APPLYING PRECAUTION IN ENVIRONMENTAL DECISION-MAKING IN CANADA

Final Report of the New Directions Group Precaution Project Team

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A. Our Approach to Precaution

The New Directions Group (NDG) provides a forum for the interaction of leaders from the business and NGO communities on significant sustainability issues. Corporate and NGO participants in this project (the NDG Precaution team) came together because they had shared concerns and in some cases clear differences as to how the precautionary principle or the precautionary approach (consolidated into the term "Precaution" for the purposes of this project) ought to be applied in a Canadian context, particularly as it relates to environmental decision-making in Canada.

The scope and application of Precaution is a matter of considerable debate and controversy, domestically and internationally. It is not a new concept and precautionary measures have been widely applied at the political and regulatory level in Canada. Canada's response to the SARS crisis and to the discovery of BSE in a cow in northern Alberta, pre-market risk assessments for products such as pesticides, and the incorporation of safety margins in regulatory risk assessments to compensate for lack of full scientific certainty are examples in which Precaution has been integrated into the decision-making process. The procedures and protocols for applying precautionary measures vary from one regulatory system to the next, and from case to case, however, and often lack transparency or predictability. The debate has thus shifted in recent years from whether Precaution is an acceptable policy response to how the concept ought to be codified in policy, regulation and decision-making processes, particularly to address situations in which there is high potential risk and high scientific uncertainty.

A.1 Defining Precaution

Very early in the discussions the NDG Precaution team decided that it would not debate a definition of Precaution, realizing that an abstract discussion might actually impede efforts to characterize the application of Precaution as an operational aspect of decision-making. The intent of the dialogue was principally to foster improved understanding among participants of the issues, opportunities and barriers in implementing Precaution in Canada. Participants acknowledged that conflicts over the application of Precaution seldom arise from a black-and-white dichotomy between commercial interests and societal values and often have more to do with reconciling competing societal values and bridging differing perspectives on what constitutes the public interest (e.g., the choice between the use of persistent, bioaccumulative and toxic flame-retardants in fabrics and the desire to reduce fire risks). A short bibliography of reference material used by the NDG Precaution team in their discussions is attached as Appendix I.

Despite the lack of a definition, members of the NDG Precaution team described a number of desirable characteristics of decision-making processes that reflect Precaution. Some of these are highlighted below.

Precaution includes:

- speeding up the decision-making process to ensure timely action in situations of high scientific uncertainty and potentially high risk;
- providing a process for addressing issues of concern for which no formal mechanism exists (e.g., re-evaluation of approved products or processes based on new information) or for which there is no, or an inadequate, regulatory framework or enabling authority;
- identifying and improving inadequate regulatory mechanisms; and
- adopting a weight of evidence approach.

Precaution does not encompass:

- the necessity for a complete absence of risk;
- taking action in the absence of evidence or disregarding relevant information; or
- stifling innovation.

A.2 Precaution and Existing Risk-Based Decision-Making Processes

Throughout the NDG Precaution team deliberations there was a healthy tension between the desire to apply Precaution as a trigger in determining how issues should be managed and embedding Precaution as an operational consideration in decision-making processes used to address issues, more specifically in risk-based regulatory processes. In many, if not most, instances, risk assessment and management (RA/RM) processes deal with routine situations and deliver non-controversial decisions and outcomes. In some applications of

RA/RM, though, the decision-making process itself may be inadequate or incapable of applying Precaution. For some issues, there may even be no regulatory authority in place to apply Precaution.

Real or perceived deficiencies in RA/RM are an impediment to utilizing this approach in non-routine situations or in cases in which Precaution should be paramount. Cynicism regarding some risk-based decision-making processes is due in part to:

- the legacy of toxic chemicals or by-products that have fallen through the cracks or been approved through a regulatory regime that was not sufficiently robust resulting in an inadequate assessment of safety;
- instances of "paralysis by analysis";
- the length of both the review process and the regulatory decision process; and
- issues relating to lack of information, transparency and lack of capacity.

In particular, the length of time necessary to secure a decision through RA/RM may not always serve the interests of society. It is recognized that, as a general principle, decisions can and should be made quite quickly through RA/RM. In some cases quick decisions can be taken expeditiously outside of the formal RA/RM framework, but in such instances the protocols followed are generally *ad hoc* and the basis for decisions may lack transparency.

In many ways, the demonstrated inefficiencies and inadequacies of some decision-making processes have compromised the ability to operationalize Precaution (and achieve other desirable characteristics like timely decisions) and resolving those structural deficiencies is integral to the ability to apply Precaution. Conversely, the inefficiencies in some current decision making processes, especially ones involving RA/RM, often result from a systemic inability to deal effectively with situations that call for the application of Precaution in the face of scientific uncertainty (i.e., the decision-making process is not nested within a supportive policy or regulatory regime and may become a proxy for a broader societal debate). The NDG Precaution team concluded that while it is important to streamline RA/RM processes this, by itself, is insufficient to properly apply Precaution.

NDG Precaution team participants originally approached the discussion of the relationship between Precaution and environmental decision-making processes with some participants favouring a discussion of how best to integrate Precaution into existing risk-based decision-making processes and others questioning whether Precaution might require an entirely new way of making decisions. Much of the subsequent dialogue centred on finding a balance between these differing perspectives. In the end, the NDG Precaution team chose to explore the difficulties in making Precaution systemic in decision-making and the implications of doing so. Participants recognized that Precaution can neither be "tacked on" to existing decision-making processes nor can it be a discrete element; rather, it needs to influence the selection of the decision-making process, be embedded into the selected process and be a factor in the ongoing review of decisions. NDG Precaution team members were especially interested in debating a process for securing more timely decisions in situations when scientific uncertainty and potential risks are high while ensuring certainty, accountability, transparency and decision-making rigour in the chosen process.

B. Applying Precaution in Risk-Based Decision-Making Processes

The manner in which Precaution influences and is integrated into risk-based decision-making processes is extremely important in operationalizing this concept as, without clear guidance, the concept can be either abused or subverted. The NDG Precaution team thus developed an architecture for applying Precaution that includes the selection of an appropriate decision-making process as well as mechanisms for better integrating Precaution into those processes. The Precaution architecture used by the NDG Precaution team to structure their discussions is shown in Figure #1. This architecture embeds Precaution at all stages of decision-making — from the macro level of characterizing an issue and determining which decision-making process will be followed to the micro level of integrating Precaution into risk management options. The Precaution architecture is explored in more detail in this section and those following.

The proposed approach can be employed by any entity — including government, industry, NGOs and the science community — faced with making a decision that requires the application of Precaution. The NDG Precaution team is principally concerned with its application by government, although the conclusions of the NDG Precaution team can be as applicable to other processes. It is emphasized that the proposed architecture should not hamper the ability to initiate an RA/RM process when there appears to be little scientific uncertainty or controversy associated with the issue of concern and it is not intended to add another layer of decision-making to existing processes that already integrate Precaution.

B.1 Issue Identification / Trigger

The concept of a “trigger” for applying Precaution is a key consideration in the decision-making cycle. The trigger could be the introduction of a new product or technology, new information about existing products or technologies, or a significant public concern which may warrant action from a decision-maker. Where clear regulatory authority exists for a particular issue, the trigger will likely be evident in legislation and policy. Greater difficulty will be encountered when an issue is not currently the subject of regulation or policy (e.g., water exports), when the decision-making regime is weak, or when responsibility for the issue or differing aspects of the issue is vested in different agencies (eg. applying sewage sludge to agricultural lands). In the latter cases, the potential exists for debased regulatory decisions that are suspect in the eyes of society either by forcing risk-based regulatory decisions in the face of major scientific uncertainty, or using Precaution as a proxy for debating societal values in the context of RA/RM. Ultimately, the lack of a predictable process for applying Precaution leads to a lack of confidence in decisions.

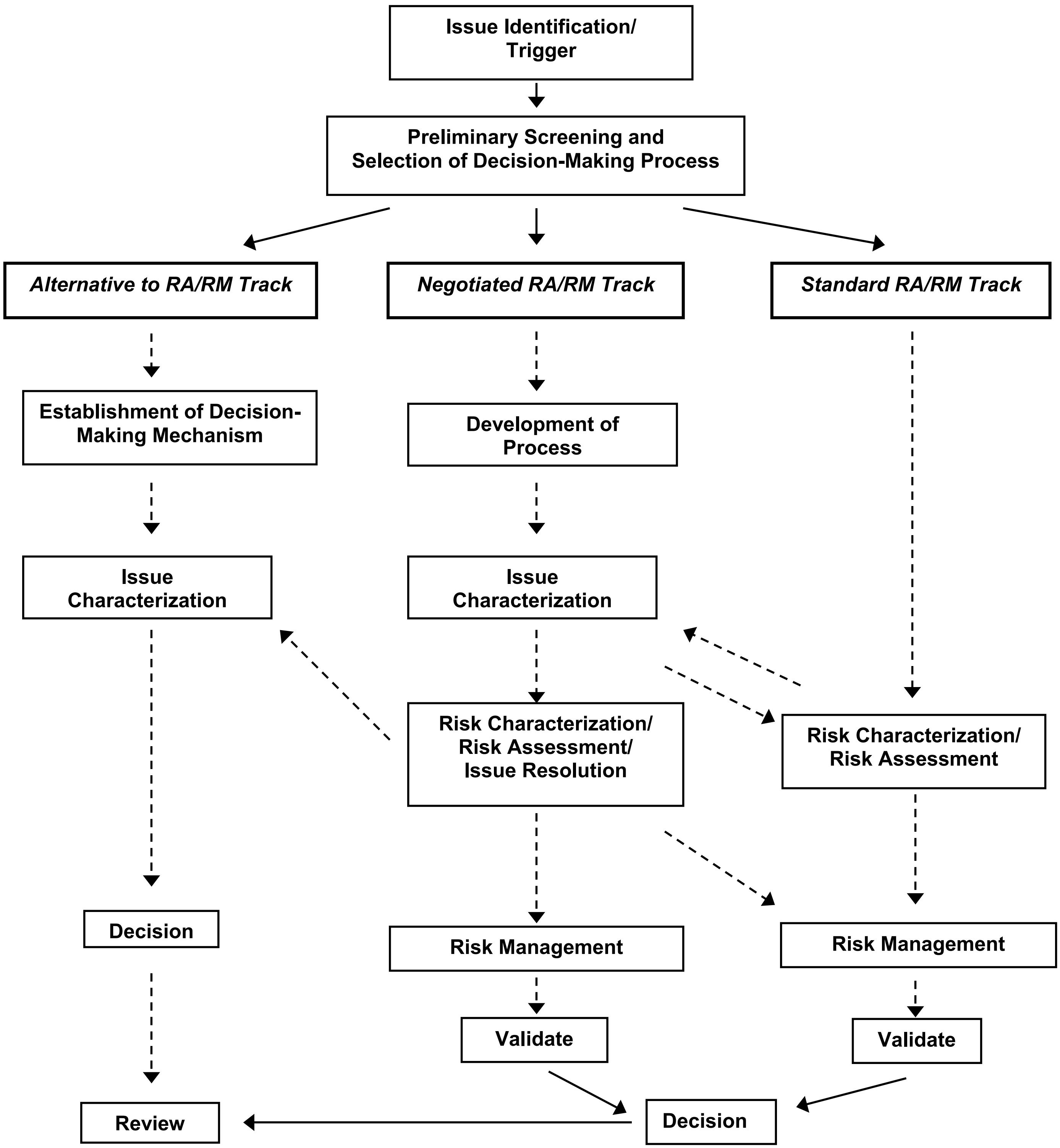
As mentioned, the process for applying Precaution can be initiated by any decision-maker who has explicit or implicit responsibility for an issue and the authority and resources to put the process in place. Clear authority for leading and managing the process is essential. The authority also has ultimate and sole responsibility for determining which of the three proposed decision-making tracks will be followed.

B.2 Preliminary Screening and Selection of Decision-Making Process

Once an issue has been identified, the decision-maker needs to undertake an initial screening to determine the level of scientific uncertainty and potential risk and the ability of the policy and regulatory regime to handle the issue as a precursor to selecting an appropriate decision-making process. It was recognized that there is little need to formalize Precaution in those circumstances in which the application of RA/RM is routine and there is little scientific uncertainty. On the other hand, RA/RM processes may be an inappropriate method of securing decisions, especially in situations where there might be a high degree of scientific uncertainty or a considerable amount of public controversy. And while it is desirable to make RA/RM more robust to Precaution, it may also be necessary to provide an enhanced process or method of decision-making for situations where the duty to act is evident but scientific uncertainty is significant.

In applying Precaution, decision-making options span a spectrum between a political approach and a largely technical approach. The NDG Precaution team broke this spectrum into three distinct tracks as illustrated in Figure #1. Where the preliminary screen indicates that there is little risk or scientific uncertainty and the need for precautionary measures is not immediately obvious, issues can be referred directly to a routine approval process or “Standard RA/RM”. Alternately, should there be a higher degree of risk and scientific uncertainty (especially if there is a potential need for early action), a fundamental clash of societal values or a lack of policy or regulatory guidance, the issue may be referred to either the “Alternative to RA/RM” or the “Negotiated RA/RM” tracks for additional review depending on the nature of the controversy. In these cases, Precaution could be applied through the early introduction of some elements of risk management (e.g., an immediate interim decision may be warranted). Scientific uncertainty increases from right to left in the diagram as does the potential need to take precautionary measures. The robustness of the policy and regulatory regime is likely to increase from left to right. It should be expected, then, that the vast majority of issues will be addressed through the Standard RA/RM track (incorporating Precaution) on the right of the diagram.

Figure #1: **NDG ARCHITECTURE FOR APPLYING PRECAUTION IN RISK-BASED DECISION-MAKING PROCESSES**



B.2.1 Alternative to RA/RM Track

While it is tempting to consider the Alternative to RA/RM track as a mechanism for dealing with "hot" issues such as SARS or reproductive technologies, this track is also appropriate when the issue in question is seen as a proxy for a broader societal debate (i.e., review of a product or technology in an area in which the policy or regulatory environment is not well established). One example might be a product or technology that represents innovation for which the supporting science may be in its infancy. Another could be a situation in which the lifecycle or environmental fate consequences of using a product or technology result in a problem that is outside the aegis of any regulatory authority.

Issues are appropriate for the Alternative to RA/RM track when:

- there is a significant lack of societal consensus based on a clash of values;
- there is a considerable amount of scientific uncertainty and/or controversy and potential risk, especially if it leads to public alarm; and when
- the policy or regulatory framework is unclear or inadequate or no regulatory authority is willing to assume responsibility for the process.

In reality, risk-based political decisions are often taken outside of an RA/RM process as the examples in Section A attest. The processes for taking such decisions, though, may be *ad hoc* and lack transparency. However, as the issues sent into the Alternative to RA/RM track will primarily be those on which there are fundamental differences in values or in scientific understanding, or a lack of a policy or regulatory framework, it is not possible to prescribe a standard process for addressing them.

It is anticipated that the Alternative to RA/RM track would be invoked only if it were clearly evident that the existing decision-making processes of the authority were unsuited to address the particular issue of concern. As this depends on the nature of issues coming forward and the robustness of the decision-making processes of the authority, it is difficult to pre-judge the extent of its invocation with some members of the NDG Precaution team arguing that it would be employed only in exceptional circumstances.

No matter to what extent the Alternative to RA/RM track is followed, however, NDG Precaution project team participants are united in their view that all decisions based on Precaution that are taken outside of the RA/RM process should be grounded in the best available science. In the view of NDG Precaution project team members, public policy in Canada would benefit from the establishment of a national science academy to provide best advice on scientific matters, contribute to the effective resolution of issues on which there is a considerable degree of scientific uncertainty or controversy, and help bring about informed decisions in the application of Precaution.

B.2.2 Negotiated RA/RM Track

If the potential risks or benefits to society are considerable and the level of scientific uncertainty high then Precaution can be applied through an RA/RM process specifically modified to address the issue. The key characteristic of the Negotiated RA/RM process is enhanced stakeholder involvement in decision-making. The Negotiated RA/RM track became the principal focus of the NDG Precaution team deliberations and is addressed in more detail in Section C.

B.2.3 Standard RA/RM Track

If there is a reasonable amount of risk and scientific uncertainty and clear regulatory authority exists, then a Standard RA/RM process, incorporating Precaution, should be invoked. Originally, the NDG Precaution team intended to debate how to better integrate Precaution into existing risk-based decision-making processes. In practice, though, the NDG Precaution team did not dwell on the re-engineering of regulatory and political decision-making processes, principally because there are a multitude of approaches and systems in current use, believing that if the context and a framework for the application of Precaution was defined and established then the direction in which decision-making processes ought to evolve would be self-evident. As stated, the principal interest of the NDG Precaution team was in those situations in which potential risks or benefits are high and there is high scientific uncertainty which are not issues that, at least in the NDG Precaution team's Precaution architecture, would proceed down the Standard RA/RM track.

For reference and to facilitate its discussions, the NDG Precaution team used *Canadian Standards Association, CAN/CSA-Q850-97 Risk Management: Guideline for Decision-Makers* (Q850) as the *de facto* standard for RA/RM rather than debating the strengths and weaknesses of specific RA/RM processes. The NDG Precaution project team undertook a preliminary analysis of the relationship between Q850 and Precaution to help frame its discussions.

B.3 Issue Characterization

Where the preliminary screen has identified a situation where scientific uncertainty and risks or benefits are high and an issue is being referred to the "Alternative to RA/RM" or "Negotiated RA/RM" tracks, it may be appropriate to undertake a more detailed analysis of the situation (i.e., issue characterization) to determine how best to design the decision-making process. This stage in the Precaution architecture has four components:

- identification of the type and degree of scientific uncertainty;
- assessment of the level of public and/or scientific controversy surrounding the issue;
- determination of the questions that need to be asked or the additional information that will be required in the chosen decision-making process; and
- evaluation of the potential need for immediate introduction of some elements of risk management (e.g., an interim decision).

Figure #2: Sample Issue Characterization Questions

Scientific Knowledge	• what is the extent and quality of scientific knowledge? • what range and type of data sets are available? • in which domain is data vested (industry, government, academia) and is it accessible? • what level of scientific controversy or uncertainty exists?
Societal Values	• do similar products or processes exist? • what is the level of societal demand for the product or process? • to what extent do societal values compete on the issue? • are the benefits and risks broadly understood? • how will the benefits and risks be distributed? • to what extent is/will be the product or technology available to society?
Regulatory and Policy Aspects	• is there a clear regulatory authority to address all relevant aspects of the situation? • has a similar issue been dealt with before by this or another jurisdiction and, if so, is the information relevant and what was the outcome? • to what extent will the chosen decision-making process become a "proxy" for resolving broader public policy issues?
Market Issues	• are there alternatives available which have been or can be subjected to rigorous risk assessment? • what are the benefits and risks of the product or technology? • are there any market based controversies?

In conducting the Issue Characterization, the authority should:

- make use of all relevant information from the proponent;
- consider the best practices of companies who undertake internal issue characterization processes; and
- ensure formal opportunities for input by stakeholders that are inclusive and transparent as internal screens may not bring the full range of perspectives to an issue.

As Issue Characterization is a broad description of the factors that need to be considered in decision-making it is advantageous to get all issues on the table early, even those that may at the outset appear to be of little relevance. Figure #2 provides a sample list of the type of information that may be examined at this stage.

As information becomes available through Issue Characterization, it may be advisable or necessary to apply some elements of risk management as an interim decision may be warranted while the product or technology proceeds through the chosen decision-making stream. For example, in cases where there is an immediate risk of irreversible harm to human health or the environment and the duty to act is self-evident, an interim decision on the product or technology could be made at this stage pending a fuller review of the product or technology using the appropriate decision-making process.

B.4 Consideration of Alternatives

Precaution is not just about mitigation it is about prevention and thus Precaution encourages the consideration of alternatives. For example, if an incinerator were the subject of an RA/RM process the output would likely be an incinerator that worked better or that met certain parameters. Determining whether incineration is the most appropriate approach, or what role it should have, for waste management in general would be beyond the scope of the RA/RM process. In this example, critics would argue that focusing an RA/RM process on the incinerator precluded a broader societal debate of waste management options and hence prevented a structured discussion of alternative approaches.

Alternatives should be a component of applying Precaution on two levels. During Issue Characterization, it is important to understand where the product or technology fits with respect to other products or technologies that have been, or could be, subject to a similar level of analysis. In some cases, the product or technology may be believed to confer greater benefits but perhaps at a higher level of risk or scientific uncertainty. In others the product or technology may be believed to be a reduced risk alternative to a product or technology currently in use. The identification of alternatives at this stage is made without any value judgments as to their relative benefits or risks and a choice between products or technologies (e.g., product comparisons) is not made during Issue Characterization, nor should risk management options be implemented prematurely. Rather, the emphasis is on identifying comparable means of achieving the same objective and ensuring that these relevant factors are properly documented. Alternatives may be further addressed at the risk management stage of decision-making.

B.5 Modifying Decision-Making Processes

The Precaution architecture presented in Figure #1 provides the option of moving products or technologies from one decision-making track to another depending on the information available at different stages (as indicated by the dashed arrows).

In the *Alternative to RA/RM* track, a product or technology could be transferred to the *Negotiated RA/RM* track should additional information become available or uncertainties or conflicting values resolved to the point where a negotiated approach to RA/RM is likely to produce a credible outcome.

In rare circumstances, a product or technology in the *Negotiated RA/RM* track could be referred to the *Alternative to RA/RM* track, for example if stakeholders were completely unable to come to an agreement on how the process should unfold or if subsequent risk assessment determined that the scientific uncertainties or risks were much greater than originally envisioned through Issue Characterization and a political decision may be required. Conversely, a product or technology could be referred from the *Negotiated RA/RM* track to the *Standard RA/RM* track if the negotiations or the subsequent risk assessment showed that scientific uncertainties were much less than originally envisioned or the concerns that prompted the selection of the *Negotiated RA/RM* process diminished as the process unfolded.

As the *Negotiated RA/RM* track may result in an interim decision, it is possible for a product or technology to pass first through the *Negotiated RA/RM* track and then either loop back through that track or be referred to the *Standard RA/RM* track as part of the review process, depending on the conditions attached to the decision and the nature of remaining scientific uncertainties.

Finally, in the *Standard RA/RM* track, a product or technology could be referred to either the *Negotiated RA/RM* track or the *Alternative to RA/RM* track should new scientific information come to light through risk assessment or should societal values change sufficiently to compromise the ability of a *Standard RA/RM* process to produce a credible decision.

B.6 Sample Application of the NDG Precaution Architecture

To test the Precaution architecture, NDG Precaution team members brainstormed a list of issues that had proceeded through a regulatory or political process in recent years to determine to which track in the Precaution architecture each of these might have been best suited. Figure #4 summarizes the outcome of this discussion.

Figure #4: Retroactive Application of the Precaution Architecture

Issue	Alternative to RA/RM Track	Negotiated RA/RM Track	Standard RA/RM
MMT in gasoline		X	
Chlorination of Drinking Water			X
Fluoridation of Drinking Water	X ←	←	
Brominated Flame Retardants	NGO		IND
Mercury in light fixtures		→	→ X
PCB disposal	X		
CFC virtual elimination		X	
Mercury in car switches	NGO		IND

An 'X' indicates general agreement among team members (although not always consensus) as to the appropriate process. Where an arrow leads to an 'X', the agreement was that the issue would likely have started down one track and then moved to another as more information became available. The two issues on which there is disagreement are illustrative as both cases are issues on which a decision has yet to be made.

In the case of mercury in car switches, industry participants felt that as mercury was a known toxin there was little scientific uncertainty and as a result a Standard RA/RM process was equipped to handle the issue. NGO participants, on the other hand, argued that as the mercury is contained in the switches and is not released to the environment until recycling or destruction there is a lack of clear regulatory authority, which requires an alternate approach to decision-making.

Similarly, in the case of brominated fire retardants, industry participants saw the lack of scientific uncertainty of their impacts as being an insufficient reason to exclude them from a Standard RA/RM process whereas NGOs were concerned that a Standard RA/RM process would take too long to produce a decision and argued for an alternate method of decision-making.

These two areas of disagreement, highlight the importance of Issue Characterization in the Precaution architecture as, by placing all information and views on the table, the decision-making authority is able to select the process that best addresses the issues that are of concern to all parties.

C. Applying Precaution Through a Negotiated Approach to RA/RM

The proposed Negotiated RA/RM track is seen as the main process for resolving issues where there is a significant scientific uncertainty, the potential for serious harm and the possibility of an urgent need for action. As the Negotiated RA/RM process is modified from a Standard RA/RM process, it should be based on best practices in RA/RM, such as *Canadian Standards Association, CAN/CSA-Q850-97 Risk Management: Guideline for Decision-Makers*, which is customized through a negotiated approach engaging stakeholders. The intent is to facilitate an interim decision if one is required and apply risk management options that fully reflect Precaution, occur in a timely manner, and are supported by all parties to the issue. As the Negotiated RA/RM track deals with scientific uncertainty in potentially high risk or benefit situations, the review of decisions and risk management options is a key component of this track. Although based on a Standard RA/RM process, the Negotiated RA/RM process will likely differ from issue to issue depending on the results of negotiations with stakeholders.

The challenges in taking a negotiated approach to RA/RM are to ensure that:
- decision-making rigour is maintained (rationale for decision, balancing of interests);
- decisions are informed by good, if incomplete, science; and that the
- outcome is credible (e.g., transparency, stakeholder engagement).

C.1 Characteristics of a Negotiated RA/RM Process

A Negotiated approach to RA/RM should provide fair and equitable decisions in a timely and cost-effective manner and is likely to have the following characteristics. The process will:

- need to trigger action expeditiously as time is of the essence;
- require the allocation of adequate resources and have clear authority and timelines;
- be open and transparent, recognizing that the final decision rests with the authority;
- ensure that capacity issues of participants are taken into account;
- take a weight of evidence approach based on all current available data;
- potentially compress certain stages in the Standard RA/RM approach based on agreement among stakeholders;
- ensure that the best available science informs decision-making;
- have a strategic and streamlined process for public consultation;
- err on the side of caution by placing greater emphasis on avoiding false negatives (type II errors) to ensure that potential risks are not ignored or underestimated; and will
- result in provisional decisions and a clear process, with timetables, for further review.

This is not a completely new concept; for example the Screening Level Risk Assessments provided for under the *Canadian Environmental Protection Act* are less stringent than a risk assessment process carried out under CEPA for substances on the Priority Substance List. These assessments allow Ministers the option of taking interim decisions that would move the issue more quickly into risk management which, given the implied priority of the issue, would also move more quickly than normal perhaps again taking interim measures. The proposed Negotiated RA/RM track is based on the need to apply Precaution in a similar manner and extends right through to the process for review of the interim decisions taken.

C.2 Negotiating an RA/RM Process

The very nature of products or technologies which are selected for the Negotiated RA/RM track mitigates against one single methodology for addressing them. A flexible approach that meets established criteria is warranted with the details negotiated on a case-by-case basis among government, industry and other key stakeholders. The NDG thus recommends that the Negotiated RA/RM track be the subject of a formal agreement between the key parties. Any instrument developed to structure such a process should be consistent with the NDG's *Criteria and Principles for the Use of Voluntary or Non-Regulatory Approaches to Achieve Environmental Policy Objectives*. The executive summary of this document is attached as Appendix II.

A Negotiated approach to RA/RM forces all stakeholders to assess the true priority of the issue. It also provides all participants with certainty regarding the process which predisposes the participants to accept the outcome. Through negotiation, the proponent(s) of the product or technology would agree to take action based on the results of the process and there is thus a need to ensure that the outcome of the process is not predetermined. As decisions would be made with perhaps bigger gaps in information than would normally occur, a feedback loop to monitor the impact of the decision and a review process with negotiated timelines are critical to the success of this approach.

Some of the issues that ought to be included in negotiations include:

- requirements for transparency and stakeholder engagement, including the resources made available for this purpose;
- the criteria to distinguish quality science and data;
- data requirements for risk assessment and exposure;
- how weight of evidence will be applied (e.g., considering information from experimental, epidemiological and environmental studies in the literature);
- acceptable risk management options (i.e., should the range of control options for products or processes be restricted);
- responsibility for and approaches to risk communication;
- the process for determining the cost-effectiveness of proposed management actions;
- the processes for validation and review prior to decision-making;
- whether decisions can be qualified in differing ways (time limited, usage conditions, etc.);

- the process for subsequent review of a decision, including the responsibility for monitoring and securing additional information; and
- whether there should be appeal provisions.

C.2.1 Issue Resolution

Depending on the issues identified during Issue Characterization, there may be a need for an issue resolution process within the Negotiated RA/RM track. One benefit of an open, inclusive and transparent issue resolution process is to clarify the true areas of disagreement among stakeholders with respect to the uncertainties, benefits, etc. of a product or technology. On one level, there could be truly conflicting societal values with respect to the issue. On another, divisions may be the result of confusion in terminology, misinformation, misrepresentation of the views of others, or apprehension about the perceived decision-making process to be employed. An issue resolution process can help to isolate areas of disagreement and can ensure that both the appropriate decision-making process is invoked and that the right questions are put to that process. Issue resolution may also require the gathering of additional information or the consideration of other alternatives.

C.2.2 Capacity

Due to the nature of the products or technologies to be addressed through a Negotiated RA/RM, there is a significant public interest in the process and the outcome. Nongovernmental organizations (NGOs), industry and government will be expected to devote a considerable amount of human, financial and technical resources to the process in a short period of time. This will be compounded when multiple processes are underway simultaneously. The negotiation of an RA/RM process should thus include consideration of the provision of sufficient resources to allow participants in the process to contribute effectively. Due to the commitment required on the part of all participants in a Negotiated RA/RM, it is expected that this approach to the application of Precaution would be employed judiciously.

C.2.3 Risk Assessment

The transparency of the risk assessment component of a Negotiated RA/RM process needs to be addressed with care as risk assessors ought to be able to undertake their work free of interference. If conducted effectively, Issue Characterization should clarify the questions to be addressed through risk assessment and the disciplines that need to be engaged. The quality assurance of the subsequent risk assessment process is very important and participating stakeholders should have the opportunity to question the findings of risk assessment.

It is anticipated that in many situations the risk assessment stage of the Negotiated RA/RM process will be compressed to enable the risk management stage to be launched more quickly. It should be noted that the option of implementing risk management options is provided throughout the Precaution architecture enabling interim decisions to be taken at several levels depending on the amount and type of information that becomes available.

C.2.4 Risk Management

While much of the discussion of the NDG Precaution team centred on process and risk characterization or risk assessment, the risk management stage is where acceptable options and potential decisions are considered. As the principal concern in applying Precaution is having the authority fulfill a duty to act in a timely manner, it is important to move quickly to risk management in situations of high scientific uncertainty and for the risk management stage to be expedited to the greatest extent possible. In order for risk management decisions to be credible, however, it is important that the process leading to the development of risk management options and a decision is also credible and transparent, hence the focus of the NDG Precaution team on the Precaution architecture. It should be evident that due to the nature of issues referred to the Alternative to RA/RM or Negotiated RA/RM tracks, time will be of the essence in the risk management stage, especially as both types of process may lead to an interim decision that is subject to review. And, as mentioned above, in these two tracks provisions are made for entering risk management and securing interim decisions at various stages according to the information available.

C.2.5 Review of Decisions

It is inappropriate to view the Alternative to RA/RM, Negotiated RA/RM and Standard RA/RM tracks described in Figure #1 as parallel exercises. A product or technology will not go through each of them once to arrive at a similar destination; rather the Alternative to RA/RM and Negotiated RA/RM tracks may result in interim decisions with respect to the product or technology which will then be subject to review based on additional information as it becomes available, and securing additional information may be a condition of the decision made. It is possible that a product or technology addressed under the Alternative to RA/RM or Negotiated RA/RM tracks may loop through the Precaution architecture more than once. The procedures for review of the decisions taken in these tracks should be explicit in order that all stakeholders are clear on the process to be followed, and the timelines, for securing a final decision.

Appendix 1: Preliminary Identification of Issues Associated with NDG Precaution Project

In the course of preparing the NDG Precaution project, a number of documents were made available to members NDG Precaution team. The following is a short synopsis of each of these reports, identifying their major conclusions or recommendations. These documents were not discussed at length but simply provided all participants in the project with a common foundation for the ensuing discussions.

A. European Environmental Agency, *Late Lessons from Early Warnings: The Precautionary Principle 1896–2000*, Environmental Issue Report #22.

This report is based on 14 case studies of the application of (or the failure to apply) Precaution over the past century. It is available at http://reports.eea.eu.int/environmental_issue_report_2001_22/en.

Twelve "Late Lessons"
- Respond to ignorance as well as uncertainty
- Research and monitor for "early warnings"
- Search out and address "blind spots" and gaps in scientific knowledge
- Identify and reduce interdisciplinary obstacles to learning
- Ensure that real world conditions are fully accounted for
- Systematically scrutinize and justify the claimed "pros" and "cons"
- Evaluate alternatives and promote robust, diverse and adaptable solutions
- Use "lay" and local knowledge as well as all relevant specialist expertise
- Take account of wider social interests and values
- Maintain regulatory independence from economic and political special interests
- Identify and reduce institutional obstacles to learning and action
- Avoid paralysis by analysis

B. Government of Canada, *A Canadian Perspective on the Precautionary Approach/Principle Discussion Document,* September 2001

The following points are taken from the draft report prepared by the Privy Council Office. Near the end of the NDG Precaution project, the final version of the federal government report was released and it can be viewed at: http://www.pco-bcp.gc.ca/default.asp?Language=E&Page=publications&Sub=precaution&Doc=precaution_e.htm.

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.

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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.

C. Pollution Probe, *Applying the Precautionary Principle to Standard Setting for Toxic Substances in Canada*, September 2001

The full report is available at: http://www.pollutionprobe.org/Publications/Policy.htm.

Recommendations:

1. Governments must maintain sufficient in-house scientific capacity to ensure that risk assessments are based on adequate toxicity and exposure data, and on adequate independent research on the potential hazards to human health and the environment. Risk assessments should ideally be based on balanced and extensive peer-reviewed scientific research, but time, resources and the availability of quality research often limit the effective application of this approach.
2. Given the severe cuts to Health Canada's and Environment Canada's research staff and funding that have occurred in recent years, an independent review of the federal government's health and environmental science capacity to perform and oversee risk assessments should be conducted. The Royal Society of Canada would be an appropriate body to oversee this review.
3. Governments must maintain sufficient capacity to monitor and regulate the release of toxic substances in air and water and to enforce health-based standards. This capacity is essential to effectively implement the precautionary principle and the precautionary approach. Government monitoring and enforcement capacity provides industry with the greatest incentive to undertake meaningful voluntary pollution prevention and control initiatives for toxic substances.
4. The federal and provincial/territorial governments should develop a national policy framework to encourage and support performance-oriented, publicly transparent and accountable voluntary initiatives for preventing and managing the release of toxic substances. The policy framework should include incentives, such as the removal of barriers and the alignment of government programs, to enhance performance beyond the normal business case for such initiatives.
5. Evidence-based risk assessment should be maintained as a key foundation of RA/ RM, but provision should be made for public and stakeholder consultation on the questions that scientists are asked to answer, as well as on the appropriateness of risk assessment as the approach to follow to address a particular toxic substance. Provision should also be made for selective involvement, or for observer status, of appropriately qualified health and environmental groups, as well as a broader range of experts from disciplines other than just science, in risk assessments for potentially toxic substances to ensure that assumptions and value judgments are identified and satisfactorily explained to the public.
6. Scientific uncertainties encountered in risk assessment should be carefully documented and made available for public review. Discussion should also be held on the adequacy of the data and research available to conduct evidence-based risk assessment, and an assessment of "what is not known" about a

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toxic substance or group of substances should be made.

7. Quantitative cost-benefit analysis is a valid part of RA/RM and the precautionary principle, but it should only be an input to decision-making, not a constraint. Many of the benefits of precautionary actions cannot be adequately quantified and may appropriately supersede quantifiable costs in precautionary principle decision-making.
8. The entire RA/RM process should be publicly transparent. The implementation of the precautionary principle should be understood to be, in significant measure, extra-scientific and value-driven, since it must deal with considerable scientific uncertainty and appropriately involves value judgments in its application.

D. Stirling, A. and Mayer, S., *Precautionary Approaches to the Appraisal of Risk: A Case Study of a Genetically Modified Crop*, International Journal of Occupational and Environmental Health, Oct/Dec00, v.6, n.4.

The document is best viewed on-line as there are some formatting problems involved in downloading it (all figures are lost as they are embedded files). It can be viewed or downloaded from http://www.mindfully.org/GE/Precautionary-Approaches-Risk.htm.

A series of eight evaluative criteria against which the regulatory appraisal of risk can be assessed in terms of both its scientific rigor and its precautionary qualities.

Humility	Maintain a culture of humility in the face of the many sources of uncertainty, ignorance, and subjectivity in appraisal. Avoid claims to complete or otherwise definitive knowledge.
Completeness	Broaden the scope of the regulatory appraisal of technologic risk to address cumulative, additive, complex, synergistic, and indirect effects as well as more direct causal processes.
Benefits and justifications	Include systematic consideration of the claimed benefits and justifications as well as adverse effects, in order to allow determination of net benefits under different contexts.
Comparison	Conduct appraisal on a comparative rather than a case-by-case basis, including account of a variety of technologic and policy options and the cumulative effects across different cases.
Participation	Ensure full engagement by all interested and affected parties, both to elicit all relevant knowledge and to include consideration of all pertinent priorities and framing assumptions.
Mapping	Express appraisal results not as discrete numerical values, but using sensitivity analysis systematically to map the consequences of different value judgments and framing assumptions.
Transparency	Use the most straightforward of methods. Minimize the number of hidden variables. Provide for detailed auditing of how particular results derive from particular inputs.
Diversity	Extend appraisal to address the ways that diverse mixes of different options may help to hedge against uncertainty and ignorance and help accommodate divergent social perspectives.

E. Industry Canada, *A Framework for Science and Technology Advice: Principles and Guidelines for the Effective Use of Science and Technology Advice in Government Decision Making*

This document can be obtained from http://strategis.gc.ca.

Principle I: Early Issue Identification
The government needs to anticipate, as early as possible, those issues for which science advice will be required, in order to facilitate timely and informed decision making.

Principle II: Inclusiveness
Advice should be drawn from a variety of scientific sources and from experts in relevant disciplines, in order to capture the full diversity of scientific schools of thought and opinion.

Principle III: Sound Science and Science Advice
The government should employ measures to ensure the quality, integrity and objectivity of the science and science advice it uses, and ensure that science advice is considered in decision making.

Principle IV: Uncertainty and Risk
Science in public policy always contains uncertainty that must be assessed, communicated and managed. Government should develop a risk management framework that includes guidance on how and when precautionary approaches should be applied.

Principle V: Transparency and Openness
The government is expected to employ decision-making processes that are open, as well as transparent, to stakeholders and the public.

Principle VI: Review
Subsequent review of science-based decisions is required to determine whether recent advances in scientific knowledge have an impact on the science advice used to reach the decision.

F. Canadian Standards Association, *CAN/CSA-Q850-97 Risk Management: Guideline for Decision-Makers*

This document can be purchased from the CSA (www.csa.org).

Step 1: Initiation

This first step defines the context and organizational structure under which a specific risk management problem will be resolved, including such issues as: the scope of the problem, the terms of reference under which the problem will be addressed, the concerned parties or stakeholders who will be invited to act as participants in the risk management process, the decision-making bodies responsible for resolving the problem, the legislative and legal mandates for anticipated regulatory actions, and the time frame under which the process will operate.

Step 2: Preliminary Analysis / Risk Identification

The Risk Identification step assesses the likelihood that an environmental agent might constitute a potential health hazard, based on its physico-chemical properties, its toxicological effects in test animals, and its observed human health effects. Because the terms risk and hazard are often used interchangeably in different parts of the world, both risk identification and hazard identification denote the same type of activity within the Q850 framework.

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Step 3: Risk Estimation

- *Dose-response assessment*
- *Exposure Assessment*
- *Risk Characterization*

Step 4: Risk Evaluation

The major issues to be addressed at the *risk evaluation* stage include social factors, economic factors, political factors and legal factors. A balancing between the costs of control and the predicted health benefits from reduced exposure are estimated, informally by consensus, or analytically by cost-benefit analysis and similar economic methods. Factors not readily quantifiable, such as the societal acceptance of a risk in affected groups, and the legal and political aspects of regulation within existing federal-provincial jurisdictions are also reviewed.

Step 5: Risk Control

Under the Q850 framework, the *Risk Control* step consists of several major activities: *Identifying Feasible Risk Control Options, Evaluating Risk Control Options,* and *Stakeholder Assessment of Options.* This involves a process of evaluating alternative regulatory and non-regulatory options and selecting the most appropriate option. The option selection task entails the use of value judgments on such issues as acceptability of risk and the reasonableness of the cost of control.

Step 6: Implementation and Action / Monitoring

This final step includes the implementation of regulatory and voluntary actions, and monitoring of the compliance with and effectiveness of the actions.

Appendix II: New Directions Group Criteria and Principles for the Use of Voluntary or Non-regulatory Initiatives to Achieve Environmental Policy Objectives

Executive Summary

An Emphasis on Quality and Public Trust

New Directions Group (NDG) members wish to ensure the quality and credibility of voluntary or non-regulatory initiatives (VNRIs) employed instead of, or as a complement to, regulations to achieve environmental policy objectives. Recent years have seen an increase in the number of VNRIs but there is as yet no widespread agreement on how to develop these programs, their essential design features and the circumstances in which they should be applied. Existing programs are thus uneven in their rigour and quality. The NDG believes that to engender public trust in VNRIs they must be applied appropriately and designed according to a standard set of principles.

The NDG has brought together leaders from the business and environmental communities to identify those attributes of VNRIs that are essential to ensure their quality, effectiveness and credibility. This document presents a framework of criteria and principles that can provide guidance to governments, industry, nongovernmental organizations (NGOs) and others involved in the development and review of VNRIs.

<u>Criteria for the Utilization of VNRIs to Achieve Environmental Policy Objectives</u>

A. *VNRIs should be positioned within a supportive public policy framework that includes appropriate legislative and regulatory tools.*
B. *Interested and affected parties should agree that a VNRI is an appropriate, credible and effective method of achieving the desired environmental protection objective.*
C. *There should be a reasonable expectation of sufficient participation in the VNRI over the long term to ensure its success in meeting its environmental protection objectives.*
D. *All participants in the design and implementation of the VNRI must have clearly defined roles and responsibilities.*
E. *Mechanisms should exist to provide all those involved in the development, implementation and monitoring of a VNRI with the capacity to fulfill their respective roles and responsibilities.*

<u>Principles Governing the Design of VNRIs</u>

Credible and effective VNRIs:

1) *are developed and implemented in a participatory manner that enables the interested and affected parties to contribute equitably;*
2) *are transparent in their design and operation;*
3) *are performance-based with specified goals, measurable objectives and milestones;*
4) *clearly specify the rewards for good performance and the consequences of not meeting performance objectives;*
5) *encourage flexibility and innovation in meeting specified goals and objectives;*
6) *have prescribed monitoring and reporting requirements, including timetables;*
7) *include mechanisms for verifying the performance of all participants; and*
8) *encourage continual improvement of both participants and the programs themselves.*

The full document can be obtained from www.newdirectionsgroup.org/projects/voluntary.php.