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
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Judy A. Stober, PhD
Executive Secretary, IFCS
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Annex (corrected version)

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: FINLAND

Ministry/Agency/Institute/Organization: Ministry of the Environment

Contact Person: Ms. Pirkko Kivelä

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

   Please provide greater detail (1 para).

   In legislation:

   The Treaty establishing the European Union (Title XIV, Article 174 point 2) states that "Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be ***based on the precautionary principle*** *and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay."*

   Although the precautionary principle is only mentioned in the Treaty in regard to the environmental field, the scope of applying precaution is far wider. The Council Resolution on the precautionary principle describes that this principle is also applicable to human health, as well as to the animal health and plant health sectors.

   In government policy:

   In May 2006 the Finnish Government approved a National Chemicals Programme. The objective of the programme is to bring into effect in Finland the Johannesburg goal, that chemicals do not pose significant adverse effects on human health and the environment in 2020. A starting point for the National Chemicals Programme is the precautionary principle whereby risk reduction measures shall be applied when scientific evidence shows that a

chemical may cause adverse effects, even if there is no conclusive scientific evidence of the degree and nature of the damage.

In Guidance documents
Also the European Union Technical Guidance Document on Risk Assessment of chemicals and biocides refers to the precautionary principle.

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 Commission of the European Communities adopted in February 2000 a Communication from the Commission on the Precautionary Principle; COM (2000)1 final. The aim of this Communication is to inform all interested parties of the manner in which the Commission applies and intends to apply the principle and to establish guidelines for its application.

In December 2000 the European Council adopted a Council Resolution on the precautionary principle. In this Resolution the Council considers that the precautionary principle applies to the policies and action of the Community and its Member States and concerns action by public authorities both at the level of the Community Institutions and at that of Member States.

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

Yes X No ☐

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

The Commission Communication on the Precautionary Principle (reference given above) provides general principles for applying precaution. It covers those specific circumstances where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection. The precautionary principle should be considered within a structured approach to the analysis of the risk and that it is particularly relevant to the management of risk. An assessment of the potential consequences of inaction and of the uncertainties of the scientific evaluation should be considered by decision makers when determining whether to trigger action based on the precautionary principle. All interested parties should be involved to the fullest extent possible in the study of various risk management options that may be envisaged once the results of the scientific evaluation and/or risk assessment are available and the procedure be as transparent as possible. Measures based on the precautionary principle may assign responsibility for producing the scientific evidence necessary for a comprehensive risk evaluation.

There are however no defined national guidance.

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?	X
o Screening, comparison of alternatives, informed substitution?	X
o Stakeholder and Public involvement?	☐
o Other	☐

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

The European Union Technical Guidance Document on Risk Assessment of chemicals and biocides refers to the precautionary principle. It has also been referred to in connection with the framework for phasing out as soon as possible of persistent organic pollutants (Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants)

c. How are gaps in knowledge addressed?

Please check all that apply.

o Though conservative risk assessment assumptions	X
o Through safety factors	X
o Through modeling techniques	X
o Through an assumption that lack of information is indication of potential harm	☐
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.

Several approaches are used, combined or step wise, to address gaps in knowledge. The starting point is the risk assessment. In cases where scientific evidence is insufficient, inconclusive or uncertain, safety factors are used, especially concerning plant protection products and biocides. On assessment factors used in the environmental risk assessment the EU Technical Guidance Document on Risk Assessment states e.g.: "The assessment factors reflect the degree of uncertainty in extrapolation from laboratory toxicity test data for a limited number of species to the 'real' environment. Assessment factors applied for long-term tests are smaller as the uncertainty of the extrapolation from laboratory data to the natural environment is reduced.".

Conventionally, additional information is also requested. The future trend goes in the

direction of modelling techniques i.e. read across and (Q)SAR's.

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.

   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.

Positive		Negative	
Ecological or Health benefits	☐	Ecological or health impacts	☐
Economic benefit	☐	Economic impacts	☐
Improved government/industry image	☐	Substitutes/alternatives did not work	☐
Improved government/public morale	☐	Negative public reaction	☐
Improvements to scientific tools/decision processes	☐	Other?	☐
Other?	☐		

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

   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.

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 X No ☐

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

   For chemicals requiring advance approval like plant protection products and biocides the approval is time-limited and hence the grounds for the approval are re-examined. Also risk management decisions on chemicals such as marketing and use restrictions may be subject to a periodic review to see if alternatives are available for the allowed uses and to propose if appropriate further restrictions on the basis of the results of this review.

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 X
- Legal challenges ☐
- Technical challenges X
- 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?

Sufficient information on possible alternatives is often difficult to obtain.

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

Yes X 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 X
- o Tools for risk assessment ☐
- o Decision-making tools/frameworks X
- o Technical assistance in risk assessment processes ☐
- o Technical assistance in risk management processes ☐
- o Financial support for implementation ☐
- o International dialogue ☐
- o Information sharing to facilitate understanding of the issues ☐
- o Other ☐

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

A new European chemicals regulation REACH is currently under preparation.

The REACH Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.

The REACH regulation will incorporate tools for prioritization of hazardous chemicals subject to data requirements as well as decision-making. For example the authorization process of certain chemicals aims to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are eventually replaced by suitable alternative substances or technologies where these are economically and technically viable.

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.

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 Treaty establishing the European Community:
http://eur-lex.europa.eu/en/treaties/dat/12002E/pdf/12002E_EN.pdf

Commission of the European communities; Communication from the Commission on the precautionary principle:
http://eur-lex.europa.eu/LexUriServ/site/en/com/2000/com2000_0001en01.pdf

European Council; Council Resolution on the precautionary principle:
http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressdata/en/ec/00400-r1.ann.en0.htm (see Annex III of the precidency conclusions on the European Council meeting 7, 8 and 9 December 2000)

European Parliament resolution on the Commission communication on the precautionary principle (COM(2000) 1 - C5-0143/2000 - 2000/2086(COS)):
http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P5-TA-2000-0583+0+DOC+XML+V0//EN&language=EN

Some practical examples on the use of precaution in the EC legislation are presented in the following. The list is not intended to be comprehensive but it provides some examples.

Practical examples of precaution in the EC legislation

- **The Treaty establishing the European Community**,
  - Title XIX, Article 174 point 2: "Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on **the precautionary principle** and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay."
- **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)**
  - Preamble 8: "**The precautionary principle** should be applied where scientific evaluation does not allow the risk to be determined with sufficient certainty in order to ensure a high level of protection of health, in particular for children."
  - Preamble 12: "The uncertainties in the evaluation of exposure to these phthalates, such as mouthing times and exposure to emissions from other sources require that **precautionary considerations** be taken into account."
  - Preamble 14: "In line with the Commission Communication on the **Precautionary Principle**, the measures based on this principle should be subject to review in the light of new scientific information."
- **Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety**
  - Preamble 1): "It is necessary to amend Directive 92/59/EEC in several

respects,… and in the light of the **precautionary principle**."

- Article 8.2: 2. "When the competent authorities of the Member States take measures such as those provided for in paragraph 1, in particular those referred to in (d) to (f), they shall act in accordance with the Treaty, and in particular Articles 28 and 30 thereof, in such a way as to implement the measures in a manner proportional to the seriousness of the risk, and taking due account of the **precautionary principle**."

- **Commission decision of 7 December 1999 adopting measures prohibiting the placing on the market of toys and childcare articles intended to be placed in the mouth by children under three years of age made of soft PVC containing one or more of the substances di-iso-nonyl phthalate (DINP), di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), di-iso-decyl phthalate (DIDP), di-n-octyl phthalate (DNOP), and butylbenzyl phthalate (BBP)** *(NOT IN FORCE ANYMORE)*
  - Preamble 21: "The Commission considers that, should the use of DNOP, DIDP, BBP and DBP be allowed to replace DINP and DEHP, as a consequence of the prohibition of these two substances as plasticisers in the products in question, the exposure of children to them would increase and consequently the risk would be higher. Therefore, the Commission, adopting a **precautionary approach**, considers that this Decision should also apply to them;"
- **Commission Directive 2003/2/EC of 6 January 2003 relating to restrictions on the marketing and use of arsenic (tenth adaptation to technical progress to Council Directive 76/769/EEC)**
  - Preamble 8: "With regard to the risk assessment and taking account of the **precautionary principle**, pending harmonisation of rules under Directive 98/8/EC or a Decision pursuant to Article 6(3) of Regulation (EC) No 1896/2000, it is necessary to adapt the restrictions on arsenic in Directive 76/769/EEC to technical progress"…[cont.]
- **Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC**
  - Preamble 7: "Moreover, considering that the provisions of this Regulation are underpinned by the **precautionary principle** as set forth in the Treaty, and mindful of Principle 15 of the Rio Declaration on Environment and Development and in view of the aim of elimination, where feasible, of the release of persistent organic pollutants into the environment, it is appropriate in certain cases to provide for control measures stricter than those under the Protocol and the Convention."
  - Article 1: "Taking into account, in particular**, the precautionary principle**, the objective of this Regulation is to protect human health and the environment from persistent organic pollutants by prohibiting, phasing out as soon as possible, or restricting the production, placing on the market and use of substances subject to the Stockholm Convention on Persistent Organic Pollutants, hereinafter "the Convention", or the 1998 Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants, hereinafter "the Protocol", and by minimising, with a view to eliminating where feasible as soon as possible, releases of such substances, and by establishing provisions regarding waste consisting of, containing or contaminated by any of these substances."
- **The REACH Proposal** (Council Common position, not final legislation yet)
  - Preamble 9: "The assessment of the operation of the four main legal instruments governing chemicals in the Community, i.e. Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations

and administrative provisions relating to the classification, packaging and labelling of dangerous substances1, Council Directive 76/769/EEC of 27 July 1976 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 preparations2, Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations3 and Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances4, identified a number of problems in the functioning of Community legislation on chemicals, resulting in disparities between the laws, regulations and administrative provisions in Member States directly affecting the functioning of the internal market in this field, and the need to do more to protect public health and the environment in accordance with **the precautionary principle**."

- Preamble 63: "To ensure a sufficiently high level of protection for human health, including having regard to relevant human population groups and possibly to certain vulnerable sub-populations, and the environment, substances of very high concern should, in accordance with **the precautionary principle**, be subject to careful attention. Authorisation should be granted where natural or legal persons applying for an authorisation demonstrate to the granting authority that the risks to human health and the environment arising from the use of the substance are adequately controlled. Otherwise, uses may still be authorised if it can be shown that the socio-economic benefits from the use of the substance outweigh the risks connected with its use and there are no suitable alternative substances or technologies that are economically and technically viable. Taking into account the good functioning of the internal market it is appropriate that the Commission should be the granting authority.
- Article 1(3): "This Regulation is based on the principle that it is up to manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by **the precautionary principle**"

European Court of Justice:

"Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent." (Judgement of the Court, 5.5.1998, case C-157/96, paragraph 63)

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

ADDITIONAL INFORMATION

Extract from the Precidency conclusions from Nice European Council (Heads of State or Government of the European Union's Member States) meeting of 7, 8 and 9 December 2000, found at http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressdata/en/ec/00400-r1.%20ann.en0.htm

ANNEX III

COUNCIL RESOLUTION

ON THE PRECAUTIONARY PRINCIPLE

The Council,

A. Whereas the principles laid down in the EC Treaty provide that Community action must aim at a high level of protection of human health, consumers and the environment and that these objectives must be integrated into the European Union's policies and action;

B. Whereas the Treaty recognises, in Article 174(2), that the precautionary principle is one of the principles to be taken into account in Community policy on the environment; whereas this principle is also applicable to human health, as well as to the animal health and plant health sectors;

C. Whereas it might be useful to examine, in due course and in the appropriate fora, whether it is necessary and possible formally to consolidate the precautionary principle, in accordance with the case law of the Court of Justice of the European Communities, also in other Treaty provisions specifically concerning health and consumer protection;

D. Recalling that the recognition of this principle is to be seen from a perspective of sustainable development;

E. Recalling that this principle is included in various international texts, inter alia the 1992 Rio Declaration, the 1992 Convention on Climate Change, the 1992 Convention on Biological Diversity, the 2000 Protocol on Biosafety and a number of Conventions on protection of the marine environment;

F. Pointing to the importance of work in progress on the subject in the Codex Alimentarius context;

G. Whereas the precautionary principle must not be used in order to introduce disguised trade restrictions;

H. Whereas the preamble to the World Trade Organisation (WTO) Agreement sets out general objectives which include sustainable development and environmental protection and conservation; whereas Article XX of the GATT and Article XIV of the GATS contain general exceptions, while Article 5(7) of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) lays down rules on the procedure to be followed in the event of risk and insufficient scientific evidence; whereas the Agreement on Technical Barriers to Trade (TBT) allows account to be taken of the risks that failure to apply measures might pose for human health or safety, animal or plant life or the environment;

I. Whereas the European Union attaches great importance to helping developing countries to participate in the SPS and TBT Agreements in view of their particular difficulties in that respect;

J. Recalling the recommendations made by WTO panels, in particular by the Appellate Body in the hormones case, concerning the right of WTO members to "establish their own appropriate level of sanitary protection, which level may be higher than that implied in existing international standards, guidelines and recommendations", and to take into consideration minority expert opinion;

K. Realising that public authorities have a responsibility to ensure a high level of protection of human health and the environment and have to address increased public concern regarding the risks to which the public are potentially exposed;

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1. Welcomes the Commission's initiative in presenting a communication on the precautionary principle, the broad lines of which the Council endorses;

2. Considers that the precautionary principle applies to the policies and action of the Community and its Member States and concerns action by public authorities both at the level of the Community institutions and at that of Member States; that such authorities should endeavour to have that principle fully recognised by the relevant international fora;

3. Notes that the precautionary principle is gradually asserting itself as a principle of international law in the fields of environmental and health protection;

4. Considers that WTO rules do basically allow account to be taken of the precautionary principle;

5. Believes that under international law the Community and the Member States are entitled to establish the level of protection they consider appropriate in risk management, that they may to that end take appropriate measures under the

precautionary principle and that it is not always possible to determine in advance the level of protection appropriate to all situations;

6. Sees a need to establish guidelines for use of the precautionary principle, in order to clarify arrangements for its application;

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7. Considers that use should be made of the precautionary principle where the possibility of harmful effects on health or the environment has been identified and preliminary scientific evaluation, based on the available data, proves inconclusive for assessing the level of risk;

8. Considers that the scientific assessment of the risk must proceed logically in an effort to achieve hazard identification, hazard characterisation, appraisal of exposure and risk characterisation, with reference to procedures recognised at Community level and internationally, and that, owing to insufficient data and the nature or urgency of the risk, it may not always be possible to complete every stage systematically.

9. Considers that, in order to carry out the risk assessment, public authorities must have suitable research facilities and rely in particular on scientific committees and on relevant national and international scientific work; that the public authorities are responsible for organising the risk assessment, which must be carried out in a multidisciplinary, independent and transparent manner and ensure that all views are heard;

10. Considers that an assessment of risk must also report any minority opinions. It must be possible to express such opinions and bring them to the knowledge of the parties involved, in particular if they draw attention to scientific uncertainty;

11. Affirms that those responsible for scientific assessment of risk must be functionally separate from those responsible for risk management, albeit with ongoing exchange between them;

12. Considers that risk management measures must be taken by the public authorities responsible on the basis of a political appraisal of the desired level of protection;

13. Believes that, in selecting the risk management measures to be taken, consideration should be given to the whole range of measures enabling the desired level of protection to be achieved;

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14. Considers that all stages must be conducted in a transparent manner, in particular the risk assessment and management stages, including the monitoring of measures decided upon;

15. Considers that civil society must be involved and special attention must be paid to consulting all interested parties as early as possible;

16. Considers that appropriate means must be used for communicating information on scientific opinion and risk management measures;

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17. Considers that measures must observe the principle of proportionality, taking account of short-term and long-term risks and aiming to achieve the desired high level of protection;

18. Considers that measures must not be applied in a way resulting in arbitrary or unwarranted discrimination; where there are a number of possible means of attaining the same level of health or environmental protection, the least trade-restrictive measures should be opted for;

19. Considers that measures should be consistent with measures already adopted in similar circumstances or following similar approaches, having due regard to the latest scientific developments and developments in the level of protection sought;

20. Stresses that the measures adopted presuppose examination of the benefits and costs of action and inaction. This examination must take account of social and environmental costs and of the public acceptability of the different options possible, and include, where feasible, an economic analysis, it being understood that requirements linked to the protection of public health, including the effects of the environment on public health, must be given priority;

21. Considers that decisions taken in accordance with the precautionary principle should be reviewed in the light of developments in scientific knowledge. To that end the impact of such decisions should be monitored and additional research conducted in order to reduce the level of uncertainty;

22. Considers that, when determining measures taken in accordance with the precautionary principle and in monitoring them, the competent authorities should be able to decide case by case, on the basis of clear rules established at the appropriate

level, who is responsible for providing the scientific data required for a fuller risk assessment;

Such an obligation may vary according to the circumstances and the aim must be to strike a satisfactory balance between the public authorities, scientific bodies and economic operators, taking into account in particular the responsibility held by economic operators by virtue of their activities.

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23. Undertakes to put into practice the principles contained in this Resolution;

24. Calls on the Commission to:

- systematically apply its guidelines on the conditions for use of the precautionary principle, making allowance for the specific features of the various areas in which they may be implemented;

- incorporate the precautionary principle, wherever necessary, in drawing up its legislative proposals and in all its actions;

25. Calls on the Member States and the Commission to:

- **attach particular importance to the development of scientific expertise and to the necessary institutional coordination;**

- ensure that the precautionary principle is fully recognised in the relevant international health, environment and world trade fora, in particular on the basis of the principles put forward in this Resolution; to pursue that aim and ensure that it is taken into account as fully as possible, particularly at the WTO, and at the same time help to explain it;

- ensure that the public and the various parties involved are informed as fully as possible about the state of scientific knowledge, the issues at stake and the risks to which they and their environment are exposed;

- work actively for international partners' commitment to reaching an understanding on the application of the principle;

- have this Resolution as widely disseminated as possible.