



FORUM V
Chemical Safety
for Sustainable Development
IFCS
Budapest, Hungary
25-29 September 2006

Plenary Information/Discussion Session on Tools and Approaches for Applying Precaution in the Context of Chemicals Safety

Information Request for Background Paper

Dear Colleague,

A Forum V Plenary Open Information/Discussion Session has been organized to advance open dialogue and understanding about how precaution is applied in practice with regards to chemical safety to protect health and environment and implementation of goals identified in IFCS declarations and recommendations and the SAICM Overarching Policy Strategy (OPS). A Forum V Thought Starter paper presents the rationale, objectives and organization of the session.¹

Through a series of practical case examples, the session will explore tools and approaches for applying precaution in chemical safety decision-making as well as commonalities and differences in these approaches. Following these presentations, guided discussion with delegates will occur, with the goal of identifying some key commonalities and differences in approaches and providing practical next steps for the future.

To ensure adequate thinking occurs in individual countries before the start of Forum V and thoughtful discussion at the Forum, an Information Background Document will be provided to delegates in advance of Forum V. This Backgrounder Document will summarize information collected on how governments and other organizations domestically apply precaution in chemicals management including:

- A collection of structured information requested from governments and organizations to provide examples of tools and frameworks for how they have applied precaution in the context of domestic chemicals safety efforts.
- Interviews with selected active members in IFCS to understand differences in how precaution is applied and some of the controversies in its application; how they are applying precaution in chemicals management including tools and approaches and the types of tools and processes that would support precautionary decision-making in the context of chemicals management.

¹ Thought Starter: Forum V Plenary Open Information/Discussion Session On Tools And Approaches For Applying Precaution In The Context Of Chemicals Safety, Prepared By: Forum Standing Committee (IFCS/FORUM-V/01-TS
http://www.who.int/ifcs/documents/forums/forum5/meet_docs/en/index.html)

Information Request

The purpose of this structured information collection process is to collect examples of tools, approaches and frameworks for applying precaution (or making decisions in the face of uncertainty) with regards to national chemical safety efforts. The goal is to understand similarities and differences in how precautionary decisions (or decisions in circumstances of uncertainty) are made across countries; what tools and approaches countries use to apply precaution in chemicals management; how policy, regulatory and scientific processes support precautionary decision-making in the context of chemicals management; the challenges and needs for applying precaution in the context of chemicals management; and varying perceptions with its application.

This information will be collected via the template questionnaire (Annex) which consists of specific and more open-ended questions. We ask that you fill in the template as thoroughly as possible. *Please provide any links or additional supporting materials that provide information on particular policies, tools, or activities.*

Process of soliciting information

The request for information submissions is being sent to the entire IFCS mailing list. Submissions are welcomed from everyone and government staff are encouraged to coordinate submissions through the IFCS National Focal Point (see IFCS website for list of designated NFP: <http://www.who.int/ifcs/focalpoints/en/>).

We ask that submissions be returned by **20 July 2006**. Please return completed form to:

IFCS Secretariat
Email: ifcs@who.int
Fax: +41 22 791 4875

If you have any questions, please do not hesitate to contact us.

Thank you for your willingness to participate in this important effort.

Sincerely,

Joel A. Tickner, ScD
Special Advisor, IFCS
Email: joel_tickner@uml.edu

Judy A. Stober, PhD
Executive Secretary, IFCS
Email: ifcs@who.int

Annex

IFCS Forum V
Plenary Information/Discussion Session on Tools and Approaches for
Applying Precaution in the Context of Chemicals Safety

Information Request for Background Paper

Structured Questionnaire

Background Information

Country: Canada

Ministry/Agency/Institute/Organization: Health

Contact Person: Steve Clarkson

Contact Details:

Mailing address:

269 Laurier Avenue, 5th Floor 4905C, Ottawa K1A 0K9, Canada

Email: steve_clarkson@hc-sc.gc.ca

For telephone and fax numbers, please indicate country and city codes:

Tel : 1 613 957 3133

Fax : 1 613 952 9798

Please submit completed questionnaire by 20 July 2006 to:

IFCS Secretariat
Email: ifcs@who.int
Fax: +41 22 791 4875

Please note: Unless you indicate otherwise in your response, these submissions will be posted on the IFCS website.

Please provide any links or additional supporting materials that provide additional information on particular policies, tools, or activities.

National chemicals policy or management:

1. How is the concept of precaution explicitly or implicitly (in terms of decision-making under conditions of uncertainty) incorporated in national chemicals policy or management in your country/organization?

Please check all that apply.

- | | |
|--|--------------------------|
| In the country constitution ? | <input type="checkbox"/> |
| In legislation? | √ |
| In agency/ministry/organization policy? | √ |
| In specific guidance documents for risk assessment or risk management? | <input type="checkbox"/> |
| Applied in specific cases but no particular policy? | <input type="checkbox"/> |
| Not applied at all? | <input type="checkbox"/> |

Please provide greater detail (1 para).

The federal government released “*A Framework for the Application of Precaution in Science-Based Decision Making About Risk*” in July 2003. The Framework outlines ten guiding principles for application of precaution and for precautionary measures in areas of federal regulatory activity in order to describe and strengthen existing practice. Departmental and agency officials are expected to consider its guiding principles in decision making and to work together in developing, in consultation with their stakeholders, guidance for the application of precaution in their particular area of responsibility.

The document can be found at the following web site:

http://www.pco-bcp.gc.ca/docs/Publications/precaution/precaution_e.pdf

French:

http://www.pco-bcp.gc.ca/docs/Publications/precaution/precaution_f.pdf

Tools and approaches for applying precaution:

2. What are some of the key tools and approaches used by your country/organization in applying precaution (or making decisions in circumstances of uncertainty) in the context of chemicals safety?

The type of actions that may be justified from the application of the precautionary principle under the Canadian Environmental Protection Act, 1999 (CEPA 1999) will depend on the circumstances of each case. Such actions may range along a wide spectrum that includes, for example:

- changed priorities for science, risk assessment or risk management;
- requiring information under the various information gathering powers under the Act;
- risk assessment for environment and human health hazard characterization
- preliminary risk management measures in conjunction with ongoing scientific or risk assessment work;
- formal risk management decisions under CEPA 1999

Both Environment Canada and Health Canada support significant ongoing scientific research focused on identifying and understanding risks to human health and the environment. By including research on emerging issues, and contributing to ongoing international dialogue on these issues, the Departments ensure that they are well situated to identify and address serious or irreversible risks in a timely manner.

The Departments are committed to the implementation and ongoing refinement of risk assessment processes that support the effective application of the precautionary principle through the use of precautionary methods and practices. Risk assessments are based on sound science and use a defined methodology to identify substances that pose a risk to the environment or human health. The assessments describe the level and nature of risks as well as the extent of uncertainty, which is always present. These two factors, risk and uncertainty, are explained in science assessment reports and taken into account in decision-making about further work on assessment, initiating risk management measures or pursuing no further steps.

The risk assessment process takes a conservative approach and we strive to ensure that the risks are not underestimated. In accordance with section 76.1 of CEPA 1999 and the precautionary principle, a weight of evidence approach is applied to the assessment conclusion. This approach to characterizing risks is based on inter-disciplinary, qualitative and quantitative information. It is designed to account for sensitive populations, cumulative effects and interactions, and a broad range of health effects and endpoints that provide early identification of risks. The approach is a weighted evaluation of all lines of evidence of risk and considers the level of scientific uncertainty. On a case by case basis, one line of evidence may be given more weight than others in determining risk. The result of the science assessment and the weight of evidence approach is a conclusion on whether a substance is toxic.

In addition, there are regular re-evaluation of existing registrations for pest control products.

a. Is there a defined approach to applying precaution or decision-making under uncertainty?

Yes No

If yes, can you outline the elements of that approach or provide references to it?

b. Is precaution integrated in other decision-making processes, tools and approaches such as;

Please check all that apply.

- Data collection?
- Prioritization of substances for risk management actions
- Uncertainty characterization?
- Socio-economic analysis (e.g., social impact, proportionality/cost-benefit assessment, trade concern)?
- Risk assessment and risk management options?
- Screening, comparison of alternatives, informed substitution?
- Stakeholder and Public involvement?
- Other

Please refer to the Government of Canada Framework for the application of precaution in science-based decision-making about risk (see question 1 for URL).

Decisions made under CEPA 1999 are almost always made in the absence of absolute scientific certainty. Subject to the basic requirement that there must be a basis to establish a scientific suspicion of serious or irreversible damage, the precise level of scientific certainty required to justify preventive action will vary depending on the circumstances of each case. In general, this means that:

- The level of scientific certainty required to justify some form of preventive action will vary depending on the seriousness or irreversibility of the potential damage. A preponderance or balance of evidence may be sufficient to justify some form of preventive action. In cases where the threat is extremely serious, it may be appropriate to act based only on a prima facie indication of potential for harm. In these circumstances, suspicion of serious or irreversible damage based upon preliminary scientific data or models may be sufficient to establish a prima facie case for action.
- Where the federal government has identified a presumptive need to take preventive measures, the level of scientific certainty required to change that presumption will vary depending on the seriousness or irreversibility of the potential damage. The more serious the threat, the higher the threshold required to change that presumption.

There may be instances where the federal government will decide not to act to address an issue about which there is considerable scientific uncertainty. In these cases, the federal government will apply the precautionary principle in considering new evidence. When evaluating this new evidence, the level of scientific certainty required to overturn a decision of non-action will be directly related to the seriousness or irreversibility of the potential harm. This decision will vary according to the circumstances of each case.

c. How are gaps in knowledge addressed?

Please check all that apply.

- Though conservative risk assessment assumptions
- Through safety factors
- Through modeling techniques
- Through an assumption that lack of information is indication of potential harm
- Through requesting additional research
- Gaps are not addressed

For those boxes checked, please briefly provide greater detail or links to additional information.

3. Please provide details of a particular case (or example) where precaution was applied (or decisions made in the face of uncertainty) in the context of chemicals management?

1) A request was made to industry to cease selling products that children put into their mouths that contained the phthalate plasticizer DINP, e.g. teething rings, rattles, baby bottle nipples.

2) The Montreal Protocol on Substances that Deplete the Ozone Layer would be another example. The Montreal Protocol entered into force in 1989 and is one of the earliest examples of the acceptance of the precautionary principle. It applies the precautionary principle by implementing controls on reducing levels in the consumption and production of Ozone Depleting Substances before the availability of clear scientific evidence of the contribution of these substances to atmospheric depletion. In 1991, scientists from around the world agreed that chlorofluorocarbons are depleting the ozone layer in both the northern and southern hemispheres.

a. What stimulated/initiated the precaution process/action?

Please check all that apply.

- Government concern over hazards and/or exposures
- Stakeholder concerns over the particular threat
- International policy requirements/pressures
- Negative impacts/experience(s) from not acting on a previous chemical risk
- Other

For those boxes checked, please briefly provide greater detail or links to additional information.

b. What process was used to make the decision? (please briefly describe the process or tools used to make the decision)

1) Data were gathered on presence of DINP in these products, and on release rates. Information was collected on toxic effects. Consultations were made with stakeholders and consideration was made of potential threats, and the availability of alternatives. The Government announced its decision when industry did not agree to act voluntarily.

c. Were there positive or negative impacts of this process/action?

Please check all that apply.

<u>Positive</u>		<u>Negative</u>	
Ecological or Health benefits	<input checked="" type="checkbox"/>	Ecological or health impacts	<input type="checkbox"/>
Economic benefit	<input type="checkbox"/>	Economic impacts	<input checked="" type="checkbox"/>
Improved government/industry image	<input type="checkbox"/>	Substitutes/alternatives did not work	<input type="checkbox"/>
Improved government/public morale	<input checked="" type="checkbox"/>	Negative public reaction	<input type="checkbox"/>
Improvements to scientific tools/decision processes	<input type="checkbox"/>	Other?	<input type="checkbox"/>
Other?	<input checked="" type="checkbox"/>		

The public was pleased that a threat to infants was removed. Industry bore the costs for products that could not be sold.

Other: The vinyl products industry took measures to improve its practices and its communications for manufacturing and distributing vinyl products.

d. Were there any unintended consequences from this process/action?

Positive – please describe

Negative - please describe

-
4. Are there any particular cases in your country/organization where precaution was not applied (decisions not made in the face of uncertain chemical risks) resulting in adverse impacts?

Yes No

If yes, briefly describe if and how decision-making processes have been modified as a result.

No modifications come to mind.

5. Does your government have processes in place to re-examine decisions made based on precaution or made in the face of uncertainty as additional data are available?

Yes No

If yes, briefly describe the process and how this process may be used to modify decisions, decision-making process, or tools.

The Framework document for the application of precaution in science-based decision making about risk outlines as a principle for the application of precaution that mechanisms should exist for re-evaluating the basis for decisions and for providing a transparent process for further consideration.

While there is no formal process with a specific trigger to launch a review of a decision-based precaution, proponents of a chemical can submit new or additional data or information and can request a re-examination of the decision. Overall, the responsibility for providing the sound scientific basis should rest with the party who is taking an action associated with a risk of serious harm (e.g. the party engaged in marketing a product, employing a process or extracting natural resources). In pesticide registration, decisions are re-examined through several processes, including the receipt of additional data through mandatory reporting by industry of adverse incidents, mandatory regular re-evaluation of pesticide products, and special reviews due to environmental or health concerns (triggered through a request from the public, new information from other government departments or regulatory action by other OECD countries to ban all uses of specific pesticide)

We would also note that given the significant scientific uncertainty implicit in the application of precaution, follow-up activities such as research and scientific monitoring are usually a key part of the application of precaution.

Lessons Learned from applying precaution in chemicals management

6. What are some of the biggest challenges to your country's (organization's) application of precaution in the context of chemicals management or in chemicals management decision-making in the face of uncertainty?

Please check all that apply.

- Scientific capacity
- Lack of scientific information
- Legal challenges
- Technical challenges
- Financial challenges
- Trade Challenges
- Other?

For those checked boxes, please briefly indicate what were the implications of these barriers and how have they been addressed or if not yet addressed, how could they be addressed?

While uncertainty about a threat's severity is an impediment to a decision to act, a lack of clarity on what corrective measure will be effective can defer a decision.

In a pre market assessment, lack of full scientific certainty does not defer or delay a decision. Once a pesticide is on the market, lack of scientific certainty when information points to threats, triggers measures to mitigate the risk which can include additional information requirements, additional precautions in use of the product or removal of the product from the market depending on the degree of the concern.

Are these challenges also applicable to decision-making and actions regarding established risks?

Yes No (Less so)

Next steps

7. What are the most important needs of your country or organization for more effectively applying precaution (or making decisions in the face of uncertainty) and overcoming barriers in chemicals management decision-making?

Please check all that apply.

- | | | |
|-----------------------|---|--------------------------|
| <input type="radio"/> | Data on chemical toxicity/risks | √ |
| <input type="radio"/> | Tools for prioritization | <input type="checkbox"/> |
| <input type="radio"/> | Tools for risk assessment | √ |
| <input type="radio"/> | Decision-making tools/frameworks | √ |
| <input type="radio"/> | Technical assistance in risk assessment processes | <input type="checkbox"/> |
| <input type="radio"/> | Technical assistance in risk management processes | <input type="checkbox"/> |
| <input type="radio"/> | Financial support for implementation | <input type="checkbox"/> |
| <input type="radio"/> | International dialogue | <input type="checkbox"/> |
| <input type="radio"/> | Information sharing to facilitate understanding of the issues | <input type="checkbox"/> |
| <input type="radio"/> | Other | <input type="checkbox"/> |

For those boxes checked, please briefly provide greater detail or links to additional information.

Agreement on environmental protection goals would be very useful, i.e., what is being protected in the environment and why

Exposure models validated in various relevant Canadian situations would permit greater certainty about predictions.

8. Briefly describe your perceptions as to some of the concerns regarding application of precaution in the context of chemicals safety?

Please briefly provide details or links to additional information.

It seems that precaution is often cited as a justification to prohibit use of a chemical rather than a reason for applying measures to control releases. In addition, there needs to be greater dialogue across various chemical program within the country, or the same chemical program in several countries, to understand how precaution is applied and to facilitate sharing of best practices and lessons learned.

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9. Do you have any additional information on tools and approaches for applying precaution that would be helpful to inform discussion?
Please provide any additional materials or web links.

Please note: Unless you indicate otherwise in your response, your submission and those of others will be posted on the IFCS website.

Please also include the web link to the document cited in question 1.