their relative competitive position in attracting and retaining investment. This continues to be an important consideration for Canada.

Given this, Canada cannot afford to be “tongue-tied.” Domestically, a clear and consistent framework for applying the precautionary approach to decision making would help the federal government meet its responsibilities in a manner that takes account of a wide range of stakeholder interests. Internationally, such a framework would give Canadian officials a firmer basis to more actively engage in the discussion on the precautionary approach in a clear, coherent and consistent manner. The subject will continue to be discussed and debated in a variety of negotiating and non-negotiating fora. Canada should ensure that international rules are shaped in a way that respects Canadian interests, which will in turn often require Canada to be able to work with other like-minded countries.

Decision makers must be alert to the consequences of the precautionary approach acquiring the status of a rule of customary international law. If Canada were to decide that precaution should evolve to become a rule of customary international law, it would be important to seek to shape that

rule so as to embrace criteria sufficient to enable Canada to determine, with a reasonable degree of precision, its obligations.

Thus, from an international perspective, it is imperative that we develop a firm view on the precautionary approach in Canada, that we use the results of this work to engage actively internationally, and that we explore and test to what extent specific formulations contained in existing international instruments could be applied more generally in various fields such as health, safety, the environment and resource conservation.

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 appropriate or acceptable level of protection (ALP), also referred to as ‘risk tolerance’ levels;
- , setting out clearly the threshold of harm that would trigger precautionary measures;
- , distinguishing between a routine and an emergency situation;
- , creating an obligation to use the least trade-restrictive measures;
- , establishing and assigning the 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 discussion 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.

1. 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?
2. 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?
3. Would the principles achieve the goal of preventing misuse or abuse (misinterpretation, misapplication) when implementing the precautionary approach?
4. 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?
5. 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 briefer exposé on the proposed guiding principles, “A Canadian Perspective on the Precautionary Approach/Principle — Proposed Guiding Principles,” September 2001; the second is a backgrounder on the precautionary approach, both of which may be obtained through the departments listed below or their Web site. 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