The Precautionary Principle

Henri Belvèze, Directorate-General, Health and Consumer Protection
European Commission, Brussels

Ladies and Gentlemen, in 20 minutes, it is difficult to give an overview on this Communication on Precautionary Principle adopted by the Commission and addressed to European Parliament and Council 3 years ago.

The Communication contains the general scientific, legal and political orientation on the essential elements of the Precautionary Principle, establishing its use and limitations and guidelines for its application.

The aim of the communication is:

- first : to inform all interested parties, in particular the Community Institutions, of the manner in which the Commission applies or intends to apply the Precautionary Principle;

- second: to set up guidelines for its application based on reasoned and coherent principles;

- third: to build a common understanding of how to assess, manage and communicate risks that science is not yet able to fully evaluate;

- fourth: to avoid unwarranted recourse to the Precautionary Principle which could serve as a justification for disguised protectionism.

However, the Commission does not claim this Communication to be the final word. Rather, the idea is to provide input to the ongoing debate both at Community and international level.

I. Essential Elements of the Communication

I don't want to describe in detail this communication which was published 2 years ago. Everybody who is interested can get it. I just want to stress some essential elements:

1. Scope

The Commission considers that in cases of insufficient scientific basis, the application of the Precautionary Principle has a scope far wider than the environment field and covers, in particular, the protection of human, animal and plant health.

2. Level of protection

As with other members of WTO, the Commission recalls that the Community is entitled to prescribe the level of protection that it considers appropriate, notably as regards environmental protection and human, animal or plant health. Judging what is an acceptable level of risk for society is a very political responsibility in a democracy. This level of protection can be achieved by implementing measures soundly based on scientific evidence.

3. What is the Precautionary Principle?

This principle is nothing else than a policy decision saying that a lack of full scientific evidence does not prevent the decision-maker to act when there is a strong perception of a potential risk for the consumer, the public or the environment.

Two conditions are necessary for the implementation of the Precautionary Principle: firstly, the identification of a potentially negative effect resulting from a phenomenon, a product or a process, and secondly the impossibility to fully assess the risk because of the lack of data and/or their inconclusive or imprecise nature.

4. Decision to act

The decision whether to or not to act, is the result of a policy decision, a function of the level of risk that is "acceptable" to society, a specific population on which the risk is imposed. An assessment of the possible consequences of inaction should be considered and may be used as a trigger by the decision-makers.

5. What is the place of the Precautionary Principle in the decision-making process?

The Commission considers that measures applying the Precautionary Principle must be taken within the general framework of risk analysis. Risk analysis is a process consisting of 3 components: risk assessments, risk management and risk communication. Applying the Precautionary Principle belongs in particular to risk management, when scientific information is insufficient or inaccurate, and where there is identification of potentially negative effects resulting from a phenomenon, a product or a process.

As such, it is a risk management tool for the decision-makers. It is not a separate and redundant tool in addition to the process of risk analysis. It cannot be envisaged out of this framework.

6. Scientific evaluation

In any case, the first step of the application of the PP is to collect and evaluate all pertinent existing scientific knowledge and available information and, where possible, to attempt to perform a risk assessment as complete as possible. Risk managers should be fully aware of the uncertainties and of the insufficiency of the data, of their inconclusive or imprecise nature, and if divergent opinions of the scientists exist.

7. Transparency

The legitimacy of measures based on incomplete risk assessment relies on procedures which are as transparent as possible. All interested parties should be involved at the earliest possible stage of the decision-making process. There should be a clear

explanation of the need for the measures and the reasoning followed in determining them.

8. Precaution in risk assessment

There is a controversy as to the role of scientific uncertainty in risk analysis. This controversy springs from a confusion between a prudential approach routinely used by scientists in the risk assessment process (eg in relying on animal models, using inter-species comparison, setting safety factors, using No Observable Effect Level, adopting ALARA principle, etc) and the PP, which belongs to risk management when a preventive measure has to be adopted. These two aspects are complementary but should not be confounded.

9. The Communication set up guidelines for applying the PP

Applying the PP is not a means to by-pass the WTO rules and not an excuse for derogating from the general principles applicable to risk management, such as proportionality, non-discrimination, consistency and cost-effectiveness. This is a key message of the Communication. Decision-makers should make all efforts in order to fulfil these principles when the scientific basis of the measure remain uncertain. In addition, the measure should be reviewed within a reasonable period of time on the basis of assessment of scientific developments.

II. Follow-up of the Communication

As I said before, this communication was intended to provide input to the ongoing debate both at Community and international level.

1. At Community level

The European Parliament and Economic and Social Committee welcomed and supported this Communication.

The Nice Summit of Head of State endorsed a Council resolution,

- committing Member States to implement theses principles
- inviting the Commission : - to apply systematically these guidelines on the PP
  - to integrate the PP in the legislative proposal where necessary (Food Law article 7)

2. At international level

World Trade Organisation

The Commission presented the Communication at the SPS Committee in Geneva (15 March). The aim was to inform members of the SPS of how we intend to implement Article 5.7 of the SPS Agreement. The Committee considered that Codex Alimentarius should be the appropriate forum to discuss this issue.

Codex Alimentarius

The Codex Alimentarius Commission in July 2001, decided that the precaution should be addressed in the working principles of risk analysis as follows:

> "When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence."

III. Conclusion

Recourse to the PP has been increasingly in the spotlight in recent years, stimulating a growing public debate about the circumstances in which precautionary action is justified and necessary. The European Commission, therefore, considers that there is a real need for clarification about the use of the PP, and a need to establish guidelines for a correct and reasonable application of the principle internationally. The Commission

hopes that its communication will help to build a common understanding on the subject.