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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: **Bulgaria**

Ministry/Agency/Institute/Organization: **Ministry of Environment and Water**

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**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?
- In legislation?
- In agency/ministry/organization policy?
- In specific guidance documents for risk assessment or risk management?
- Applied in specific cases but no particular policy?
- Not applied at all?

Please provide greater detail (1 para).

**The concept of precaution is to preserve human health and environment by the harmful impact of chemicals in all their life-cycle.**

**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 main tool is the national legislation in the field of chemicals, labor safety and human health and strict control under its implementation.**

- 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?

**There are different authorities in Bulgaria that are responsible for the development and implementation of the precautionary measures as follow:**

- **Ministry of Environment and Water is a competent authority for the**

- chemicals management and the environmental protection;**
- **Ministry of Health is a competent authority for the chemicals management related to the human health impact including labor and social policy;**
  - **Ministry of Labor and Social policy is a competent authority for the occupational safety and labor related to the chemicals management including children protection and well-being.**
- All these competent authorities separately and together are decision-makers and take care of applying precaution by their competence.**

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?
- 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.

**Each competent authority keeps its own database, for example the Ministry of Health has a register for the biocides with issued permits for placing on the market and the Ministry of Environment and Water keeps registries for enterprises produced and/or used dangerous chemicals, for the exported and imported chemicals, for the notified chemical substances and so on.**

**In accordance with the Bulgarian legislation, the Ministry of Environment and Water and the Ministry of Health share responsibilities for the chemicals risk assessment and risk management in respect of the environment and human health.**

**There are opportunities for joint control and monitoring by competence of the chemicals impact in all stages of their life-cycle.**

**There are different opportunities stakeholders and public to be involved in the decision-making process for example through open-ended public discussions on the regulatory base, public available on-line forum on the web side of the MoEW and so on.**

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
- o Through an assumption that lack of information is indication of potential harm
- o Through requesting additional research

- Gaps are not addressed

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

**Some modeling techniques have been used in the area of the accidents prevention according to Bulgarian legislation from the enterprises with high risk potential in process of development of their documentation for the risk evaluation.**

**It is legislatively based that additional information and studies would be requested in regard with risk assessment and risk management.**

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.

**In connection with the fulfillment of its international arrangement, the Bulgarian government pursues environmental and healthy sound chemicals management policy.**

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

**The governmental decisions have been made after a comprehensive harmonized legislatively-based procedure with the intergovernmental authorities and stakeholders.**

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 checked="" 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 checked="" type="checkbox"/>	Other?	<input type="checkbox"/>
Other?	<input type="checkbox"/>		

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

**As a whole the results of the governmental decision-making process are positive because the implementation of the chemicals legislation provide ecological and health benefits. The negative impact is connected with the increased financial resources that industry has to invest for determination of the chemical properties and following further measures, for example like appropriate environment and health friendly best available technologies and practices and so on.**

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

Positive  – please describe

Negative  - please describe

**Till this moment there are no unintended consequences as a result of the governmental decision-making approach in the chemicals management field.**

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.

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.

**There is a legislative procedure that is placed in process of re-examine decisions. For example if there is available new additional chemical data or information about its properties or impact that will lead to higher risk for human or environment than it was necessary immediately governmental measures to be undertaken.**

<b>Lessons Learned from applying precaution in chemicals management</b>
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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?

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*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?

**The main difficulties and challenges in the chemicals management in Bulgaria are connected with the lack of enough financial resources for providing of additional studies or scientific researches for certain chemicals.**

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.*

- o Data on chemical toxicity/risks
- o Tools for prioritization
- o Tools for risk assessment
- o Decision-making tools/frameworks
- o Technical assistance in risk assessment processes
- o Technical assistance in risk management processes
- o Financial support for implementation

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- 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.

**The most important needs of Bulgaria are connected with providing of data on chemical risk/toxicity/ecotoxicity tools for risk assessment and financial support for the effective implementation.**

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.*  
**Some precautions in the context of chemicals safety apply for example in respect to the labor of children and pregnant/ suckling mothers till their child age become 2.**

**Permit regime is applied for the enterprises that produced, used and/ or manufactured dangerous chemicals in high amounts as one of the requirements of the regime is a Safety Management System to be developed and implemented.**

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.*  
**Yes, we have, but in Bulgarian. For additional information:**  
[www.moew.government.bg](http://www.moew.government.bg), [www.mh.government.bg](http://www.mh.government.bg).

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