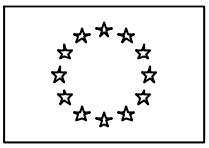

COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMUNICATION FROM THE COMMISSION

on the precautionary principle

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SUMMARY

1. The issue of when and how to use the precautionary principle, both within the European Union and internationally, is giving rise to much debate, and to mixed, and sometimes contradictory views. Thus, decision-makers are constantly faced with the dilemma of balancing the freedom and rights of individuals, industry and organisations with the need to reduce the risk of adverse effects to the environment, human, animal or plant health. Therefore, finding the correct balance so that the proportionate, non-discriminatory, transparent and coherent actions can be taken, requires a structured decision-making process with detailed scientific and other objective information.

2. The Communication's fourfold aim is to:

   - outline the Commission's approach to using the precautionary principle,
   - establish Commission guidelines for applying it,
   - build a common understanding of how to assess, appraise, manage and communicate risks that science is not yet able to evaluate fully, and
   - avoid unwarranted recourse to the precautionary principle, as a disguised form of protectionism.

   It also seeks to provide an input to the ongoing debate on this issue, both within the Community and internationally.

3. The precautionary principle is not defined in the Treaty, which prescribes it only once - to protect the environment. But *in practice*, its scope is much wider, and specifically where preliminary objective scientific evaluation, indicates 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 high level of protection chosen for the Community.

   The Commission considers that the Community, like other WTO members, has the right to establish the level of protection - particularly of the environment, human, animal and plant health, - that it deems appropriate. Applying the precautionary principle is a key tenet of its policy, and the choices it makes to this end will continue to affect the views it defends internationally, on how this principle should be applied.

4. The precautionary principle should be considered within a structured approach to the analysis of risk which comprises three elements: risk assessment, risk management, risk communication. The precautionary principle is particularly relevant to the management of risk.

   The precautionary principle, which is essentially used by decision-makers in the management of risk, should not be confused with the element of caution that scientists apply in their assessment of scientific data.

Recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty.

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.

5. Decision-makers need to be aware of the degree of uncertainty attached to the results of the evaluation of the available scientific information. Judging what is an "acceptable" level of risk for society is an eminently *political* responsibility. Decision-makers faced with an unacceptable risk, scientific uncertainty and public concerns have a duty to find answers. Therefore, all these factors have to be taken into consideration.

In some cases, the right answer may be not to act or at least not to introduce a binding legal measure. A wide range of initiatives is available in the case of action, going from a legally binding measure to a research project or a recommendation.

The decision-making procedure should be transparent and should involve as early as possible and to the extent reasonably possible all interested parties.

6. Where action is deemed necessary, measures based on the precautionary principle should be, *inter alia*:

- *proportional* to the chosen level of protection,
- *non-discriminatory* in their application,
- *consistent* with similar measures already taken,
- *based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis),
- *subject to review*, in the light of new scientific data, and
- *capable of assigning responsibility for producing the scientific evidence* necessary for a more comprehensive risk assessment.

Proportionality means tailoring measures to the chosen level of protection. Risk can rarely be reduced to zero, but incomplete risk assessments may greatly reduce the range of options open to risk managers. A total ban may not be a proportional response to a potential risk in all cases. However, in certain cases, it is the sole possible response to a given risk.

Non-discrimination means that comparable situations should not be treated differently, and that different situations should not be treated in the same way, unless there are objective grounds for doing so.

Consistency means that measures should be of comparable scope and nature to those already taken in equivalent areas in which all scientific data are available.

Examining costs and benefits entails comparing the overall cost to the Community of action and lack of action, in both the short and long term. This is not simply an economic cost-benefit analysis: its scope is much broader, and includes non-economic considerations, such as the efficacy of possible options and their acceptability to the public. In the conduct of such an examination, account should be taken of the general principle and the case law of the Court that the protection of health takes precedence over economic considerations.

Subject to review in the light of new scientific data, means measures based on the precautionary principle should be maintained so long as scientific information is incomplete or inconclusive, and the risk is still considered too high to be imposed on society, in view of chosen level of protection. Measures should be periodically reviewed in the light of scientific progress, and amended as necessary.

Assigning responsibility for producing scientific evidence is already a common consequence of these measures. Countries that impose a prior approval (marketing authorisation) requirement on products that they deem dangerous *a priori* reverse the burden of proving injury, by treating them as dangerous unless and until businesses do the scientific work necessary to demonstrate that they are safe.

Where there is no prior authorisation procedure, it may be up to the user or to public authorities to demonstrate the nature of a danger and the level of risk of a product or process. In such cases, a specific precautionary measure might be taken to place the burden of proof upon the producer, manufacturer or importer, but this cannot be made a general rule.

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1. INTRODUCTION

A number of recent events has shown that public opinion is becoming increasingly aware of the potential risks to which the population or their environment are potentially exposed.

Enormous advances in communications technology have fostered this growing sensitivity to the emergence of new risks, before scientific research has been able to fully illuminate the problems. Decision-makers have to take account of the fears generated by these perceptions and to put in place preventive measures to eliminate the risk or at least reduce it to the minimum acceptable level. On 13 April 1999 the Council adopted a resolution urging the Commission inter alia " *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"*. This Communication is part of the Commission's response.

The dimension of the precautionary principle goes beyond the problems associated with a short or medium-term approach to risks. It also concerns the longer run and the well-being of future generations.

A decision to take measures without waiting until all the necessary scientific knowledge is available is clearly a precaution-based approach.

Decision-makers are constantly faced with the dilemma of balancing the freedoms and rights of individuals, industry and organisations with the need to reduce or eliminate the risk of adverse effects to the environment or to health.

Finding the correct balance so that proportionate, non-discriminatory, transparent and coherent decisions can be arrived at, which at the same time provide the chosen level of protection, requires a structured decision making process with detailed scientific and other objective information. This structure is provided by the three elements of risk analysis: the assessment of risk, the choice of risk management strategy and the communication of the risk.

Any assessment of risk that is made should be based on the existing body of scientific and statistical data. Most decisions are taken where there is sufficient information available for appropriate preventive measures to be taken but in other circumstances, these data may be wanting in some respects.

Whether or not to invoke the Precautionary Principle is a decision exercised where scientific information is insufficient, inconclusive, or uncertain and where there are indications that the possible effects on the environment, or human, animal or plant health may be potentially dangerous and inconsistent with the chosen level of protection.

2. THE GOALS OF THIS COMMUNICATION

The aim of this Communication is to inform all interested parties, in particular the European Parliament the Council and Member States of the manner in which the Commission applies or intends to apply the precautionary principle when faced with taking decisions relating to the containment of risk. However, this general Communication does not claim to be the final word - rather, the idea is to provide input to the ongoing debate both at Community and international level.

This Communication seeks to establish a common understanding of the factors leading to recourse to the precautionary principle and its place in decision making, and to establish guidelines for its application based on reasoned and coherent principles.

The guidelines outlined in this Communication are only intended to serve as general guidance and in no way to modify or affect the provisions of the Treaty or secondary Community legislation.

Another objective is to avoid unwarranted recourse to the precautionary principle, which in certain cases could serve as a justification for disguised protectionism. Accordingly the development of international guidelines could facilitate the achievement of this end. The Commission also wishes to stress in this Communication that, far from being a way of evading obligations arising from the WTO Agreements, the envisaged use of the precautionary principle complies with these obligations.

It is also necessary to clarify a misunderstanding as regards the distinction between reliance on the precautionary principle and the search for zero risk, which in reality is rarely to be found. The search for a high level of health and safety and environmental and consumer protection belongs in the framework of the single market, which is a cornerstone of the Community.

The Community has already relied on the precautionary principle. Abundant experience has been gained over many years in the environmental field, where many measures have been inspired by the precautionary principle, such as measures to protect the ozone layer or concerning climate change.

3. THE PRECAUTIONARY PRINCIPLE IN THE EUROPEAN UNION

The Community has consistently endeavoured to achieve a high level of protection, among others in environment and human, animal or plant health. In most cases, measures making it possible to achieve this high level of protection can be determined on a satisfactory scientific basis. However, when there are reasonable grounds for concern that potential hazards may affect the environment or human, animal or plant health, and when at the same time the available data preclude a detailed risk evaluation, the precautionary principle has been politically accepted as a risk management strategy in several fields.

To understand fully the use of the precautionary principle in the European Union, it is necessary to examine the legislative texts, the case law of the Court

of Justice and the Court of First Instance, and the policy approaches that have emerged.

Legal Texts

The analysis starts with the legal texts which explicitly or implicitly refer to the precautionary principle (Annex I, Ref. 1).

At Community level the only explicit reference to the precautionary principle is to be found in the environment title of the EC Treaty, and more specifically Article 174. However, one cannot conclude from this that the principle applies only to the environment (Annex I, Refs. 2 and 3). Although the principle is adumbrated in the Treaty, it is not defined there.

Like other general notions contained in the legislation, such as subsidiarity or proportionality, it is for the decision-makers and ultimately the courts to flesh out the principle. In other words, the scope of the precautionary principle also depends on trends in case law, which to some degree are influenced by prevailing social and political values.

However, it would be wrong to conclude that the absence of a definition has to lead to legal uncertainty. The Community authorities' practical experience with the precautionary principle and its judicial review make it possible to get an ever-better handle on the precautionary principle.

Case law

The Court of Justice of the European Communities and the Court of First Instance have already had occasion to review the application of the precautionary principle in cases they have adjudicated and hence to develop case law in this area. (see Annex I, Refs. 5, 6 and 7)

Policy orientations

Policy orientations were set out by the Commission in the Green Paper on the General Principles of Food Safety and the Communication of 30 April 1997 on Consumer Health and Food Safety, by Parliament in its Resolution of 10 March 1998 concerning the Green Paper, by the Council in its Resolution of 13 April 1999 and by the Joint Parliamentary Committee of the EEA (European Economic Area) in its Resolution of 16 March 1999 (Annex I, Refs. 8-12).

Hence the Commission considers that the precautionary principle is a general one which should in particular be taken into consideration in the fields of environmental protection and human, animal and plant health.

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

At international level, the precautionary principle was first recognised in the World Charter for Nature, adopted by the UN General Assembly in 1982. It was subsequently incorporated into various international conventions on the protection of the environment. (cf. Annex II).

This principle was enshrined at the 1992 Rio Conference on the Environment and Development, during which the Rio Declaration was adopted, whose principle 15 states that: *"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"*. Besides, the United Nations' Framework Convention on Climate Change and the Convention of Biological Diversity both refer to the precautionary principle. Recently, on 28 January 2000, at the Conference of the Parties to the Convention on Biological Diversity, the Protocol on Biosafety concerning the safe transfer, handling and use of living modified organisms resulting from modern biotechnology confirmed the key function of the Precautionary Principle (see Annex II).

Hence this principle has been progressively consolidated in international environmental law, and so it has since become a full-fledged and general principle of international law.

The WTO agreements confirm this observation. The preamble to the WTO Agreement highlights the ever closer links between international trade and environmental protection[1]. A consistent approach means that the precautionary principle must be taken into account in these agreements, notably in the Agreement on Sanitary and Phytosanitary Measures (SPS) and in the Agreement on Technical Barriers to Trade (TBT), to ensure that this general principle is duly enforced in this legal order.

Hence, each Member of the WTO has the independent right to determine the level of environmental or health protection they consider appropriate. Consequently a member may apply measures, including measures based on the precautionary principle, which lead to a higher level of protection than that provided for in the relevant international standards or recommendations.

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) clearly sanctions the use of the precautionary principle, although the term itself is not explicitly used. Although the general rule is that

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[1] *"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 ..."*

all sanitary and phytosanitary measures must be based on scientific principles and that they should not be maintained without adequate scientific evidence, a derogation from these principles is provided for in Article 5 (7) which stipulates that: *"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.*"

Hence, according to the SPS Agreement, measures adopted in application of a precautionary principle when the scientific data are inadequate, are provisional and imply that efforts be undertaken to elicit or generate the necessary scientific data. It is important to stress that the provisional nature is not bound up with a time limit but with the development of scientific knowledge.

The use of the term "more objective assessment of risk" in Article 5.7 infers that a precautionary measure may be based on a less objective appraisal but must nevertheless includes an evaluation of risk.

The concept of risk assessment in the SPS leaves leeway for interpretation of what could be used as a basis for a precautionary approach. The risk assessment on which a measure is based may include non-quantifiable data of a factual or qualitative nature and is not uniquely confined to purely quantitative scientific data. This interpretation has been confirmed by the WTO's Appellate body in the case of growth hormones, which rejected the panel's initial interpretation that the risk assessment had to be quantitative and had to establish a minimum degree of risk.

The principles enshrined in Article 5.7 of the SPS must be respected in the field of sanitary and phytosanitary measures; however, because of the specific nature of other areas, such as the environment, it may be that somewhat different principles will have to be applied.

International guidelines are being considered in relation to the application of the Precautionary Principle in Codex Alimentarius. Such guidance in this, and other sectors, could pave the way to a harmonised approach by the WTO Members, to drawing up health or environment protection measures, while avoiding the misuse of the precautionary principle which could otherwise lead to unjustifiable barriers to trade.

In the light of these observations, the Commission considers that, following the example set by other Members of the WTO, the Community is entitled to prescribe the level of protection, notably as regards the environment and human, animal and plant health, which it considers appropriate. In this context, the Community must respect Articles 6, 95, 152 and 174 of the Treaty. To this end, reliance on the precautionary principle constitutes an essential plank of its policy. It is clear that the choices made will affect its positions at international and notably multilateral level, as regards recourse to the precautionary principle.

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

An analysis of the precautionary principle reveals two quite distinct aspects: (i) **the political decision to act or not to act as such,** which is linked to the **factors triggering** recourse to the precautionary principle; (ii) in the affirmative, **how to act, i.e.** the **measures** resulting from application of the precautionary principle.

There is a controversy as to the role of scientific uncertainty in risk analysis, and notably as to whether it belongs under risk assessment or risk management. This controversy springs from a confusion between a prudential approach and application of the precautionary principle. These two aspects are complementary but should not be confounded.

The prudential approach is part of risk assessment policy which is determined before any risk assessment takes place and which is based on the elements described in 5.1.3; it is therefore an integral part of the scientific opinion delivered by the risk evaluators.

On the other hand, application of the precautionary principle is part of risk management, when scientific uncertainty precludes a full assessment of the risk and when decision-makers consider that the chosen level of environmental protection or of human, animal and plant health may be in jeopardy.

The Commission considers that measures applying the precautionary principle belong in the general framework of risk analysis, and in particular risk management.

5.1. Factors triggering recourse to the precautionary principle

The precautionary principle is relevant only in the event of a potential risk, even if this risk cannot be fully demonstrated or quantified or its effects determined because of the insufficiency or inclusive nature of the scientific data.

It should however be noted that the precautionary principle can under no circumstances be used to justify the adoption of arbitrary decisions.

5.1.1. Identification of potentially negative effects

Before the precautionary principle is invoked, the scientific data relevant to the risks must first be evaluated. However, one factor logically and chronologically precedes this evaluation, namely identification of the potentially negative effects of a phenomenon. To understand these effects more thoroughly it is necessary to conduct a scientific examination. The decision to conduct this examination without awaiting additional information is bound up with a less theoretical and more concrete perception of the risk.

5.1.2. Scientific evaluation

A scientific evaluation of the potential adverse effects should be undertaken based on the available data when considering whether measures are necessary to protect the environment, the human, animal or plant health. An assessment of risk should be considered where feasible when deciding whether or not to invoke the precautionary principle. This requires reliable scientific data and logical reasoning, leading to a conclusion which expresses the possibility of occurrence and the severity of a hazard's impact on the environment, or health of a given population including the extent of possible damage, persistency, reversibility and delayed effect. However it is not possible in all cases to complete a comprehensive assessment of risk, but all effort should be made to evaluate the available scientific information.

Where possible, a report should be made which indicates the assessment of the existing knowledge and the available information, providing the views of the scientists on the reliability of the assessment as well as on the remaining uncertainties. If necessary, it should also contain the identification of topics for further scientific research.

Risk assessment consists of four components - namely hazard identification, hazard characterisation, appraisal of exposure and risk characterisation (Annex III). The limits of scientific knowledge may affect each of these components, influencing the overall level of attendant uncertainty and ultimately affecting the foundation for protective or preventive action. An attempt to complete these four steps should be performed before decision to act is taken.

5.1.3. Scientific uncertainty

Scientific uncertainty results usually from five characteristics of the scientific method : the variable chosen, the measurements made, the samples drawn, the models used and the causal relationship employed. Scientific uncertainty may also arise from a controversy on existing data or lack of some relevant data . Uncertainty may relate to qualitative or quantitative elements of the analysis.

A more abstract and generalised approach preferred by some scientists is to separate all uncertainties into three categories of – Bias, Randomness and True Variability. Some other experts categorise uncertainty in terms of estimation of confidence interval of the probability of occurrence and of the severity of the hazard’s impact.

This issue is very complex and the Commission launched a project "Technological Risk and the Management of Uncertainty" conducted under the auspices of the European Scientific Technology Observatory. The four ESTO reports will be published shortly and will give a comprehensive description of scientific uncertainty.

Risk evaluators accommodate these uncertainty factors by incorporating prudential aspects such as :

– relying on animal models to establish potential effects in man;

– using body weight ranges to make inter-species comparisons;

– adopting a safety factor in evaluating an acceptable daily intake to account for intra- and inter-species variability; the magnitude of this factor depends on the degree of uncertainty of the available data;

– not adopting an acceptable daily intake for substances recognised as genotoxic or carcinogenic;

– adopting the "ALARA" (as low as reasonably achievable) level as a basis for certain toxic contaminants.

Risk managers should be fully aware of these uncertainty factors when they adopt measures based on the scientific opinion delivered by the evaluators.

However, in some situations the scientific data are not sufficient to allow one to apply these prudential aspects in practice, i.e. in cases in which extrapolations cannot be made because of the absence of parameter modelling and where cause-effect relationships are suspected but have not been demonstrated. It is in situations like these that decision-makers face the dilemma of having to act or not to act.

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

In the kind of situation described above - sometimes under varying degrees of pressure from public opinion - decision-makers have to respond. However, responding does not necessarily mean that measures always have to be adopted. The decision to do nothing may be a response in its own right.

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

The nature of the decision influences the type of control that can be carried out. Recourse to the precautionary principle does not necessarily mean adopting final instruments designed to produce legal effects that are open to judicial review. There is a whole range of actions available to decision-makers under the head of the precautionary principle. The decision to fund a research programme or even the decision to inform the public about the possible adverse effects of a product or procedure may themselves be inspired by the precautionary principle.

It is for the Court of Justice to pronounce on the legality of any measures taken by the Community institutions. The Court has consistently held that when the Commission or any other Community institution has broad discretionary powers, notably as regards the nature and scope of the measures it adopts, review by the Court must be limited to examining whether the institution committed a manifest error or misuse of power or manifestly exceed the limits of its powers of appraisal.

Hence the measures may not be of an arbitrary nature.

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

When decision-makers become aware of a risk to the environment or human, animal or plant health that in the event of non-action may have serious consequences, the question of appropriate protective measures arise. Decision-makers have to obtain, through a structured approach, a scientific evaluation, as complete as possible, of the risk to the environment, or health, in order to select the most appropriate course of action

The determination of appropriate action including measures based on the precautionary principle should start with a scientific evaluation and, if necessary, the decision to commission scientists to perform an as objective and complete as possible scientific evaluation. It will cast light on the existing objective evidence, the gaps in knowledge and the scientific uncertainties.

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

Once the scientific evaluation has been performed as best as possible, it may provide a basis for triggering a decision to invoke the precautionary principle. The conclusions of this evaluation should show that the desired level of protection for the environment or a population group could be jeopardised. The conclusions should also include an assessment of the scientific uncertainties and a description of the hypotheses used to compensate for the lack of the scientific or statistical data. An assessment of the potential consequences of inaction should be considered and may be used as a trigger by the decision-makers. The decision to wait or not to wait for new scientific data before considering possible measures should be taken by the decision-makers with a maximum of transparency. The absence of scientific proof of the existence of a cause-effect relationship, a quantifiable dose/response relationship or a quantitative evaluation of the probability of the emergence of adverse effects following exposure should not be used to justify inaction. Even if scientific advice is supported only by a minority fraction of the scientific community, due account should be taken of their views, provided the credibility and reputation of this fraction are recognised.[2]

The Commission has confirmed its wish to rely on procedures as transparent as possible and to involve all interested parties at the earliest possible stage[3]. This will assist decision makers in taking legitimate measures which are likely to achieve the society's chosen level of health or environmental protection

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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[2] *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 »*

[3] *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

The general principles are not limited to application of the precautionary principle. They apply to all risk management measures. An approach inspired by the precautionary principle does not exempt one from applying wherever possible these criteria, which are generally used when a complete risk assessment is at hand.

Thus reliance on the precautionary principle is no excuse for derogating from the general principles of risk management.

These general principles include:

- proportionality,
- non-discrimination,
- consistency,
- examination of the benefits and costs of action or lack of action
- examination of scientific developments.

6.3.1. Proportionality

The measures envisaged must make it possible to achieve the appropriate level of protection. Measures based on the precautionary principle must not be disproportionate to the desired level of protection and must not aim at zero risk, something which rarely exists. However, in certain cases, an incomplete assessment of the risk may considerably limit the number of options available to the risk managers.

In some cases a total ban may not be a proportional response to a potential risk. In other cases, it may be the sole possible response to a potential risk.

Risk reduction measures should include less restrictive alternatives which make it possible to achieve an equivalent level of protection, such as appropriate treatment, reduction of exposure, tightening of controls, adoption of provisional limits, recommendations for populations at risk, etc. One should also consider replacing the products or procedures concerned by safer products or procedures.

The risk reduction measure should not be limited to immediate risks where the proportionality of the action is easier to assess. It is in situations in which the adverse effects do not emerge until long after exposure that the cause-effect relationships are more difficult to prove scientifically and that – for this reason – the precautionary principle often has to be invoked. In this case the potential long-term effects must be taken into account in evaluating the proportionality of measures in the form of rapid action to limit or eliminate a risk whose effects will not surface until ten or twenty years later or will affect future generations. This applies in particular to effects on the eco-system. Risks that are carried forward into the future cannot be eliminated or reduced except at the time of exposure, that is to say immediately.

Measures should be proportional to the desired level of protection.

6.3.2. Non-discrimination

The principle of non-discrimination means that comparable situations should not be treated differently and that different situations should not be treated in the same way, unless there are objective grounds for doing so.

Measures taken under the precautionary principle should be designed to achieve an equivalent level of protection without invoking the geographical origin or the nature of the production process to apply different treatments in an arbitrary manner.

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. Risk evaluations include a series of factors to be taken into account to ensure that they are as thorough as possible. The goal here is to identify and characterise the hazards, notably by establishing a relationship between the dose and the effect and assessing the exposure of the target population or the environment. If the absence of certain scientific data makes it impossible to characterise the risk, taking into account the uncertainties inherent to the evaluation, the measures taken under the precautionary principle should be comparable in nature and scope with measures already taken in equivalent areas in which all the scientific data are available.

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

A comparison must be made between the most likely positive or negative consequences of the envisaged action and those of inaction in terms of the overall cost to the Community, both in the long- and short-term. The measures envisaged must produce an overall advantage as regards reducing risks to an acceptable level.

Examination of the pros and cons cannot be reduced to an economic cost-benefit analysis. It is wider in scope and includes non-economic considerations.

However, examination of the pros and cons should include an economic cost-benefit analysis where this is appropriate and possible.

Besides, other analysis methods, such as those concerning the efficacy of possible options and their acceptability to the public may also have to be taken

into account. A society may be willing to pay a higher cost to protect an interest, such as the environment or health, to which it attaches priority.

The Commission affirms, in accordance with the case law of the Court that requirements linked to the protection of public health should undoubtedly be given greater weight than economic considerations.

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

The measures should be maintained as long as the scientific data are inadequate, imprecise or inconclusive and as long as the risk is considered too high to be imposed on society. The measures may have to be modified or abolished by a particular deadline, in the light of new scientific findings. However, this is not always linked to the time factor, but to the development of scientific knowledge.

Besides, scientific research should be carried out with a view to obtaining a more advanced or more complete scientific assessment. In this context, the measures should be subjected to regular scientific monitoring, so that they can be reevaluated in the light of new scientific information.

The Agreement on Sanitary and Phytosanitary Measures (SPS) provides that measures adopted in the context of inadequate scientific evidence must respect certain conditions. Hence these conditions concern only the scope of the SPS Agreement, but the specific nature of certain sectors, such as the environment, may mean that somewhat different principles have to be applied.

Article 5(7) of the SPS agreement includes certain specific rules:

- The measures must be of a provisional nature pending the availability of more reliable scientific data. However this provisional nature is linked to the development of scientific knowledge rather than to a time factor.

- Research must be carried out to elicit the additional scientific data required for a more objective assessment of the risk.

- The measures must be periodically reviewed to take account of new scientific data. The results of scientific research should make it possible to complete the risk evaluation and if necessary to review the measures on the basis of the conclusions.

- Hence the reasonable period envisaged in the SPS Agreement includes the time needed for completion of the necessary scientific work and, besides, the time needed for performance of a risk evaluation based on the conclusions of this scientific work. It should not be possible to invoke budgetary constraints or political priorities to justify excessive delays in obtaining results, re-evaluating the risk or amending the provisional measures.

Research could also be conducted for the improvement of the methodologies and instruments for assessing risk, including greater integration of all pertinent factors (e.g. socio-economic information, technological perspectives).

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.

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

- Community rules and those of many third countries enshrine the principle of prior approval (positive list) before the placing on the market of certain products, such as drugs, pesticides or food additives. This is one way of applying the precautionary principle, by shifting responsibility for producing scientific evidence. This applies in particular to substances deemed "a priori" hazardous or which are potentially hazardous at a certain level of absorption. In this case the legislator, by way of precaution, has clearly reversed the burden of proof by requiring that the substances be deemed hazardous until proven otherwise. Hence it is up to the business community to carry out the scientific work needed to evaluate the risk. As long as the human health risk cannot be evaluated with sufficient certainty, the legislator is not legally entitled to authorise use of the substance, unless exceptionally for test purposes.

- In other cases, where such a prior approval procedure does not exist, it may be for the user, a private individual, a consumer association, citizens or the public authorities to demonstrate the nature of a danger and the level of risk posed by a product or process. Action taken under the head of the precautionary principle must in certain cases include a clause reversing the burden of proof and placing it on the producer, manufacturer or importer, but such an obligation cannot be systematically entertained as a general principle. This possibility should be examined on a case-by-case basis when a measure is adopted under the precautionary principle, pending

supplementary scientific data, so as to give professionals who have an economic interest in the production and/or marketing of the procedure or product in question the opportunity to finance the necessary research on a voluntary basis.

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

7. CONCLUSION

This Communication of a general scope sets out the Commission's position as regards recourse to the precautionary principle. The Communication reflects the Commission’s desire for transparency and dialogue with all stakeholders. At the same it is provides concrete guidance for applying the precautionary principle.

The Commission wishes to reaffirm the crucial importance it attaches to the distinction between the decision to act or not to act, which is of an eminently political nature, and the measures resulting from recourse to the precautionary principle, which must comply with the general principles applicable to all risk management measures. The Commission also considers that every decision must be preceded by an examination of all the available scientific data and, if possible, a risk evaluation that is as objective and comprehensive as possible. A decision to invoke the precautionary principle does not mean that the measures will be adopted on an arbitrary or discriminatory basis.

This Communication should also contribute to reaffirming the Community's position at international level, where the precautionary principle is receiving increasing attention. However the Commission wishes to stress that this Communication is not meant to be the last word; rather, it should be seen as the point of departure for a broader study of the conditions in which risks should be assessed, appraised, managed and communicated.

ANNEX I

LEGAL AND OTHER BASES FOR EC DECISIONS ON PRECAUTIONARY MEASURES

The legislative texts

Ref. 1

The EC Treaty, incorporating provisions already introduced by the Maastricht Treaty of 1992, and more specifically Article 174 thereof, states:

– *"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 …"*

Ref. 2

Article 6 of the EC Treaty provides that *"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".*

Ref. 3

Hence, Article 95(3) of the EC Treaty provides that: *"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".*

Ref. 4

The first paragraph of Article 152 of the EC Treaty provides that: *"A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities".*

Case law

Ref. 5

In its judgement on the validity of the Commission's decision banning the exportation of beef from the United Kingdom to reduce the risk of BSE transmission (Judgements of 5 May 1998, cases C-157/96 and C-180/96), the Court held:

"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." (Grounds 99). The next section fleshes out the Court's reasoning: *"That approach is borne out by Article 130r(1) of the EC Treaty, according to which Community policy on the environment is to pursue the objective inter alia of protecting human health. Article 130r(2) provides that that policy is to aim at a high level of protection and is to be based in particular on the principles that preventive action should be taken and that environmental protection requirements must be integrated into the definition and implementation of other Community policies."(Grounds 100).*

Ref. 6

In another judgement concerning protection of consumer health (Judgement of 16 July 1998, case T-199/96), the Court of First Instance cites the above passage from the BSE judgement (see Grounds 66 and 67).

Ref. 7

Recently, in the Order of 30 June 1999 (Case T-70/99), the President of the Court of First Instance confirmed the positions expressed in the abovementioned judgements. Note that this judgement contains an explicit reference to the precautionary principle and affirms that "*requirements linked to the protection of public health should undoubtedly be given greater weight that economic considerations."*

Policy orientations

Ref. 8

In its Communication of 30 April 1997 on consumer health and food safety (COM(97) 183 final), the Commission states: *"the Commission will be guided in its risk analysis by the precautionary principle, in cases where the scientific basis is insufficient or some uncertainty exists".*

Ref. 9

In its Green Paper on the General Principles of Food Law in the European Union of 30 April 1997 (COM(97) 176 final), the Commission reiterates this point:

"The Treaty requires the Community to contribute to the maintenance of a high level of protection of public health, the environment and consumers. In order to ensure a high level of protection and coherence, protective measures should be based on risk assessment, taking into account all relevant risk factors, including technological aspects, the best available scientific evidence and the availability of inspection sampling and testing methods. Where a full risk assessment is not possible, measures should be based on the precautionary principle."

Ref. 10

In its Resolution of 10 March 1998 on the Green Paper, the European Parliament states:

"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."

Ref. 11

The Joint Parliamentary Committee of the EEA (European Economic Area), adopted a Resolution on Food Safety in the EEA on 16 March 1999. In this connection, on the one hand, it *"emphasises the importance of application of the precautionary principle"* (point 5) and, on the other, *"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).*

Ref. 12

On 13 April 1999, the Council adopted a Resolution urging the Commission, inter alia, *"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

Although applied more broadly, the Precautionary Principle has been developed primarily in the context of environmental policy.

Hence, the Ministerial Declaration of the Second International Conference on the Protection of the North Sea (1987) states that "*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*". A new Ministerial Declaration was delivered at the Third International Conference on the Protection of the North Sea (1990). It fleshes out the earlier declaration, stating that "*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*"

The Precautionary Principle was explicitly recognised during the UN Conference on Environment and Development (UNCED) in Rio de Janeiro 1992 and included in the so-called Rio Declaration. Since then the Precautionary Principle has been implemented in various environmental instruments, and in particular in global climate change, ozone depleting substances and biodiversity conservation.

The precautionary Principle is listed as Principle 15 of the Rio Declaration among the principles of general rights and obligations of national authorities:

"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".

Principle 15 is reproduced in similar wording in:

1. The preamble of the Convention of Biological Diversity (1992):

(…) *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* (…)

2. In article 3 (Principles) of the Convention of Climate Change (1992):

(..)The Parties should take *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.* To achieve this, such policies and measures should take into account different socio-

economic contexts, be comprehensive, cover all relevant sources, sinks and reservoirs of greenhouse gases and adaptation, and comprise all economic sectors. Efforts to address climate change may be carried out cooperatively by interested Parties.

In the Paris Convention for the protection of the marine environment of the north-east Atlantic (September 1992), the precautionary principle is defined as the principle "*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.*"

Recently, on 28 January 2000, at the Conference of the Parties to the Convention on Biological diversity, the Protocol on Biosafety concerning the safe transfer, handling and use of living modified organisms resulting from modern biotechnology confirmed the key function of the Precautionary Principle. In fact, article 10, paragraph 6 states: *"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".*

Besides, the preamble to the WTO Agreement highlights the ever closer links between international trade and environmental protection.

The WTO SPS Agreement

Although the term „Precautionary Principle" is not explicitly used in the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), the Appellate Body on EC measures concerning meat and meat products (Hormones) (AB-1997-4, paragraph 124) states that it finds reflection in Article 5.7 of this Agreement. Art 5.7 reads:„*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.*"

The Appellate Body on Hormones (Paragraph 124) recognises…." that there is no need to assume that Article 5.7 exhausts the relevance of a precautionary principle". Moreover, Members have the "right to establish their own level of sanitary protection, which level may be higher (i.e. more cautious) than that implied in existing international standards, guidelines and recommendations". Furthermore, it accepts that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned." The Appellate Body on Japan-Measures affecting agricultural products (AB-1998-8, paragraph 89) clarifies the four requirements which must be met in order to adopt and

maintain provisional SPS measures. A Member may provisionally adopt an SPS measure if this measure is:

1.) imposed in respect of a situation where „relevant scientific information is insufficient“; and

2.) adopted “on the basis of available pertinent information“.

Such a provisional measure may not be maintained unless the Member which adopted the measure:

1.) „seek(s) to obtain the additional information necessary for a more objective risk assessment“; and

2.) „review(s) the … measure accordingly within a reasonable period of time“

These four requirements are clearly cumulative and are equally important for the purpose of determining consistency with the provision of Art 5.7. Whenever one of these four requirements is not met, the measure at issue is inconsistent with Art 5.7. As to what constitutes a „reasonable period of time“ to review the measure, the Appellate Body points out (Paragraph 93), that this has to be established on a case-by-case basis and depends on the specific circumstances of each case, including the difficulty of obtaining the additional information necessary for the review *and* the characteristics of the provisional SPS measure.

ANNEX III

THE FOUR COMPONENTS OF RISK ASSESSMENT

An attempt to complete as far as possible these four components should be performed before action is taken.

Hazard identification means identifying the biological, chemical or physical agents that may have adverse effects. A new substance or biological agent may reveal itself through its effects on the population (illness or death), or on the environment and it may be possible to describe the actual or potential effects on the population or environment before the cause is identified beyond doubt.

Hazard characterisation consists of determining, in quantitative and/or qualitative terms, the nature and severity of the adverse effects associated with the causal agents or activity. It is at this stage that a relationship between the amount of the hazardous substance and the effect has to be established. However, the relationship is sometimes difficult or impossible to prove, for instance because the causal link has not been established beyond doubt.

Appraisal of exposure consists of quantitatively or qualitatively evaluating the probability of exposure to the agent under study. Apart from information on the agents themselves (source, distribution, concentrations, characteristics, etc.), there is a need for data on the probability of contamination or exposure of the population or environment to the hazard.

Risk characterisation corresponds to the qualitative and/or quantitative estimation, taking account of inherent uncertainties, of the probability, of the frequency and severity of the known or potential adverse environmental or health effects liable to occur. It is established on the basis of the three preceding and closely depends on the uncertainties, variations, working hypotheses and conjectures made at each stage of the process. When the available data are inadequate or non-conclusive, a prudent and cautious approach to environmental protection, health or safety could be to opt for the worst-case hypothesis. When such hypotheses are accumulated, this will lead to an exaggeration of the real risk but gives a certain assurance that it will not be underestimated.