



**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**

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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.<sup>1</sup>

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.

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<sup>1</sup> 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](http://www.who.int/ifcs/documents/forums/forum5/meet_docs/en/index.html) )

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## 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](mailto: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](mailto:joel_tickner@uml.edu)

Judy A. Stober, PhD  
Executive Secretary, IFCS  
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## 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: SLOVENIA

Ministry/Agency/Institute/Organization: MINISTRY OF HEALTH, National  
Chemicals Bureau

Contact Person: Karmen Krajnc, Undersecretary

Contact Details:

Mailing address:  
National Chemicals Bureau, Mali trg 6, 1000 Ljubljana

Email: [karmen.krajnc@gov.si](mailto:karmen.krajnc@gov.si)

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

Tel : + 386 1 478 6054

Fax : + 386 1 478 6266

**Please submit completed questionnaire by 20 July 2006 to:**

**IFCS Secretariat**  
**Email: [ifcs@who.int](mailto: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?  | <input checked="" type="checkbox"/> |
| In agency/ministry/organization policy?                                | <input type="checkbox"/>            |
| 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 chemicals act (O.J. No. 110/03- official consolidated text and O.J. No. 47/04), Article 50 (temporary measures) states:

"When there are reasonable grounds for suspecting that a certain chemical may have irreparable consequences for human health and the environment, the Government of the Republic of Slovenia may pose a temporary restriction or ban on its manufacturing, trade or use, introduce measures for steering its manufacturing, trade or use, and introduce further measures limiting or preventing the consequences to an acceptable level before concrete and reliable scientific evidence on the effects and action/activity of such chemical are available.

When deciding on measures from the preceding paragraph the Government of the Republic of Slovenia shall in particular take into account the seriousness and scope of possible consequences for human health and the environment, the measures taken in similar cases, the overall positive and negative consequences of possible measures and the progress of scientific findings connected with the effects and action of the chemical".

Biocidal products act (O.J. No.61/06), Article 27 states:

"If it is established that there is just cause that a biocidal product represents an unacceptable risk for humans, animals and the environment once the authorisation has already been granted, the competent authority can on a provisional basis restrict or ban the marketing or use of this product on the territory of the Republic of Slovenia."

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**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?

So far, no measure which would directly apply "precautionary principle" on the basis of art. 50 of the Law on chemicals have been accepted. Same goes for art. 27 of Biocidal products act.

Otherwise precaution is applied through variety of mechanisms, like:

- data collection on chemicals, which are on the market in Slovenia,
- awareness raising,
- labeling of dangerous chemicals,
- safety data sheets,....

- 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?

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

*Please check all that apply.*

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

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

Slovenia is following the Communication from the Commission of the EC on the precautionary principle (2000) , The chemicals act (2004), Biocidal products act (2006) and its secondary legislation.

c. How are gaps in knowledge addressed?

*Please check all that apply.*

- |                       |  |                          |
|-----------------------|--|--------------------------|
| <input type="radio"/> | Though conservative risk assessment assumptions                                  | X                        |
| <input type="radio"/> | o Through safety factors   | X                        |
| <input type="radio"/> | Through modeling techniques  | <input type="checkbox"/> |
| <input type="radio"/> | o Through an assumption that lack of information is indication of potential harm | X                        |
| <input type="radio"/> | Through requesting additional research   | X                        |
| <input type="radio"/> | Gaps are not addressed   | <input type="checkbox"/> |

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

Slovenia is following the Communication from the Commission of the EC on the precautionary principle (2000) and Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market.

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?

So far, no national measures which would directly apply "precautionary principle" on the basis of art. 50 of the Law on chemicals have been accepted. Risk management decisions are usually made on EU level ( i.e. dir. 76/769/EC).

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)

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

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

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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 X

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

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 X

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

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**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?

During the Risk Assessment of individual chemical lack of scientific information is crucial. In the process of risk management the possible consequences for industry in comparison to health and/or environmental benefits.

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

Yes  No

## 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="checkbox"/>            |
| <input type="radio"/> | Tools for prioritization                                      | <input type="checkbox"/>            |
| <input type="radio"/> | Tools for risk assessment                                     | <input type="checkbox"/>            |
| <input type="radio"/> | Decision-making tools/frameworks                              | <input type="checkbox"/>            |
| <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 checked="" 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.

The most important is sharing of information, how the precautionary principle is applied in risk management of chemicals around the world. Especially important is establishment of common approaches to implementation of the principle, because of what international guidelines for implementation of precautionary principle would be desirable. Data base, which could compile information on precautionary measures, would also contribute to better use of the principle.

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.*

When applying precautionary principle the required "level of proof" in individual cases is always problematic. The cost benefit consideration is always problematic, due to series of uncertainty factors. All precautionary measures have to be made in public interest, where avoidance of possible "misuse" of the principle is crucial.

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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.**