COMMISSION OF THE EUROPEAN COMMUNITIES

COMMUNICATION FROM THE COMMISSION

on the precautionary principle

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SUMMARY

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to be in the future even more determined to be guided by the precautionary principle in preparing proposals for legislation and in its other consumer-related activities and develop as priority clear and effective guidelines for the application of this principle"

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Although the precautionary principle is not explicitly mentioned in the Treaty except in the environmental field, its scope is far wider and 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 .

4. THE PRECAUTIONARY PRINCIPLE IN INTERNATIONAL LAW

"in order to protect the environment, the precautionary approach shall be widely applied by States according to their capability. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation".

"The parties to this agreement ... recognising that their relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing to in a manner consistent with their respective needs and concerns at different levels of economic development ..."

in cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

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Bearing in mind the very origins of the precautionary principle and its growing role in international law, and notably in the agreements of the World Trade Organisation, this principle must be duly addressed at international level in the various areas in which it is likely to be of relevance.

Following the example set by the other members of the WTO, the Commission considers that the Community is entitled to prescribe the level of protection, notably as regards environmental protection and human, animal and plant health, that it considers appropriate. Recourse to the precautionary principle is a central plank of Community policy. The choices made to this end will continue to influence its positions at international level, and notably at multinational level, as regards the precautionary principle.

5. THE CONSTITUENT PARTS OF THE PRECAUTIONARY PRINCIPLE

the political decision to act or not to act as such,
factors triggering
how to act, i.e. measures

5.1. Factors triggering recourse to the precautionary principle

5.1.1. Identification of potentially negative effects

5.1.2. Scientific evaluation

5.1.3. Scientific uncertainty

Recourse to the precautionary principle presupposes:

identification of potentially negative effects resulting from a phenomenon, product or process;

a scientific evaluation of the risk which because of the insufficiency of the data, their inconclusive or imprecise nature, makes it impossible to determine with sufficient certainty the risk in question.

5.2. Measures resulting from reliance on the precautionary principle

5.2.1. The decision whether or not to act

The appropriate response in a given situation is thus the result of an political decision, a function of the risk level that is "acceptable" to the society on which the risk is imposed.

5.2.2. Nature of the action ultimately taken

Recourse to the precautionary principle does not necessarily mean adopting final instruments designed to produce legal effects, which are subject to judicial review.

6. GUIDELINES FOR APPLYING THE PRECAUTIONARY PRINCIPLE.

6.1. Implementation

The implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty.

6.2. The triggering factor

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.

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cf The WTO Appellate Body report on hormones, paragraph 194 : « In some cases, the very existence of divergent views presented by qualified scientists who have investigated the particular issue at hand, may indicate a state of scientific uncertainty »

A considerable effort has already been made notably as regards public health and the environment. As regards the latter, the Community and the Member States have demonstrated the importance they attach to access to information and justice by signing the Aarhus Convention of June 1998.

6.3. The general principles of application

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6.3.1. Proportionality

Measures should be proportional to the desired level of protection.

6.3.2. Non-discrimination

Measures should not be discriminatory in their application.

6.3.3. Consistency

Measures should be consistent with the measures already adopted in similar circumstances or using similar approaches.

6.3.4. Examination of the benefits and costs of action and lack of action

The measures adopted presuppose examination of the benefits and costs of action and lack of action. This examination should include an economic cost/benefit analysis when this is appropriate and feasible. However, other analysis methods, such as those concerning efficacy and the socio-economic impact of the various options, may also be relevant. Besides the decision-maker may, in certain circumstances, by guided by non-economic considerations such as the protection of health.

6.3.5. Examination of scientific developments

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> ***The measures, although provisional, shall be maintained as long as the scientific data remain incomplete, imprecise or inconclusive and as long as the risk is considered too high to be imposed on society.***
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> ***Maintenance of the measures depends on the development of scientific knowledge, in the light of which they should be reevaluated. This means that scientific research shall be continued with a view to obtaining more complete data.***
>
> ***Measures based on the precautionary principle shall be reexamined and if necessary modified depending on the results of the scientific research and the follow up of their impact.***

6.4. The burden of proof

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Measures based on the precautionary principle may assign responsibility for producing the scientific evidence necessary for a comprehensive risk evaluation.

7. CONCLUSION

ANNEX I

LEGAL AND OTHER BASES FOR EC DECISIONS ON PRECAUTIONARY MEASURES

"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 …

3. In preparing its policy on the environment, the Community shall take account of:

available scientific and technical data, …

the potential benefits and costs of action or lack of action …"

"environmental protection requirements must be integrated into the definition and implementation of the Community policies and activities referred to in Article 3, in particular with a view to promoting sustainable development".

"The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective".

"A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities".

Case law

"That approach is borne out by gowicle 130o(1) of the EC

"European food law is based on the principle of preventive protection of consumer health;

stresses that policy in this area must be founded on a scientifically-based risk analysis supplemented, where necessary, by appropriate risk management based on the precautionary principle;

invites the Commission to anticipate possible challenges to Community food law by WTO bodies by requesting the scientific committees to present a full set of arguments based on the precautionary principle."

"emphasises the importance of application of the precautionary principle"

"reaffirms the over-riding need for a precautionary approach within the EEA to the assessment and evaluation of applications for the marketing of GMOs intended to enter the food chain…" (point 13).

"to be in the future even more determined to be guided by the precautionary principle in preparing proposals for legislation and in its other consumer-related activities and develop as a priority clear and effective guidelines for the application of this principle"

ANNEX II

THE PRECAUTIONARY PRINCIPLE IN INTERNATIONAL LAW

The environment

in order to protect the North Sea from possibly damaging effects of the most dangerous substances, a precautionary approach is necessary which may require action to control inputs of such substances even before a causal link has been established by absolutely clear scientific evidence .

the participants ... will continue to apply the precautionary principle, that is to take action to avoid potentially damaging impacts of substances that are persistent, toxic and liable to bioaccumulate even where there is no scientific evidence to prove a causal link between emissions and effects

"In order to protect the environment, the precautionary approach should be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation".

Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimise such a threat

precautionary measures to anticipate, prevent or minimise the causes of climate change and mitigate its adverse effects. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures, taking into account that policies and measures to deal with climate change should be cost-effective so as to ensure global benefits at the lowest possible cost.

by virtue of which preventive measures are to be taken when there are reasonable grounds for concern that substances or energy introduced, directly or indirectly, into the marine environment may bring about hazards to human health, harm living resources and marine ecosystems, damage amenities or interfere with other legitimate uses of the sea, even when there is no conclusive evidence of a causal relationship between the inputs and the effects.

"Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects".

The WTO SPS Agreement

In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available scientific information, including that from the relevant international organizations as well as from sanitary and phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time

and

ANNEX III

THE FOUR COMPONENTS OF RISK ASSESSMENT