

SUBMISSION OF THE CANADIAN PLASTICS INDUSTRY ASSOCIATION

“A CANADIAN PERSPECTIVE ON THE PRECAUTIONARY APPROACH/PRINCIPLE”

March 5, 2002

The Canadian Plastics Industry Association is a national trade association comprised of over 300 member companies across Canada. The plastics processing sector accounts for 0.5% of national gross domestic product, 0.5% of total national employment and 3.9% of manufacturing employment. Approximately 45% of plastics manufactured in Canada are exported abroad. Plastic is a key component in the packaging, construction, automotive and medical sectors to name a few.

The Canadian Plastics Industry Association commends the Government for releasing “A Canadian Perspective on the Precautionary Principle/Approach” and welcomes the opportunity to comment. We support the policies and objectives underlying the Government’s Discussion Document. We are particularly pleased with the Government’s acknowledgement that the precautionary approach is a principled risk-based, science-based and cost-effective approach to decision-making. Finally, we are encouraged by the Government’s urging that the precautionary approach not be used as a disguised barrier to trade, nor as a means to stifle innovation.

While the Canadian Plastics Industry Association commends the government for bringing considerable clarity to the discussion of the precautionary approach, we are seriously concerned that this clarity is undermined by the use of imprecise language. We believe that our concerns can be addressed without any significant changes to the policies and objectives underlying the Discussion Document.

The plastics industry has a unique interest in and perspective on the precautionary approach for two principal reasons. First, plastics provide a key link between chemicals and the consumer. Concerns about the safety of chemicals frequently result in efforts to deselect plastic products using the precautionary principle as their vehicle. Indeed, our industry has seen a number of instances where efforts have been made to "deselect" plastic products on the basis of frivolous allegations under the guise of the "precautionary principle". In our view, it is imperative that clear principles for operationalizing the precautionary approach be put in place to ensure good decision-making that strikes the appropriate balance between environmental protection, and the benefits of productive activity and innovation. Second, the plastics industry depends for its continued economic vitality and growth on liberalized trade. The manner in which the precautionary approach is operationalized will have an impact on Canada's innovations and trading policies, which in turn will affect the competitiveness of the plastics industry. "

1. THE NEED TO DISTINGUISH BETWEEN "THE PRECAUTIONARY APPROACH" AND "THE PRECAUTIONARY PRINCIPLE"

The discussion document consciously uses the terms "the precautionary approach" and "the precautionary principle" interchangeably, while acknowledging that these terms may have different meanings. In addition, at times the paper speaks of "precautionary approaches" and "a precautionary approach", implying that there are several. To the casual reader, this will likely seem simply to be puzzling. To the informed reader, this will be seen as dangerous.

The terms "the precautionary approach" and "the precautionary principle" do indeed have distinct meanings. We acknowledge that this confusion arises in part from the fact that Principle 15 of the Rio Declaration (UN 1992) proclaims that: "the precautionary approach shall be widely applied by States according to their capabilities." A more precise use of these terms and a recognition of their distinctions are essential for

achieving the government's objective of providing "guidance and clarity", and for diminishing its liability.

The term "the precautionary approach" refers to precautionary measures in domestic laws and policies, whereas the term "the precautionary principle" refers to a principle of international treaty law.ⁱⁱⁱ As the discussion document notes, there are those that regard the precautionary principle to be a principle of customary international law. The most ardent supporter of this view is the European Union.^{iv}

This issue is highly significant. International treaties and conventions are not part of domestic law unless they have been implemented by statute. Unless Parliament implements a treaty or convention, it has no direct application within Canadian law.^v As the discussion document notes, Canada does not yet consider the precautionary principle to be a principle of customary international law. If it were, then it would automatically become a part of domestic Canadian law. As the discussion document explains, the extent to which this would "significantly affect current Canadian law, either as a substantive and/or an interpretive rule, is unclear and should be considered further." It is presumably for this reason that the government has tended to describe its domestic approach to risk management as the precautionary approach. Keeping the terms distinct, even if there turns out to be no difference in the influence that the two terms have on the protection of human health and the environment, will help to ensure that no confusion can arise about Canada's position regarding its international and domestic legal obligations.

It is our view that if "the precautionary principle" and "the precautionary approach" are used interchangeably, Canada may be seen as at least acquiescing in the view that the precautionary principle is a principle of customary international law, and perhaps as positively asserting that its state practice represents domestic compliance with customary international law.

If this seems to be a fanciful view of the significance of what might appear to be simply a point of semantics, we note that the authors of the discussion document appear to share this view. At p.11 they note:

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

In view of this recognition of the significance of language, and the fact that it is unclear what the effect of the precautionary principle becoming a principle of customary international law will be on our domestic laws, it is hard to understand why the government would not choose to be careful to use words that are consistent with its international position. The fact, moreover, that the term “precautionary principle” already exists in domestic legislation, in our view is not the same for international law purposes, as a government wide position on the “precautionary principle/approach”.

We believe that consistent use of the term the “precautionary approach” to describe domestic practice would not create the legal and international trade issues associated with use of the term “principle”. In summary, describing the government’s policy exclusively as “the precautionary approach” would at least be harmless, and at best helpful in advancing the government’s position.

2. **THE NEED TO DISTINGUISH “THE PRECAUTIONARY APPROACH” FROM THE USE OF RISK-SAFETY FACTORS (“PRECAUTIONARY APPROACHES”) AND “DO NO HARM”**

The government should also clearly distinguish between “the precautionary approach”^{vi} and the use of risk safety factors, sometimes described as “precautionary approaches”. The latter is often used to mean conservative safety factors, including margins of error and safety assumptions, incorporated into risk assessment to accommodate uncertainties.^{vii} Keeping these concepts distinct will serve to clarify at what stage it becomes appropriate to trigger precautionary measures, if at all, in risk-management decision-making. This distinction will serve to remove any doubt about when the government’s obligations to take precautionary measures can arise.

The Precautionary Approach also needs to be distinguished from a third concept, namely, “do no harm”. This concept, sometimes referred to as the Wingspread Declaration provides:

“When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not established scientifically. In this context, the proponent of the activity, rather than the public, should bear the burden of proof”

The concept of “do no harm” is often used to imply that where there are any doubts whatsoever about an activity, the safety of a technology, or a chemical substance, the activity should be severely restricted or banned.^{viii} The importance of distinguishing between the precautionary approach and the “do no harm” concept is best illustrated by the recent recommendations of Health Canada’s Expert Advisory Panel on DEHP in Medical Devices (January 2002). The DEHP Panel was formed to address media attention on concerns about the safety of DEHP in medical devices raised by Greenpeace and other advocacy groups. The Panel was asked to advise Health Canada on the

scientific evidence of any risk arising from use of DEHP in medical products, and possible actions that would reduce or eliminate risk from DEHP. The Panel included members representing a broad range of expertise on the use of DEHP, and included a toxicologist and specialist in risk assessment. Health Canada representatives on the Panel also included a toxicologist with specific knowledge on substances used in medical devices.

In response to the Health Canada's request for input by the Panel in relation to the Government's Discussion Document on the Precautionary Principle/Approach, the Panel urged adoption and enunciation of the "do no harm" concept of precaution by Health Canada for the regulation of all medical devices. The Report provides at p. 18:

" HC has requested input on Canadian application of the precautionary principle. Dr. Graham Chance has recently written on the application of this principle to childhood risks from environmental exposures. In his article, he restates a recent version of the principle from a U.S. publication, as follows:

'When an activity raises threats of harm in human health or environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context, the proponent of an activity, rather than the public, should bear the burden of proof. The process of applying the Precautionary Principle should be open and democratic and must include potentially affected parties. It also must involve an examination of the full range of alternatives, including no action.'

The Panel would support HC in enunciating a clear precautionary principle regarding the regulation of all medical devices, even where human data are incomplete or inconclusive. An example of the type of guideline the Panel suggests might read something like:

'Products/devices should be demonstrated to have benefits that clearly outweigh risks to patients, including those potentially sensitive to substances or exposed to high levels of substances in the device; or at least be free of adverse effects in [specified] animals at [specified] levels.' "

Such an absolutist view of precaution is inconsistent with a cost-effective, risk-based, science-based approach that the Discussion Document appears to endorse. In the absence of a clear distinction being made between the precautionary approach and "do no harm", as a clear endorsement of the former, confusion and uncertainty will persist in terms of what the government intends by the risk management concept of precaution.

3. THE PRECAUTIONARY APPROACH SHOULD BE CONSISTENTLY DEFINED USING THE LANGUAGE OF THE RIO DECLARATION

We would urge the government to consistently define "the precautionary approach" using the language of Principle 15 of the Rio Declaration, that is: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capability. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." The language of Principle 15 is consistent with the science-based, risk-based and cost-effective approach described in the government paper. As well, it is consistent with the Report of the ADM Working Group on Risk Management, as well as the statement in the discussion document that "Canada supports the statement in Principle 15." It is our view that some of the other definitions of the precautionary approach in the literature are inconsistent with the approach described by the government discussion paper. To leave open the possibility that these other definitions have a place in domestic law could lead to confusion about the government's obligations.^{ix}

4. FUTURE DOMESTIC LAWS AND POLICIES SHOULD ONLY REFER TO "THE PRECAUTIONARY APPROACH"

In order to ensure that Canada remains in compliance with its international obligations and does not appear to be contributing to the emergence of the precautionary principle as a principle of international law without full consideration, we would further recommend that the government encourage adoption of the term "the precautionary approach" (and discourage reference to the term "the precautionary principle") in future domestic legislation and policies.

5. GUIDING PRINCIPLES FOR PRECAUTIONARY DECISION-MAKING

Subject to the comments below on triggers, the burden of proof and the standard of proof, we strongly support the principles outlined in the government's paper for precautionary decision-making. We particularly applaud the government for making clear that: "sound scientific information and its evaluation should be the only 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". This principle accords with our view that the starting point for applying the precautionary approach is an objective risk assessment, intended to identify and evaluate the suspected harm. Moreover, the risk assessment should consist of four steps: hazard identification, hazard characterization, evaluation of exposures and risk characterization. At each stage of the risk assessment process, the degree of uncertainty should be characterized. In this way, the weight of scientific evidence can be assessed taking into account the quality and uncertainties of the studies conducted or considered, including whether the studies have been peer reviewed, are verifiable and replicable.

We also commend the government for recognizing the need for a greater degree of "transparency, clearer accountability and increased public involvement" and also agree that public involvement should be structured into the scientific, advisory and decision-

making processes. All interested stakeholders should be involved in at the scientific, advisory and decision-making stages.

We also support the view that "mechanisms should exist for reevaluating the basis for the decisions and for providing a transparent process for further consultation." Indeed, because the precautionary approach is invoked in situations of scientific uncertainty, and the measures to deal with these are risk-based, the measures should be re-examined, where reasonably possible, as the risks become better understood, and, as appropriate, risk management measures should be fine-tuned to reflect improved knowledge. This is consistent with our obligations under the SPS Agreement to which we are a party.

We are concerned that the triggers for taking precautionary measures are not clearly spelled out in the Discussion Document. Although, the Government clearly supports the "use of sound scientific information", the Document is silent in relation to what are the appropriate triggers and timing for precautionary measures. In this regard, it is our view that the appropriate trigger is a demonstration, through an objective risk assessment, that the risk is "serious" or "irreversible" on the weight of the evidence. In the absence of a single and consistent trigger for precautionary measures, it is our view that the government's objectives of promoting clarity, consistency and predictability and diminishing liability will be undermined. This will also adversely affect our innovations, trading policies and competitiveness.

We have similar concerns in relation to the issue of timing for taking precautionary measures. Nowhere does the Discussion Document specifically set out when precautionary measures can be taken if at all. It is our view that in the absence of urgency, the timing for taking precautionary measures is in the "development of options and decision phase". This will assist the government in achieving its goal of ensuring that the precautionary approach is science based. The Report of the ADM Working Group on Risk Management amplifies this point as follows, at p. 7:

“ In the framework on public risk management, the precautionary approach is presented as affecting both the development of options and the decision phases. While the approach is clearly linked to scientific analysis, (it cannot be applied without an appropriate assessment of scientific factors and consequent risks), it may also be impacted by international considerations and ultimately, guided by judgement, based on values and priorities.”

Our views about the need to clearly delineate the trigger and timing for precautionary measures is consistent with our international obligations under, for example, the SPS Agreement, Article 5.5, to which Canada is a party. The SPS Agreement obliges us not to set standards in an arbitrary or discriminatory manner. The clear delineation of the trigger and timing for precautionary action will assist us in complying with these obligations by diminishing the possibility for arbitrary action.

We would also urge the government to clarify that the civil standard of proof is the appropriate standard to be used in the analysis or assessment of risk decision-making stage. Given that environmental and health statutes in Canada use the civil standard of proof for the determination of harm, that is, the weight of the evidence, it seems appropriate that the same standard be used when assessing the likelihood and seriousness of risk. The weight of the evidence approach, in effect, sets the lower limit or threshold for the application of the precautionary approach. While the lack of full scientific certainty is not a reason for postponing cost effective measures, the weight of the evidence approach suggests that measures need only be taken where the available scientific evidence, taking into account its reliability, at least demonstrates that harm is probable or likely.

The importance of this issue for industry is underscored by the government's comment that it may be appropriate in certain cases for the burden of proof to be assigned. Like government, industry can rarely act on the basis of full scientific certainty and cannot guarantee zero-risk. It would be an impossible burden for industry to prove beyond a reasonable doubt (the criminal standard) that its products and processes can do no harm.

6. SPECIFIC CHARACTERISTICS FOR PRECAUTIONARY MEASURES

Subject to the following comments, we support the Government's five principles describing the specific characteristics for precautionary measures. We particularly applaud the Government for bringing clarity to the principle that precautionary measures should be proportionate to the potential severity of the risk being addressed. We strongly agree that to the fullest extent possible, judgements should be based on scientific evidence.

We also strongly support the principle that measures taken should be "cost effective with the goal of (i) generating an overall net benefit for society at least cost, and (ii) efficiency in the choice of measures". It is our view that an examination of the potential benefits and costs (from a risk/risk and risk/cost perspective) should be structured into the advisory and decision-making processes.

7. NO SYSTEMATIC REVERSAL OF THE BURDEN OF PROOF

We can find no authority for the government's comment that codification of the "precautionary approach in statute is to shift the burden of proof from an intervenor, who opposes a proposal because it may threaten serious environmental harm, to the applicant of the proposal, who must then prove that the proposed action or activity will not in fact result in the alleged harm"

Does the government mean by this that incorporation of the precautionary approach/principle in statute in and of itself creates a higher duty of care on the regulated community? If so, the government should provide authority and a rationale for this position given its enormous implications for industry in terms of innovations and legal liability.

Certainly the language of the Rio definition of the precautionary approach does not explicitly deal with the issue of burden of proof. While we would concede that other definitions of the precautionary approach such as the Wingspread definition require a shifting of the burden of proof, these definitions are inconsistent and incompatible with the approach described by government in this discussion paper.

8. CONCLUSION AND SUMMARY OF RECOMMENDATIONS:

In conclusion, the Canadian Plastics Industry Association commends the government for developing a framework to apply the precautionary approach in federal government science-based risk management activities. We think that the government's discussion paper is a significant first step towards promoting consistency and understanding about an issue and area that is fraught with difficulty and controversy. Our recommendations are intended to assist the government in achieving its important objectives of promoting clarity and consistency, and diminishing government liability. If our recommendations are followed, we believe that the proposed federal framework will significantly contribute to Canada's ability to deal with the increasingly complex and uncertain risks to human health and the environment in a way that achieves the appropriate balance between our desired level of environmental and health protection, and the benefits of liberalized trade, innovation and productive activity.

1. The terms "the precautionary principle" and "the precautionary approach" should not be used interchangeably in the government's paper.
2. The government should further distinguish between "the precautionary approach" and use of risk-safety factors ("precautionary approaches") used by risk assessors to accommodate uncertainties.
3. The government should define "the precautionary approach" using the language of Principle 15 of the Rio Declaration.
4. The Government should encourage consistent use of the term "the precautionary approach" (and discourage reference to the term "the precautionary principle") as appropriate in future domestic legislation and policies.
5. The government should clarify the trigger for taking precautionary measures to be a demonstration through an objective risk assessment that the risk is "serious" or "irreversible" on the weight of the evidence.
6. The government should further clarify that the timing for taking precautionary measure is in the "development of options and decision-phase".
7. The government should not take the view that adoption of the precautionary approach in legislation results in a systematic reversal of the burden of proof. Such a stringent view could stifle innovation and impact on trade and competitiveness. At the very minimum, the government should provide a rationale and authority for this proposition given its potential impact on trade and competitiveness.

ⁱ The Vinyl Council of Canada, a Council of the Canadian Plastics Industry Association, supports the precautionary approach for environmental, health and safety issues where both scientific uncertainty and a potential for serious or irreversible harm are present.

ⁱⁱ Any operationalization of the precautionary approach should be done in accordance with Canada's Innovation Strategy (2002), which is intended in part: "to ensure effective decision-making for new and existing policies and regulatory priorities".

ⁱⁱⁱ Ozone Layer Protocol (1987); Second North Sea Declaration (1987); Third North Sea Conference (1990); Bergen Declaration on Sustainable Development (1990) Maastricht Treaty on the European Union; The Rio Declaration on the Environment and Development;

^{iv} European Communication on the Precautionary Principle, Brussels, 02.02.2000, p. 1 where it states: "this principle has been progressively consolidated in international environmental law, and so it has since become a full-fledged and general principle of international law." Indeed the Maastricht Treaty on the European Union provides: "Community policy on the environment . . . shall be based on the precautionary principle and on the principles that preventive actions should be taken, that environmental damage should as a priority be rectified at source and that the polluter shall pay."^{iv}

^v *Baker v. Canada* [1999] S.C.J. 39.

^{vi} The Document states at p. 2-3 that the precautionary approach is "a distinctive approach within risk management that primarily affects the development of options and the decision phases, and is ultimately guided by judgement based on values and priorities".

^{vii} The European Commission document lists these prudential factors at p. 15 to include:

- "relying on animal models to establish potential effects in man;
- using body weight ranges to make inter-species comparisons;
- adopting a safety factor in evaluating acceptable daily intake to account for intra- and inter-species variability; the magnitude of this factor depends on the degree of uncertainty of the available data;
- not adopting an acceptable daily intake for substances recognized as genotoxic or carcinogenic;
- adopting the "ALARA" (as low as reasonably achievable) level as a basis for certain toxic contaminants."

^{viii} Golkany, Indur. The Precautionary Principle. A Critical Appraisal of Environmental Risk Assessment. Cato Institute, (2002) at p. 2.

^{ix} See for example the 1998 Wingspread Statement on the Precautionary Principle which includes a statement that environmental regulations based on risk assessment have failed to adequately protect human health and the environment. It goes on to define the precautionary principle as "when an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."