



**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  
Email: [ifcs@who.int](mailto:ifcs@who.int)

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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: Germany

Ministry/Agency/Institute/Organization: Ministry for Environment, Nature  
Conservation and Nuclear Safety

Contact Person: Prof. Dr. Ulrich Schlottmann, Head of Division

Contact Details:

Prof. Dr. Ulrich Schlottmann  
Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit  
Federal Ministry for the Environment, Nature Conservation and Nuclear Safety  
Referat/Division IG II 3 Postfach/P.O. Box 12 06 29  
D-53048 Bonn  
Germany  
Phone: +49 228 305 -2740  
Fax: +49 228 305 -3524

Mailing address:

Email: [ulrich.schlottmann@bmu.bund.de](mailto:ulrich.schlottmann@bmu.bund.de)

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

Tel : ++49 228 305 2740

Fax : ++49 228 305 3524

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**Please submit completed questionnaire by 15 August 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 ?  | X                        |
| In legislation?  | X                        |
| In agency/ministry/organization policy?                                | X                        |
| In specific guidance documents for risk assessment or risk management? | <input type="checkbox"/> |
| Applied in specific cases but no particular policy?                    | X                        |
| Not applied at all?  | <input type="checkbox"/> |

Please provide greater detail:

The precautionary principle (PP) (we do not speak of a concept) is a guiding principle of German environment protection policy. The German Constitution contains in Article 20a an explicit reference to the responsibility of the state with regard to future generations and the protection of natural resources and animals in the framework of the constitution and democratic separation of powers.

Environment protection policy including chemicals policy is mainly harmonized at the EU level, see Article 174 ff EC Treaty. Article 174 (2) EC Treaty recognizes the PP as one of the principles to be taken into account in Community policy and that of Member States on the environment to be applicable to human health, as well as animal health and plant health sectors. Further details on the PP are laid down in the Communication on the Applicability of the PP of the EU Commission in document COM (2000) 1 final as of 2<sup>nd</sup> February 2000 followed by a Council Resolution dated 5th December 2000 (attachments 1,2). As re the role of the PP in the EU risk assessment process on industrial chemicals, see an enclosed article of the European Chemicals Bureau, Ispra, see attachment 3.

The PP is being applied on a case by case basis. One recent example on the application of the PP in European legislation is the Directive on the approximation of laws, regulations and administrative provisions of the

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Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (Phthalates in Toys and Childcare Articles), notably Directive 2005/84/EC of the European Parliament and the Council of 14<sup>th</sup> December 2005 (Official Journal of the EU L344/40 ff of 27<sup>th</sup> December 2005, attachment 4). This Directive is implemented in respective German regulations on product safety and the cosmetics.

**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?

bans and/or restrictions of production, marketing or handling/use of chemicals

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

Yes                      No

See above (case-by-case decision)

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

See above and attachments

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

*Please check all that apply.*

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

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

The tools checked above are certainly part of the decision-making process for taking measures based upon environment protection legislation (including chemicals policy).

c. How are gaps in knowledge addressed?

*Please check all that apply.*

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

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

The methods checked above are common practice when determining threshold values.

Ongoing research is an important factor to fill – where possible - gaps of uncertainty. The application of precaution in case of uncertainty is temporarily and conditioned that the decision has to be regularly monitored against availability of scientific evidence.

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?

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.

See above - Directive on the approximation of laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (Phthalates in Toys and Childcare Articles), notably Directive 2005/84/EC of the European Parliament and the Council of 14<sup>th</sup> December 2005 (Official Journal of the EU L344/40 ff of 27<sup>th</sup> December 2005, attachment 4). This Directive is implemented in respective German regulations on product safety and cosmetics.

The use of certain phthalates in toys and childcare articles made of plasticized material or including parts made of plasticized material should be prohibited as the presence of certain phthalates presents or could potentially present risks related to health of children. Toys and childcare articles which – though not intended for that purpose – can be put in the mouth, may under certain circumstances present a risk to the health of small children (less than three years) if they are produced in the described way. Since 1999, the use of six phthalates in toys and childcare articles intended to be placed in the mouth by children under the age of three is subject to a temporary ban at the EU level (following the adoption of a respective Council Decision) on general product safety and action subsequently undertaken by certain Member States on the placing of toys and childcare articles on the market. In order to ensure the functioning of the internal market in the EU, the objectives has been to approximate the restricting laws of the Member States in this field by adapting the respective Directive and applying the PP as scientific evaluation (i.a. mouthing times, exposure to emissions from other sources) did not allow the risk to be determined with sufficient certainty in order to ensure a high level of protection of health, in particular of vulnerable children.

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

see above

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

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

Case-by-case decision making; measures must observe also the principle of proportionality, taking into account short-term and long-term risks and aiming at a high level of protection of human health - against that background, the application of the PP can provide for economical, social and /or environmental benefits, given e.g. cost saving aspects compared to potential costs deriving from a damage and/or from inaction.

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

See above

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

The issue is to tackle specific cases of uncertainty that are politically handled by applying the PP and acting preventively.

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

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

See above, EU Resolution on the PP

### 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            | <input type="checkbox"/>            |
| - Lack of scientific information | <input type="checkbox"/>            |
| - Legal challenges               | <input type="checkbox"/>            |
| - Technical challenges           | x                                   |
| - Financial challenges           | X                                   |
| - Trade Challenges               | X                                   |
| - Other?                         | <input checked="" type="checkbox"/> |

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?

In general, any political decision-making contains challenges in terms of balancing the economic, social and other effects of a potential measure, differing civil society interests involved and aspects e.g. uncertain risks, proportionality and/or a timely limitation of an intended measure. In the EU, the Member States are entitled to establish the level of protection that they consider appropriate in risk management, that they may to that end take appropriate measures under the PP, and that it is not always possible to determine in advance the level of protection appropriate to all situations. Answers to these challenges include information accessibility, transparency, cooperation, close coordination and coherent action with all parties concerned.

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.*

- Data on chemical toxicity/risks
- Tools for prioritization
- Tools for risk assessment
- Decision-making tools/frameworks
- Technical assistance in risk assessment processes
- Technical assistance in risk management processes
- Financial support for implementation
- International dialogue
- Information sharing to facilitate understanding of the issues
- Other

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

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In Germany , respective instruments for the application of the PP on a case by case basis are available; however, improved data exchange and methodologies to evaluate risks and hazard aspects would always be an asset. In the field of chemicals, the future EU chemicals policy REACH will provide for the basis of more and better information on chemical substances for the sake of a high level of human health and environment protection.

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.*

Specifically with regard to chemicals, there is a high need for transparent, accessible and understandable information on exposure risks that might/do derive from chemical substances or products which contain specific substances. This should go hand in hand with the communication of practical proposals for possible approaches. This would help de-emotionalizing debates and avoiding any potential stirring up of panics by particular media. The application of the PP is one legitimate answer. However, given a broad-based belief in the soundness of science as single basis for any decision-making, often there is no agreed overall societal consensus with regard to the application of the PP which should at the same time be seen from a perspective of sustainable development.

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.*

The EC Communication on Precaution, see  
[http://ec.europa.eu/environment/docum/20001\\_en.htm](http://ec.europa.eu/environment/docum/20001_en.htm)

European Environment Agency, Copenhagen: "Late Lessons from early warnings: the precautionary principle 1896 – 2000", Environmental Issue Report , see  
<http://www.eea.eu.int>

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

## **ADDITIONAL INFORMATION**

## IFCS Forum V - Information Request on Precaution

Submission: Germany  
Prof. Dr. Ulrich Schlottmann  
Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit  
Ministry for the Environment, Nature Conservation and Nuclear Safety  
Referat/Division IG II 3 Postfach/P.O. Box 12 06 29  
D-53048 Bonn  
Germany  
Phone: +49 228 305 -2740  
Fax: +49 228 305 -3524  
Federal

Attachments to completed questionnaire:

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*Communication from the Commission on the precautionary principle  
COM (2000)1*

[ec.europa.eu/dgs/health\\_consumer/library/pub/pub07\\_en.pdf](http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf)

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*Council of the European Union*

14328/00

Brussels, 5 December 2000 (06.12)

Subject: Use of the precautionary principle

Council Resolution on the use of the precautionary principle as endorsed at the meeting of the General Affairs Council on 4 December 2000.

[register.consilium.eu.int/pdf/en/00/st14/14328en0.pdf](http://register.consilium.eu.int/pdf/en/00/st14/14328en0.pdf)

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***DIRECTIVE 2005/84/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 14 December 2005***

amending for the 22nd time Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (phthalates in toys and childcare articles)

[eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:344:0040:0043:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:344:0040:0043:EN:PDF)

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*Role of the precautionary principle in the EU risk assessment process on industrial chemicals*

*J. de Bruijn, B. Hansen, and S. Munn*

*Pure Appl. Chem.* 75(11/12), 2535-2541, 2003

<http://www.iupac.org/publications/pac/2003/7511/index.html>

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*Late lessons from early warnings: the precautionary principle 1896-2000*

Environmental issue report No 22

European Environment Agency

2001

[http://reports.eea.europa.eu/environmental\\_issue\\_report\\_2001\\_22/en](http://reports.eea.europa.eu/environmental_issue_report_2001_22/en)