

Brussels, 2 February 2000

## **Commission adopts Communication on Precautionary Principle**

***The European Commission has today adopted a Communication on the use of the precautionary principle. The objective of the Communication is to inform all interested parties how the Commission intends to apply the principle and to establish guidelines for its application. The aim is also to provide input to the on-going debate on this issue both at EU and international level. The Communication underlines that the precautionary principle forms part of a structured approach to the analysis of risk, as well as being relevant to risk management. It covers cases where scientific evidence is insufficient, inconclusive or uncertain and preliminary 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 by the EU. Today's Communication complements the recently adopted White Paper on Food Safety and the agreement reached in Montreal this week-end on the Cartagena Protocol on Bio-safety.***

The Communication also qualifies the measures that may be taken under the precautionary principle. Where action is deemed necessary, measures should be proportionate to the chosen level of protection, non-discriminatory in their application and consistent with similar measures already taken. They should also be based on an examination of the potential benefits and costs of action or lack of action and subject to review in the light of new scientific data and should thus 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. Finally, they may assign responsibility – or the burden of proof - for producing the scientific evidence necessary for a comprehensive risk assessment. These guidelines guard against unwarranted recourse to the precautionary principle as a disguised form of protectionism.

Today's Communication was presented to the Commission by Mr Erkki Liikanen, Enterprise and the Information Society Commissioner, Mr David Byrne, Health and Consumer Protection Commissioner, and Ms Margot Wallström, Environment Commissioner. It is a follow-up to President Romano Prodi's speech to the European Parliament on 5 October 1999.

The Communication recalls that a number of recent events have undermined the confidence of public opinion and consumers because decisions or absence of decisions were not supported by full scientific evidence and the legitimacy of such decisions was questionable.

The Commission has consistently striven to achieve a high level of protection, inter alia in the environmental and human, animal and plant health fields. It is the Commission's policy to take decisions aimed to achieve this high level of protection on a sound and sufficient scientific basis. However, where 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 lack of scientific information precludes a detailed scientific evaluation, the precautionary principle has been the politically accepted risk management strategy in several fields. Although the precautionary principle is not explicitly mentioned in the EC Treaty except in the environment field, the Commission considers that this principle has a scope far wider than the environment field and that it also covers the protection of human, animal and plant health.

The Communication makes it clear that the precautionary principle is neither a politicisation of science or the acceptance of zero-risk but that it provides a basis for action when science is unable to give a clear answer. The Communication also makes it clear that determining what is an acceptable level of risk for the EU is a political responsibility. It provides a reasoned and structured framework for action in the face of scientific uncertainty and shows that the precautionary principle is not a justification for ignoring scientific evidence and taking protectionist decisions.

The horizontal guidelines established in this Communication will provide a useful tool in the future for taking political decisions in this regard and will contribute to legitimate decisions taken when science is unable to assess completely the risk rather than decisions based on irrational fears or perceptions. Thus, one of the objectives of the Communication is to clearly describe the situations in which the precautionary principle could be applied and determining the scope of measures taken in this respect. It will therefore help ensuring the proper functioning of the Internal Market as well as a high level of protection and predictability for consumers and economic operators located in the EU and elsewhere.

## COMMUNICATION FROM THE COMMISSION ON THE PRECAUTIONARY PRINCIPLE

### 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.