

General introduction

By the adoption of the Cartagena Protocol on Biosafety (CPB) in January 2000, the Parties to the Convention on Biological Diversity have created an essential tool to facilitate the development of regulatory and technical frameworks necessary for the risk assessment and management of genetically modified organisms (GMOs). To support these decision-making processes, the CPB and European Union directives each require considerations based upon a comprehensive pool of valid scientific information. Under these provisions, the Italian Ministry for Environment, for the Protection of the Territory and for the Sea has strengthened its collaboration with the International Centre for Genetic Engineering and Biotechnology (ICGEB), in order to collate and make available necessary information.

The promotion of the safe use of biotechnology is one of the main goals of the ICGEB. In this context, it is recognised that the complexity of the issues related to the environmental release of GMOs raises scientific, ethical, commercial, social and political concerns, and therefore calls for a wide diffusion of information. In this framework, ICGEB serves the international community by disseminating scientific information through its Biosafety Web Pages (<http://www.icgeb.org/biosafety/>), featuring the *Bi[bli]osafety Database* (a scientific, bibliographic database containing the abstracts of scientific papers published in the most relevant international journals in this field; <http://bibliosafety.icgeb.org/>), the *Risk Assessment Searching Mechanism* (an index providing on-line access to scientific risk assessment documentation relevant to the commercialisation of GM crops world-wide; <http://rasm.icgeb.org/>), and the *BiosafeRes Database* (a worldwide, public-access database of past and current research projects in GMO biosafety; <http://www.icgeb.org/~gmores/prod/index.php>), as well as through comprehensive capacity building programmes, that include specific training and technology transfer activities.

The scientific literature compiled in the *Bi[bli]osafety Database* comprises studies relating to the effects of the release and use of GMOs. These are classified according to a number of topics relating to human health, food safety, environmental protection, enhancement of agriculture and other general concerns. A thorough analysis of the issues was undertaken, and found that specific research areas critical to the

determination of risks associated with GMOs was lacking, despite the great abundance of scientific literature on these subjects. Accordingly, ICGEB was requested by the Italian Ministry for Environment, for the Protection of the Territory and for the Sea to help resolve this situation by instigating a number of scientific studies on areas of major interest for biosafety and risk assessment. As an initial step, ICGEB approached internationally recognised scientists, asking them to prepare scientific reviews summarising the state of the art in their field of expertise. These efforts were deemed useful for dissemination to a wider audience and have resulted in this Collection of Biosafety Reviews, which are also available online on the webpages of both the ICGEB (<http://www.icgeb.org/biosafety/publications/collections.html>) and the Ministry (<http://bch.minambiente.it/IT/Pubblicazioni/>).

There is an incredible number of additional online databases and information resources of particular relevance to the biosafety of GM crops (and their products) that can be easily accessed by all stakeholders, including the public. These are investigated in the current volume as tools for the dissemination of information concerning the impact of GMOs. Further, in many respects, GMOs can no longer be considered a novelty in those countries where they form the larger part of agricultural production. The techniques used to create GMOs, as well as the introduced traits, are key element in the process of assessing the risks deriving from the use of these crops, in particular for food and feed uses. An overview of recent developments in the broad area of biotechnology is therefore provided, and regulatory aspects are also discussed in a global perspective, with a focus on the situation in the European Union. And lastly, the possible threat to biodiversity in the receiving environments where GM crops are (to be) grown, especially creatures in the lower levels of agro-ecosystem food webs, is a primary concern. Numerous species at higher trophic levels can also come in contact with plant metabolites, either directly or indirectly. GM crops developed to control insect pests are not intended to be harmful to all other organisms active in the agro-ecosystem and in adjacent habitats (defined as non-target organisms; NTOs). Therefore, a description of the main issues related to the effects of the GM crop cultivation on NTOs is also provided.

Thus, the current volume of the Collection comprises three current technical reports, as follows:

- 1) An introduction to the main issues regarding the possible effects on non-target organisms from the cultivation of insect-resistant GM crops;
- 2) General information concerning the safety of food and feed derived from GMOs, with references to the regulations adopted in different countries and a discussion of new biotechnology tools under development in GM food/feed safety;
- 3) A description of internet resources providing information on GMOs relevant to risk assessment and as a tool for disseminating information in biosafety.

Future volumes of the “Collection of Biosafety Reviews” will include subjects dealing with risk analysis in general and the application of problem formulation approaches more specifically. Moreover regulatory approaches from around the world will be discussed and lessons learned presented, whilst advances in the regulation and risk assessment of GM animals will be compared with approaches used to assess and regulate GM crops.

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