The Precautionary Principle, Risk-Related Decision Making, and Science Capacity in Federal Science-Based Regulatory Departments: A Discussion Document

Working Paper No. 4
Science Policy Branch
Environment Canada

Document de travail n° 4
Direction de la politique scientifique
Environnement Canada

Working Papers *are interim reports on work of the Science Policy Branch, Environment Canada. They have received only limited review. These reports are made available, in small numbers, in order to disseminate the studies, promote discussion and stimulate further policy studies.*

Les ***documents de travail*** *sont des rapports intérimaires sur le travail effectué par la Direction de la politique scientifique, Environnement Canada. Ils n'ont été examinés que de façon limitée. Ces rapports sont distribués en nombre restreint pour diffuser les études, promouvoir la discussion et favoriser la réalisation d'autres études d'orientations.*

Views or opinions expressed herein do not necessarily represent those of Environment Canada or of the federal government.

Les opinions exprimés dans ce document de travail ne reflètent pas nécessairement celles d'Environnement Canada ou du gouvernement fédéral.

Comments or questions should be addressed to:

Director
Science Policy Branch
Environment Canada
7th floor
351 St-Joseph Boulevard
Hull, Quebec K1A 0H3

Telephone: (819) 953 9610

Veuillez transmettre vos questions ou commentaires au :

Directeur
Direction de la politique scientifique
Environnement Canada
7e étage
351, boul. St-Joseph
Hull (Québec) K1A 0H3

Téléphone : (819) 953-9610

The Precautionary Principle, Risk-Related Decision Making, and Science Capacity in Federal Science-Based Regulatory Departments

Discussion Document for the Assistant Deputy Minister Committee on Risk Management

June 1, 1999

Richard Isnor &
Ian Shugart

CONTENTS

Introduction

The federal government's ability to implement the precautionary principle, as part of its efforts to assess and manage risk, has been put through significant tests over the past decade. The increasing role of science-based risk assessment coupled with public demand for governments to implement the precautionary principle will require the federal government to come to a better understanding of the characteristics of the precautionary principle, how this concept relates to risk assessment and management, and the science capacity needs associated with its effective implementation. While the types of specific actions, and related scientific activities, needed to put the precautionary principle into practice have not yet been fully identified, a key purpose of this paper is to provide a brief analysis of the precautionary principle and science-based risk assessment in order to focus an appropriate degree of attention on the issue of science capacity in science-based federal regulatory departments and agencies.

What Is the Precautionary Principle?

Several definitions of both the *precautionary principle* and the *precautionary approach* have been espoused in different fora. While these definitions vary somewhat depending upon the nature of the situation to which they are intended to apply, they generally hold true to a common central tenet, that:

> *where there are threats of serious or irreversible damage or harm, lack of full scientific certainty shall not be used as a reason for postponing responsive actions.*

Key words which appear in different definitions suggest that while there is a common linguistic discourse related to the precautionary principle and enough international consensus to make it a real policy concern, there are also subtle differences in points of emphasis which have prevented the emergence of a single internationally accepted definition.

For example, the Rio Declaration of 1992 referred to the precautionary approach, and focused on the need to take cost-effective measures to prevent environmental degradation in the absence of scientific certainty. The European Court of Justice ruling on the ban of U.K. beef, on the other hand, produced a far more stringent interpretation, noting that even where there is uncertainty as to the existence of (theoretical) risks to human health, protective measures should be taken without having to wait until the reality of such risks is proven. To a certain extent, therefore, definitions of the precautionary principle adopted for different policy applications reflect value judgments related to the need for differing degrees of stringency in application. To date, definitions for application to potential risks to public health and safety have tended to be more stringent than those being applied to environmental protection or resource conservation. A key concern with respect to the implementation of the precautionary principle across the federal government, therefore, concerns the *threshold* which triggers its applicability.

Some Definitions of the Precautionary Principle (emphasis added in bold)

The Rio Declaration (1992):

*In order to protect the environment, the precautionary **approach** shall be widely applied by States according to their capabilities. 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.*

European Union (1997):

The precautionary principle is a risk management approach that is exercised in a situation of scientific uncertainty, reflecting a need for action in the case of a potentially serious risk, without awaiting the results of scientific research.

European Court of Justice Ruling on Ban of U.K. Beef (BSE):

*Where there is uncertainty as to the **existence or extent** of risks to human health, the Commission may take protective measures without having to wait until the **reality and seriousness** of those risks become apparent.*

Krever Commission:

*Action to **reduce** risk should not await scientific certainty. When there was **reasonable evidence** that serious infectious diseases could be transmitted by blood, …refrained from taking **essential preventative** measures until causation had been proven with scientific certainty.*

Fisheries Resource Conservation Council (1997) Conservation Framework:

*[The Council] urges fisheries conservation approaches that are **prudent** and holds that it should not be necessary to await **final scientific analysis** before taking conservation measures. It should be enough, that, on the **balance** of evidence, **it makes sense** to take action.*

Women's Health Forum (1996):

*The precautionary principle of environmental health urges action prior to absolute proof of harm when there is **strong indication** from **more than one scientific discipline and study** that a substance is harmful, and when the consequences of not acting can be fatal.*

Clearing Up Misconceptions Regarding the Precautionary Principle

The implementation challenge related to the precautionary principle stems from the varying interpretations of its meaning. Some interpretations have taken a strict approach, creating expectations that decision makers will act to prevent any possibility of risk to public health or safety, despite the strength of the scientific case (as well as related factors, socio-economic, political or otherwise) for or against such action. Such radical or restrictive interpretations, however, have generally been deemed impractical and unworkable from a public policy or decision-making perspective. Implementation of the precautionary principle requires a significant investment in science capacity in order to provide the best available scientific information upon which public policy and regulatory decisions can be made, as well as the capacity to determine whether precautionary actions taken at a specific point in time need to be revisited and revised in the future.

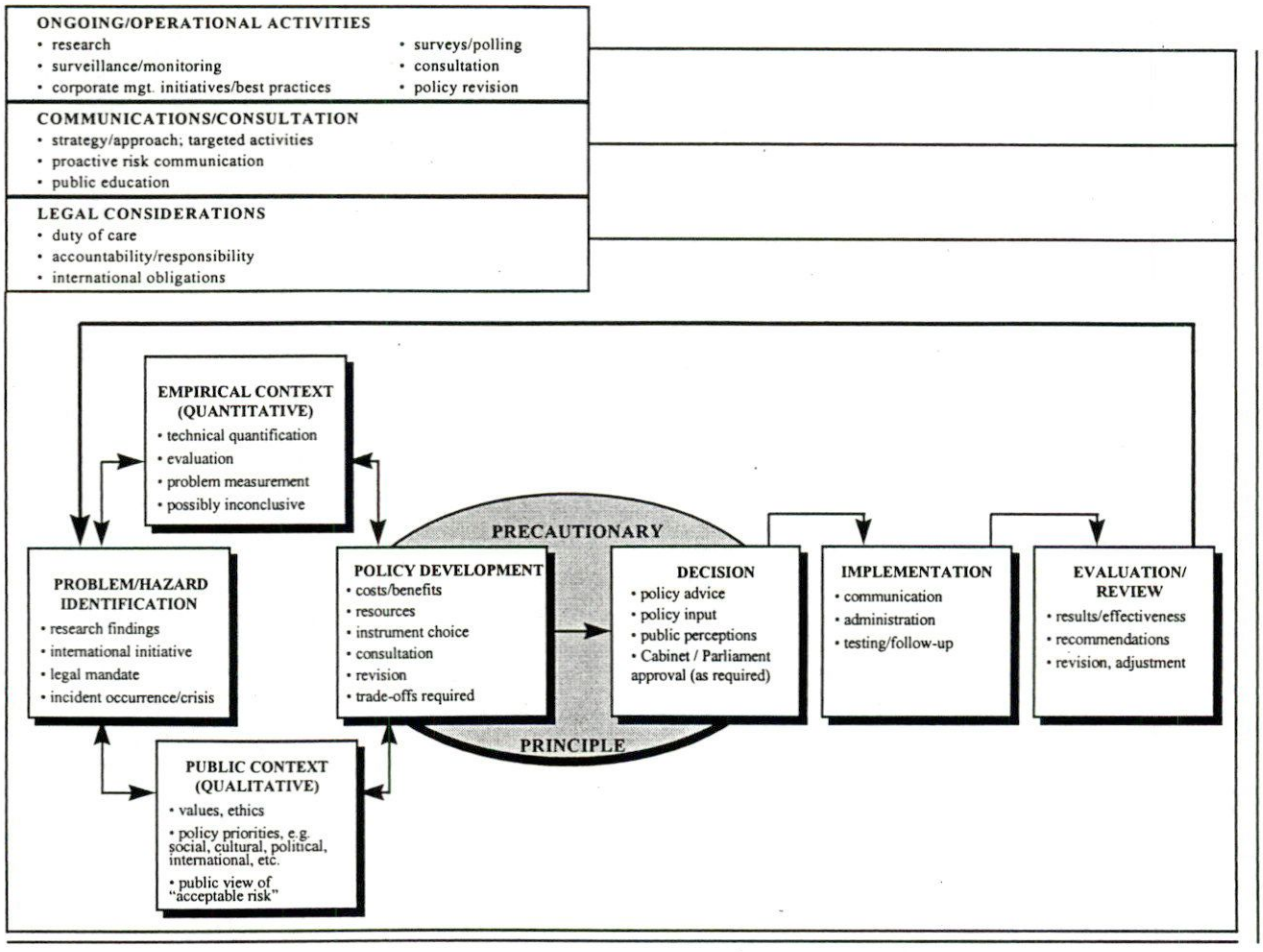
Relationship to Risk Management

The precautionary principle is not the same as risk management but is consistent with decision making needed to manage risks. The literature on risk assessment, risk management and the precautionary principle tends to portray two somewhat distinct approaches — one based on risk management, the other on the precautionary principle. The implementation of the precautionary principle can be interpreted as a form of risk management which is explicitly related to scientific activities (both prior to and following the decision) and which can include risk assessment (Figure 1). While relying strongly on the risk assessment function, however, the implementation of the precautionary principle places greater onus on the decision-making function (i.e. management) than the assessment function.

The effective and practical implementation of the precautionary principle needs to start with an objective risk assessment which fully identifies degrees of scientific certainty. Decisions not to act can also be made on the basis of objective and transparent risk assessments; however, such decisions should be accompanied by an objective assessment of the potential consequences of the decision not to act (as well as efforts to accelerate the generation of scientific knowledge that is needed). The decision not to act can also embrace a precautionary approach by regular revisiting of the risk assessment in light of new scientific information produced by accelerated efforts in specific areas of interest.

The European Union has explicitly resolved the confusion by defining the precautionary principle as a *risk management approach that is exercised in a situation of scientific uncertainty, reflecting a need for action in the case of a potentially serious risk, without awaiting the results of scientific research.* The European Union, moreover, has also developed a series of guidelines that are being used to embrace the precautionary principle, while respecting the need for transparent risk assessments upon which sound decision making can be based. An abbreviated summary of, and commentary on, these guidelines is contained in Appendix II.

Figure 1. Public Risk Management and Decision Making



Relationship to Duty of Care

The precautionary principle is not the same as duty of care but is dependent upon duty of care and often supplements it. The elements which must be established by a plaintiff in a claim of negligence in common law against the Crown are the following: 1) that he or she was owed a "duty of care" by the Crown; 2) that the Crown should have observed a particular standard of care in order to perform or fulfil that duty; 3) that the Crown was in breach of its duty; 4) that the breach of duty caused damage or loss to the plaintiff; and 5) that such damage was not too remote a consequence of action.

The question of whether the Crown is liable in a given case may be affected by the type of action the Crown was involved in when the alleged negligence occurred. On this issue, the courts have attempted to draw a line of distinction between policy and operations. Although the courts have drawn this line, they have experienced difficulties distinguishing between policy and operational decisions. Policy decisions are interpreted as being made in the course of governing and are not supposed to attract liability, whereas operations (i.e. providing a service to carry out a government function) can attract liability. In practice,

operations and policy overlap and interact, and trying to separate operational from policy decisions can be a significant challenge.

The common law does recognize factual situations where a duty of care specifically translates into a duty to notify or warn individuals or classes of persons of potential harm, thereby signalling the explicit and mutually reinforcing relationship between duty of care and the precautionary principle. In such instances, the failure to provide the required notification or warning would constitute actionable negligence, where harm is suffered that could otherwise have been avoided, or at least mitigated had the warning been given.

With respect to regulatory enforcement, the Supreme Court of Canada has rendered a number of relevant decisions related to duty of care. These include:

- regulatory enforcement and inspection activities should be treated as operational rather than policy decisions and as such may be subject to close judicial scrutiny whenever beneficiaries of a regulatory program claim to have suffered damage as a result of careless implementation or enforcement;

- in determining whether departments have been negligent, the courts will assess their regulatory inspection and enforcement activities against a general standard of *reasonableness*; and

- in actions for civil damages based on failure to implement a regulatory program, lack of resources no longer provides a conclusive defence.

Having to deal with the unintended consequences of processes, products and technologies already in use can be considered to be beyond the ambit of the precautionary principle. However, scientific evidence that shows such unintended consequences does trigger the obligation of government to utilize transparent and accountable processes involving key stakeholders to revisit the use of existing processes, products and technologies to determine whether appropriate alternatives are necessary. A precautionary approach, moreover, must take into account not only risks for the current generation, but also risks to future generations.

Lessons from the Krever Commission

The recommendations derived from the Commission of Inquiry on the Blood System in Canada (the Krever Commission) reinforced the accountabilities of Health Canada and other institutions involved in the Canadian blood system and drew attention to the required duty of care for the Minister of Health. The Krever Commission was established in October 1993 to review the mandate, organization, management, operations, financing and regulation of all activities of the blood system in Canada. The recommendations contained in the final report of the Krever Commission were intended to be generalized and applicable to other health programs. They can also be extrapolated and applied to other issues affecting public health and safety, as well as protection of the environment. The Krever Report has since become somewhat of a benchmark for science-based regulatory

departments. Some of the key lessons include:

- not awaiting scientific certainty before taking action to reduce risk;
- acting (at all times) at arm's length from the organizations being regulated;
- not delegating functions to others or relying on consensus decision making as a substitute for independent judgment;
- not relying solely on, or deferring to, manufacturers for information, expertise and judgment, but self-generating or seeking independent scientific information and advice; and
- not assuming a passive or responsive role, or relying on a philosophy of voluntary compliance, to protect Canadians.

Krever found that the single most important factor determining whether a regulator will perform its functions adequately is whether it is given sufficient resources to do so. A critical concern, given the inevitable financial constraints in the public sector, is whether public agencies can meet the duties spelled out by legislation or the standards of care imposed by public expectations. The most appropriate means to address this concern is to determine the identified capacity gaps in relation to health and safety duties. Assessing capacity gaps enables one to determine if due diligence or reasonable standards are being attained or met and where potential weaknesses exist.

Implications for Federal Scientists

Some federal scientists are under the impression that duty of care, coupled with the implications of recent cases related to the precautionary principle (e.g. the Krever Commission), could lead to situations in which they could be held personally responsible for failing to take action in a "situation of concern" where science is not yet definite. The Krever recommendations, for example, arose from a context where there was an expectation that government would protect the health of Canadians. A negligent failure in the execution of this function caused damage and resulted in liability.

The federal government scientist's duty, however, is to carry out research in a proper manner and to ensure that research results are reported to appropriate individuals or sections. Furthermore, a federal scientist has a duty to flag findings or observations of concern when these findings raise the possibility of future harm or adverse risk. The scientist and/or the science manager might also make recommendations concerning next steps and the level of urgency associated with the concern.

Federal science managers are responsible for ensuring that scientific activities are being carried out properly and that priority research questions are being addressed. If a situation of concern has been brought to the attention of decision makers via their scientific personnel (e.g. via a scientist or a science manager), it is the decision makers'

responsibility to decide whether to allocate resources to address it, or to attempt to obtain additional resources to pursue it further. Depending on the nature of the concern, the scientist and/or science manager may wish to follow up (e.g. if the situation of concern has been flagged "urgent," it would be appropriate to ask what has been decided and/or done). If more resources are required and are not forthcoming, it is the science manager's duty to advise decision makers of the potential consequences of not following up on the situation of concern.

As a result, the role of science with respect to the precautionary principle is tied integrally to the question of how science advice is provided, transferred and utilized within public regulatory agencies. Scientists or technicians are usually not the target of criticism. Liability, instead, is usually targeted at officials (or institutional mechanisms) that ignore or fail to act on the early warnings provided by scientists. This speaks to the issue of vigilance, and whether decision makers have been vigilant in acting upon the advice of their scientists and scientific managers. Complicating matters for science managers and decision makers is the issue of how to resolve and handle scientific disputes which would result in different decisions or policy stances. Taking a precautionary approach would suggest that erring on the side of caution in such situations would negate any potential for liability. Moreover, individual scientists who carry out their work according to recognized scientific procedures could not be held responsible for the type of decision-making failure which has raised interest in the precautionary principle.

Implications for Science-Based Regulatory Departments

The implementation of the precautionary principle is often linked most explicitly to risk assessment and risk management processes in science-based regulatory departments such as Health Canada, Environment Canada, and Fisheries and Oceans Canada. However, the application of the precautionary principle also extends into other federal departments and agencies, such as Transport Canada, the National Parole Board, and the Department of Finance, which all have "risk management" responsibilities in the broader context of good governance for the public good. Despite the lack of a single definition, the precautionary principle implies that all federal departments will impose a reasonable and diligent standard of action to minimize risk.

Increased interest in the precautionary principle is generally related to its potential for avoiding problems that become costly to rectify after harm has occurred or public confidence has been shaken. While scientific culture tends to avoid the presentation of premature judgments, it is important for science to continue providing information which can be used in a transparent way as a basis for risk management decisions.

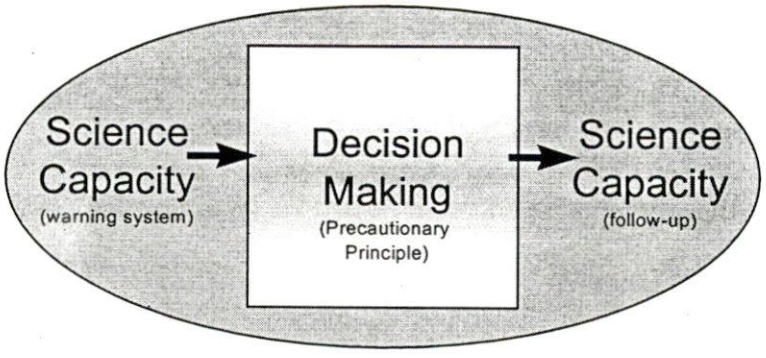
Science-based risk assessment is an important part of how risk is addressed by the federal government. The goal of such risk assessment is to reduce the uncertainty about a particular problem — its effects, how it will work, how beneficial or dangerous it will be in different circumstances and so on. Because many considerations are taken into account in deciding what to do about a problem, risk assessment is generally considered to be separate from risk management. It is important to clearly demonstrate responsibilities, especially with respect to science-based risk assessment (where specialized skills and

professional judgment are relied upon to reduce uncertainty) versus risk management, which is a form of decision making that is separate from risk assessment. Scientific resources involved in risk assessment are not usually involved in the ultimate decision making about a proper course of action to manage risk. The implementation of the precautionary principle, therefore, is ultimately a risk management decision process — it is a policy decision to take preventive action.

The precautionary principle implies the capacity to carry out certain science-based functions as well as the capacity to make decisions. It also implies an obligation for the government to assess its capacity to conduct relevant scientific activities and make decisions. While public sector scientists are not directly responsible for implementing the precautionary principle, just as they are not responsible for taking other forms of risk management action on behalf of the government, the precautionary principle does raise key implications for public sector scientists and science managers. Scientists and science managers are required to provide an effective early-warning system and sometimes need to work outside traditional scientific convention by raising issues requiring regulatory or other mitigative action before scientific certainty about cause-effect relationships has been established. Once precautionary decisions have been taken as a risk management function, moreover, an expectation is immediately created for scientific investigation to reduce the uncertainty associated with the issue in question and determine whether the risk management decision needs revision or reinforcement. Continuous provision of information about risk management decisions goes a long way toward giving the public confidence that public authorities know what they are doing and can continue to be trusted to act in the public interest.

The precautionary principle, therefore, raises significant institutional organization and resource issues related to science capacity which can involve resource allocation and re-allocation. Personnel and financial resources currently dedicated to scientific investigation, risk assessment and problem mitigation may need to be supplemented by proactive early-warning scientific and responsive regulatory activities. This requires the government to maintain a strong and flexible scientific capacity capable of providing the early-warning system needed by the public. Moreover, it requires the government to maintain a scientific capacity which can be mobilized to address issues of scientific uncertainty where decision making has already taken place. Therefore, scientific assessment and decision making are not finished after precautionary measures have been taken (Figure 2).

Figure 2. Key Relationships Between Science Capacity and Risk-Related Decision Making



Evolving Institutional Frameworks for Scientific Knowledge Production

Science-based regulatory departments also have to be concerned about the evolving institutional framework for knowledge production and how this will affect their ability to maintain public credibility for assessing risks and implementing the precautionary principle. The institutional and cultural aspects of scientific knowledge production are currently undergoing radical and fundamental change which is far from complete. New structures are being shaped by dynamics between external forces exerted by society and internal pressures intrinsic to science itself. Public authorities have had to improvise in order to adapt to these changes. Government is no longer the dominant producer of knowledge, and science is now a widely diverse activity being performed by a broad range of non-traditional institutions.

As a result of these changes, scientific information is much more readily available, and its distribution to the public is aided by new information technologies and the Internet. This has led to the use of advocacy science and, in some cases, the misuse (abuse) of scientific information. At the same time, the social accountability of scientific knowledge-producing systems is growing. There is a concomitant demand on governments to ensure the quality control of scientific information used to protect the public's interests in areas such as public health and safety, and protection of the environment. Moreover, having suitable science capacity does not mean that government departments have to conduct all scientific activities needed to act decisively. Governments can make use of external expert panels such as the Royal Society Panel, which recently provided an expert opinion regarding the public health risks from the use of cell phones.

Domestic and international science collaboration is increasing, and governments have to be part of such collaboration. All of these developments concern the issue of science capacity. Government departments are increasingly under pressure, not least from other scientific institutions such as universities, to justify their role in the national science system. As a result, science capacity analysis has to be clearly focused on the need for federal science to support sound decision making in the public interest, and has to enable government scientists to act when necessary as strategic partners in local, regional,

national and international scientific activities that will generate knowledge that could be used for decision making for the public good.

Implementing the precautionary principle, with related attention to transparency, does not mean that all federal scientific inquiry needs to be subject to a democratic needs assessment. Under a precautionary approach, scientific specialization is still required in order to generate new knowledge. Science has to serve to continuously generate new knowledge, both to initiate precautionary action and to establish certainty once precautionary actions have been taken.

Although the courts indicate that they will not recognize lack of resources as an excuse for failure to exercise duty of care, the Krever Commission found that the single most important factor determining whether a regulator will perform its functions adequately is whether it is given sufficient resources to do so. This has direct implications for science capacity within science-based regulatory departments. A critical concern, given financial constraints in the public sector, is whether public agencies can meet public expectations with respect to knowledge production and use of this knowledge in decision making. Assessing and addressing critical gaps in the knowledge-producing capacity needed to support risk assessment and implementation of the precautionary principle will need to become a more routine practice in science-based regulatory departments. Science scans and priority setting, as well as regular reviews of federal risk management decisions, can be important tools for evaluating science capacity needs against the need to implement the precautionary principle. Moreover, commitment to implement the precautionary principle automatically creates a need for science capacity itself to become the object of scrutiny, analysis and decision making within federal science departments and agencies.

Summary

Conceptually, the precautionary principle hinges on the availability of conclusive scientific evidence (or lack thereof). This does not negate the need for science; rather, it poses a new challenge to scientists and calls upon them to play a key role in a broader conceptual and decision-making framework.

Several of the challenges currently being faced by science-based regulatory departments with respect to risk assessment and the provision of scientific information to support application of the precautionary principle can be linked to the issue of science capacity. Departments are expected to play a stronger scientific role in providing an early-warning system by forming strategic domestic and international research partnerships. Departments are also expected to provide a credible source of unbiased and reliable scientific expertise in the new knowledge-producing system, which is increasingly diversified and advocacy-oriented. Science-based departments must be proactive in their championing of strategic and well-managed collaborative scientific endeavours that tackle problems of high priority to society. Finally, science-based departments are expected to direct scientific efforts toward areas where precautionary action has (or has not) been put in place, in order to generate a stronger scientific basis for risk assessment and related risk management decision making. More routine and strategic assessments of science capacity within departments will become necessary in order to assess whether a sufficient

early-warning system and post-decision scientific response system is in place for specific areas.

The precautionary principle creates several challenges for federal scientists. While scientists are not expected to play a decision-making role, they do need to be proactive in alerting decision makers to early potential risks which should be the focus of precautionary action, or to precautionary-based decisions which need to be revisited in light of new evidence. Although scientists carry neither the full burden of decision making nor the full authority to make decisions regarding risk management, the discipline and ethics of science are under pressure to become more compatible with the precautionary principle. Scientists and science culture need to explore new mechanisms which might be useful for resolving scientific disputes as well as for dealing with the misuse of scientific information.

Issues for Discussion

- Definition of the precautionary principle. Is it possible for the federal government to agree on a common definition?

- The threshold trigger for applicability of the precautionary principle. Would different federal departments require different thresholds (related to differing mandates and underlying values) that would trigger the precautionary principle?

- Federal guidelines for the application of the precautionary principle. Should the federal government develop such guidelines (along the lines of the European Union guidelines) or ask a key advisory committee (e.g. the Council of Science and Technology Advisors) to develop a draft set of guidelines for consideration?

- Dealing with transparency. How far is the federal government prepared to go regarding the transparency of overall decision making with respect to the precautionary principle? (This raises important questions related to capacity and communications.)

Appendix I: History, Scope and Spectrum of Meanings of the Precautionary Principle

The precautionary principle emerged in German national law as the *Vorsorgeprinzip*, usually translated as the "precaution" or "foresight" principle. As enunciated in 1976 by the federal government in Germany, "Environmental policy is not fully accomplished by warding off imminent hazards and the elimination of damage which has occurred. Precautionary environmental policy requires furthermore that natural resources are protected and demands on them are made with care."

The precautionary principle entered the international stage in the context of marine pollution control through the 1987 Ministerial Declaration of the Second Conference on the Protection of the North Sea. The focus was on toxic substances, and the required control measures were left rather open-ended:

> *[The participants] accept the principle of safeguarding the marine ecosystem of the North Sea by reducing polluting emissions of substances that are persistent, toxic and liable to bioaccumulate at source, by the use of the best available technology and other appropriate measures. This applies especially when there is reason to assume that certain damage or harmful effects on the living resources of the sea are likely to be caused by such substances, even where there is no scientific evidence to prove a causal link between emissions and effects ("the principle of precautionary action").*

The precautionary principle was subsequently adopted into numerous multilateral treaties and international declarations. Treaties articulating the precautionary approach include the 1987 Montreal Protocol on Substances that Deplete the Ozone Layer, the 1992 Convention on Biological Diversity, the 1992 Climate Change Convention, the 1992 Treaty on European Union, the 1992 Convention for the Protection of the Marine Environment of the North-East Atlantic and the 1992 Helsinki Convention, dealing with protection of the marine environment of the Baltic. Parties to the London Convention 1972, governing the control of ocean dumping, embraced the precautionary approach in 1991 through a resolution. International declarations containing the precautionary principle include the 1990 Bergen Declaration, issued by ministerial representatives from European countries (as well as Canada), and the 1992 Rio Declaration on Environment and Development.

The International Joint Commission (IJC), composed of U.S. and Canadian representatives, has also called for a precautionary approach to controlling chemical pollution of the Great Lakes. In its Seventh Biennial Report on Great Lakes Water Quality, the IJC called for the virtual elimination of various persistent toxic substances and the imposition of a reverse onus approach on chemical producers and users.

Some international conventions and statements limit the scope of the precautionary principle to toxic substances control and even more specifically to those toxic substances that are persistent and liable to bioaccumulate. For example, the Final Declaration of the Third North Sea Conference provides:

[The participants] will continue to apply the precautionary principle, that is to take action to avoid potentially dangerous impacts of substances that are persistent, toxic and liable to bioaccumulate even when there is no scientific evidence to prove a causal link between emissions and effects.

The precautionary principle has also been expanded to cover all government policies with the potential to degrade the environment. The Bergen Declaration states:

In order to achieve sustainable development, policies must be based on the precautionary principle. Environmental measures must anticipate, prevent and attack the causes of environmental degradation. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation.

The precautionary principle or approach has recently been extended to cover various resource extraction activities and ecosystem protection in general. The approach has emerged in the fields of fisheries management and forestry management. The Biodiversity Convention implicitly includes the principle in the Preamble:

[W]here there is a threat of significant reduction in loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat.

The practical implications of the precautionary approach have perhaps become most clear in the context of ocean dumping. For example, the precautionary approach, adopted in 1991 at the Fourteenth Consultative Meeting of Contracting Parties to the London Convention, has been behind recent decisions by the parties to the Convention to ban incineration of liquid noxious substances at sea, to ban dumping of radioactive substances at sea, and to phase out ocean dumping of industrial wastes by the end of 1995. A "reverse listing" approach is being discussed for possible inclusion in an amended Convention. Rather than allowing substances to be dumped, except when prohibited through lists of restricted substances, the Convention could impose general prohibitions on ocean dumping, with listed exceptions. A Waste Assessment Framework (WAF) has also been adopted since 1992 in harmony with the precautionary approach. The WAF involves prior environmental assessment of ocean-dumping proposals and includes requirements for waste audits and consideration of waste management alternatives.

Outside the ocean dumping context, the precautionary principle or approach has been more elusive. Varying thresholds for triggering the principle's application have evolved. For example, the London Convention 1972 and North Sea Ministerial Conferences followed a "likely to cause harm" threshold, whereas the 1992 Rio Declaration requires an indication of serious or irreversible damage. Principle 15 of the Declaration provides:

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. 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.

Most phrasings of the precautionary principle are utilitarian, allowing for some environmental trade-offs in the name of economic development and socio-economic benefits. The Rio Declaration demonstrates a utilitarian angle through its reference to "cost-effective measures." One of the most confusing areas relating to the precautionary principle is whether cost-benefit or risk-benefit analysis is considered within the ambit of the principle and, if so, the effects of a precautionary approach on the weighing process. Some authors consider the precautionary principle to be separate from risk-benefit or cost-benefit analysis and view such utilitarian approaches as depending on a rationality or scientific certainty that often is not present. Others appear to envisage risk-benefit or cost-benefit analysis as embraced by the precautionary principle but see the precautionary approach as giving greater weight to the risk or potential cost side of the equation.

Appendix II: Summary of European Union Guidelines for Application of the Precautionary Principle

Guidelines can be used to lay down the general conditions which support an approach based on the application of the precautionary principle. Without being legally binding, such guidelines should provide direction for decision makers so that they can base decisions on a reasonable application of the precautionary principle. Following is the text of guidelines for application of the precautionary principle established by the European Union, as well as a brief set of bullets containing commentary on each:

1. *The implementation of an approach based on the precautionary principle should start with an objective risk assessment identifying the degree of scientific uncertainty at each stage.*

- This guideline is valid. It highlights the need for the risk assessment process to be protected as distinct from the decision-making process. Once the risk assessment has been performed, it must be used as a basis for triggering a decision to act or not act. The conclusions of the assessment must show that there is a sufficiently serious potential hazard, with possible irreversible effects, for a population group or for ecosystem health. The conclusions must also include an assessment of the scientific uncertainties and a description of the hypotheses used to compensate for the lack of scientific or statistical data.

2. *All relevant stakeholders should be involved in the decision to study the various decision or management options that may be considered once the results of the risk assessment are available. This procedure needs to be as transparent as possible.*

- An objective assessment of the potential consequences of a non-decision or a decision not to act should be undertaken. However, where there is third-party interest, it may be prudent to avoid giving equal weight to all stakeholders. One of the lessons from the Krever Commission was that the public authority has a unique requirement to act in the public's interest. This EU guideline possibly represents the more corporatist viewpoint found in EU politics versus the Canadian and U.S. experience. Nevertheless, all relevant stakeholders should be involved in a transparent process to study the various risk management options available (as well as the assessment of potential consequences of a non-decision or decision not to act) once the results of a risk assessment are accessible.

3. *Measures based on the precautionary principle must include a cost/benefit assessment (advantages and disadvantages) in order to reduce the risk to a level that is acceptable to all stakeholders.*

- Decision making based on the precautionary principle does not necessarily absolve decision makers from the duty of performing cost-benefit analysis or an evaluation of

the advantages and disadvantages of the different options envisaged before a decision is made. The key challenge, of course, is that classic cost-benefit analysis often aims for quantification, which is not possible for key values involved in implementation of the precautionary principle. As a result, there is a need to focus on the transparency of the decision-making process. The arguments for and against a potential decision should be made fully known. However, the public authority must be able to satisfy itself and the public, rather than all key stakeholders, that a suitable decision has been made after consideration of all factors.

4. *Measures based on the precautionary principle must establish responsibility for furnishing scientific evidence required for a full risk assessment.*

- When there are enough scientific data for there to be sufficient concern about the existence of a risk, but insufficient information to fully assess the risk, it is necessary to try to fill gaps in knowledge in order to improve risk assessment, while relying on the precautionary principle in order to take preventive measures to reduce the risk. This guideline speaks to the need for governments to ensure adequate science capacity to make appropriate decisions in the public interest, as well as the need for governments to assess their ability to appraise their science capacity.

5. *Measures based on the precautionary principle must always be of a provisional nature, pending the results of scientific research performed to furnish the missing data and performance of more objective risk assessment.*

- Decisions made to implement precautionary principle measures should not be seen as definitive but rather as provisional, pending more detailed scientific data. Scientific assessment and decision making are not finished once a decision has been made. In practice, the temporary nature of precautionary measures should be set out in text that demonstrates the limited time span or stipulates a deadline for re-evaluation.

- It is also important that consistency be applied in the interpretation of the threshold for precautionary decision making where different departments share responsibility for jointly implementing single pieces of legislation (e.g. *Canadian Environmental Protection Act*; *Fisheries Act*).

- When precautionary decisions are taken, related scientific activities must be undertaken or accelerated to obtain the scientific information or consensus needed for more objective reassessments of risk. During the application of precautionary measures, it should be possible to demonstrate that scientific research is being performed to better characterize the issue for which the measures were put in place. The goals and nature of such research must be consistent with the scientific uncertainties which exist.

- Precautionary measures (including the decision not to act) must be re-examined and if necessary modified to accommodate the results of evolving scientific information.

Budgetary constraints or political priorities should not be invoked to justify excessive delays in obtaining additional scientific information, reassessing the risk in light of new scientific evidence, or modifying provisional measures. Application of the precautionary principle must be accompanied by the corresponding analysis of science capacity needed to provide post-decision scientific information and reassessment.

6. *Measures based on the precautionary principle must be proportionate to the risk which is to be limited or eliminated.*

- This guideline relates to the issue of values (i.e. the threshold issue) underlying the need for decisions which limit risk. While a certain level of risk protection must be assured across the government in order to maintain credibility and trust with the public, measures to reduce risk should take into consideration all options which would afford an equal degree of protection, while providing flexibility and demonstrating a level of balance with respect to the potential risk. This guideline recognizes a continuum of gravity associated with the stringency of application of the precautionary principle. The degree of proportionality is related to a measure of reasonableness. Reasonableness leads to proportionality of the decision-making response.

Science Policy Branch - Environment Canada

Working Paper Series

#1 *Environment Canada's Scientific Research Publications in 1995*

#2 *Science for Sustainable Development*

#3 *Communicating Science at Environment Canada: A Brief Review of Lessons Learned from Communications on Acid Rain and the Depletion of the Stratospheric Ozone Layer*

#4 *The Precautionary Principle, Risk-Related Decision Making, and Science Capacity in Federal Science-Based Regulatory Departments: A Discussion Document*

#5 *Strengthening Environmental Research in Canada: A Discussion Paper*

#6 *Environment Canada's Scientific Research Publications 1980-1997*

#7 *Research & Development and Related Science Activities in Environment Canada*

#8 *Measuring The Impacts Of Environment Canada's R&D: A Case Study of Pulp & Paper Effluent Research*

#9 *Measuring The Impacts Of Environment Canada's R&D: A Case Study of Stratospheric Ozone Depletion Research*