Environmental Risks of Biotechnology

The European Commission, in a Decision adopted on 24 July 2002, has specified the elements to be considered in assessing the environmental risks posed by the release of genetically-modified organisms (GMOs) into the environment.

The Decision identifies the objectives to be achieved, the elements to be considered, and the principles and the methodology to be applied in undertaking risk assessments.

This Decision establishing guidance notes supplements the provisions of Annex II of Directive 2001/18/EC on the *deliberate release of genetically-modified organisms (GMOs) into the environment,* which only specifies the general principles applicable to risk assessment.

Under the terms of Article 4.3 of the Directive, the Member States, or if appropriate the Commission, must ensure that potential adverse effects on human health and the environment liable to stem directly or indirectly from gene transfer from genetically-modified organisms to other organisms, are accurately assessed on a case-by-case basis.

This assessment, outlined in the Annex, is designed where necessary to permit the introduction of and determine the most appropriate approaches for risk management strategies.

The new Decision covers all GMOs, micro-organisms, flora and fauna. However, the Commission emphasises that the annex in question will probably need to be adapted and modified to take account of future scientific and technical developments.

In order to avoid any divergence of interpretation, the list specifies a number of risk-associated definitions. The text also stipulates that risk assessments should be based on the identified characteristics of GMOs and uses liable to have a damaging impact. These characteristics must be compared with those presented by the non-modified organisms from which they are derived and with the use of the latter in corresponding circumstances.

Further, evaluations must be conducted in a transparent fashion according to an established scientific method. It is also imperative that they be carried out on a case-by-case basis, given the broad range of characteristics of the various GMOs, proposed uses and potential host environments, and take account in particular of other GMOs already present in the environment. The risk assessment should include an analysis of 'cumulative long-term effects.'

The Commission proposes a six-stage method of analysis:

1) Identification of characteristics liable to have a negative basis.
2) Evaluation of the negative consequences of each negative effect were it to occur.
3) Evaluation of the probability of each negative occurring.
4) Estimation of the risk linked to each identified characteristic of a GMO.
5) Application of strategies for the management of risks stemming from the deliberate release or marketing of GMOs.
6) Confirmation of the general risk posed by GMOs. (MJ)

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