

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 ("the Ministry") 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 *Biosafety Bibliographic Database* (a scientific, bibliographic database containing the abstracts of scientific papers published in the most relevant international journals in this field; <http://www.icgeb.org/biosafety/biobiblio.html>), 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://www.icgeb.org/biosafety/db/rasm.php>), and the *BiosafeRes Database* (a worldwide, open 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 ICGEB Biosafety Bibliographic 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 Ministry 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/>).

From the moment that it was possible to modify organisms using recombinant DNA technologies there was concern that although they had an incredible potential for good, they might also potentially be dangerous. This fear of harm led first to national regulatory regimes, then to various international guidelines, and eventually to a protocol deriving from the Convention on Biological Diversity; the aforementioned Cartagena Protocol on Biosafety. Therefore a description of the main issues, some still outstanding, derived from the Protocol was considered to be of significant interest to a wide audience. In addition, the evolution of resistance in target pests to transgenic insecticidal crops is considered a significant environmental risk in some quarters. It is, however, widely agreed that resistance evolution can be successfully managed, and thus a review of the main insect resistance strategy was thought timely. Furthermore, the most debated biosafety issues internationally are the potential environmental consequences created by possible transgene escape from a GM crop to its non-GM crop counterparts (crop-to-crop) and wild or weedy relatives (crop-to-wild) via gene flow. These include e.g., the creation of new weeds, change of fitness-related characters, and loss of genetic diversity in crop landraces and wild relatives. In addition, transgene flow also arouses biosafety concerns for food/feed and health (e.g., GMO “admixture”/ “contamination”), and socio-economics and ethics (legal and trading difficulties). A review of the mechanisms of gene flow and potential containment strategies was therefore deemed to be extremely useful. Thus, the current volume of the Collection comprises three current technical reports, as follows:

1) An introduction to some of the main issues derived from the interpretation and implementation of the Cartagena Protocol on Biosafety.

2) Background information related to insect resistance management (IRM) strategies required to delay or prevent the occurrence of control failures from resistance by delaying or preventing the evolution of resistance, along with the consideration of the costs associated with implementing IRM and how to incorporate changes to the IRM strategy as new information becomes available.

3) A description of the various mechanisms for gene flow, along with risk assessment system of the potential environmental consequences caused by transgene escape to wild relatives through pollen-mediated gene flow, and an advocacy for a proper combination of transgene confinement and mitigation strategies for minimising any negative environmental consequences.

Future volumes of the “Collection of Biosafety Reviews” will include subjects dealing with food and feed safety issues derived from GM products, managing negative impacts of GM crop cultivation on non-target organisms, and a practical application of the risk analysis paradigm.

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