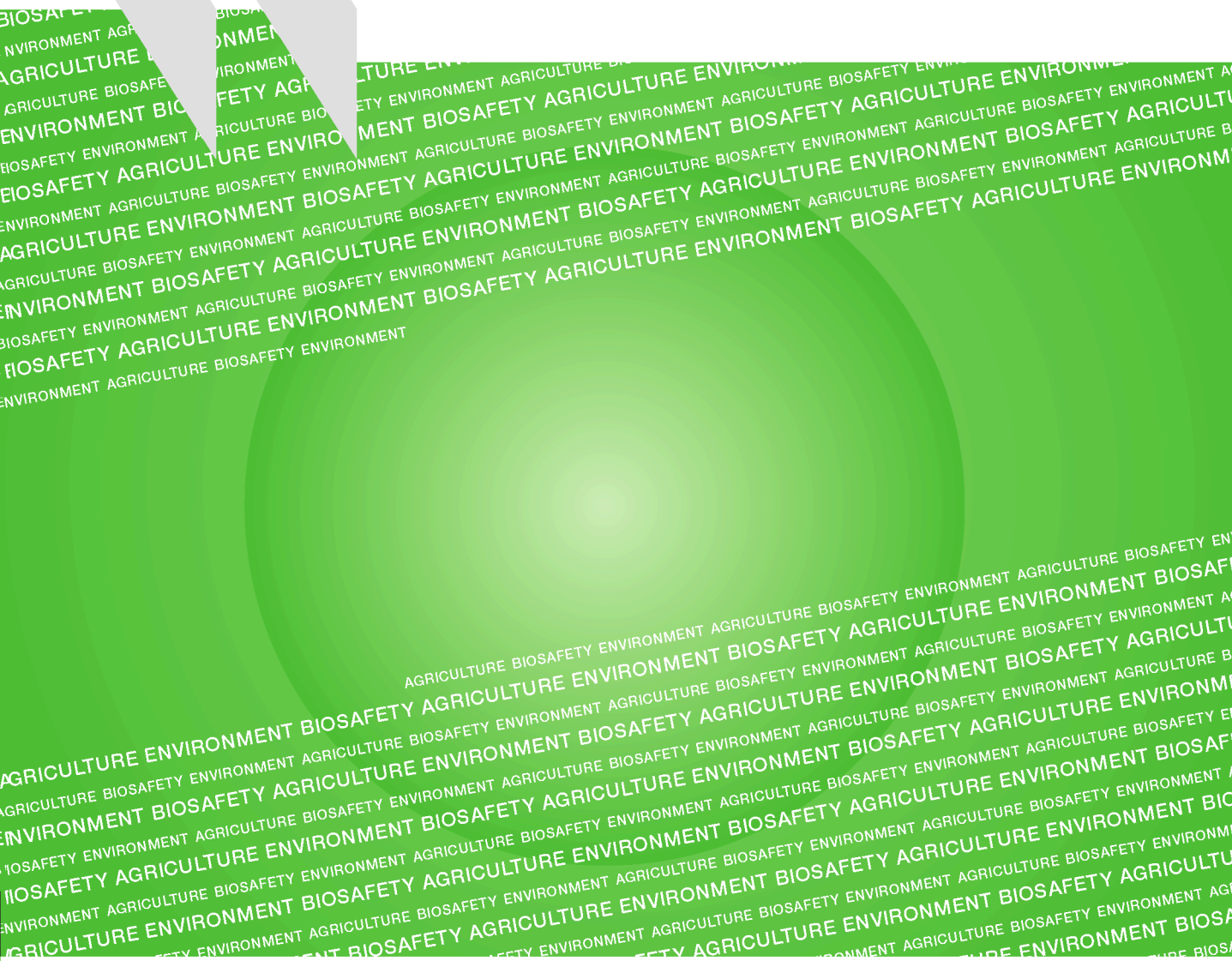
Safety Assessment of Transgenic Organisms

OECD CONSENSUS DOCUMENTS

Volume 3



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Foreword

Genetically engineered crops (also known as transgenic crops) have been approved for commercial release in an increasing number of countries, for planting or for use as commodities. Genetically engineered varieties of over a dozen different plant species have received regulatory approval in several OECD and non-OECD countries from all regions of the world, the large majority of plantings being for soybean, maize, cotton and rapeseed (canola), as outlined in *The Bioeconomy to 2030: Designing a Policy Agenda* (OECD, 2009). During the period from 1996 to 2009, for example, there was an almost eighty-fold increase in the area grown with transgenic crops worldwide, reaching 134 million hectares in 2009, as mentioned in *Global Status of Commercialized Biotech/GM Crops* (James, 2009). Such approvals usually follow a science-based risk/safety assessment.

The environmental safety/risks of transgenic organisms are normally based on the information on the characteristics of the host organism, the introduced traits, the environment into which the organism is introduced, the interaction between these, and the intended application. The OECD's Working Group on Harmonisation of Regulatory Oversight in Biotechnology decided at its first session, in June 1995, to focus its work on identifying parts of this information, which could be commonly used in countries for environmental safety/risk assessment to encourage information sharing and prevent duplication of effort among countries. Biosafety Consensus Documents are one of the major outputs of its work.

Biosafety Consensus Documents are intended to be a "snapshot" of current information on a specific host organism or trait, for use during regulatory assessments. They are not intended to be a comprehensive source of information on everything that is known about a specific host or trait, but they do address the key or core set of issues that member countries believe are relevant to risk/safety assessment. Several non-member economies, as well as other international organisations, are associated with the work and share their expertise. The information collated in the Consensus Documents is said to be mutually acceptable among member countries and also other countries wishing to use them for their assessment process.

To date, 38 Biosafety Consensus Documents have been published. They include documents which address the biology of crops, trees and micro-organisms as well as those which address specific traits which are used in transgenic crops. In addition, documents of broader nature aiming to facilitate harmonisation have been developed: *Designation of a Unique Identifier for Transgenic Plants* (2002, revised in 2006); and *Molecular Characterisation of Plants Derived from Modern Biotechnology* (2010).

Volumes 3 and 4 of this publication contain a compilation of those Biosafety Consensus Documents published between September 2006 and September 2010. These volumes also include two previously published presentation texts (slightly updated since Volumes 1 and 2):

- *An Introduction to the Biosafety Consensus Documents of OECD's Working Group for Harmonisation in Biotechnology* explains the purpose of the documents and how they are relevant to risk/safety assessment. It also describes the process by which the documents are drafted, using a "lead country" approach.

- Then, the *Points to Consider for Consensus Documents on the Biology of Cultivated Plants* offer a structured checklist of points for authors to consider when drafting, or to experts evaluating a Consensus Document. Each point is described for its relevance to risk/safety assessment.

Along with Volumes 1 and 2, the present publication offers ready access to those Consensus Documents which have been published thus far. As such, it should be of value to applicants for commercial uses of transgenic crops, regulators in national authorities as well as the wider scientific community.

As each of the Consensus Documents may be updated in the future as new knowledge becomes available, users of this book are encouraged to provide any information or opinions regarding the contents of the Consensus Documents or indeed, OECD's other harmonisation activities. Comments can be provided at: *biosafety@oecd.org*.

The published Consensus Documents are also available individually from the OECD's Biotrack website, at no cost (www.oecd.org/biotrack).

Acknowledgements

This book is the result of the common effort of the participants in the OECD's Working Group on Harmonisation of Regulatory Oversight in Biotechnology. Each section is composed of a "Consensus Document" which was prepared under the leadership of a participating country or countries, as listed at the end of this volume. During their successive draftings, valuable inputs and suggestions for the documents were provided by a number of delegates and experts in the Working Group, being from OECD Members, non member economies and observer organisations.

Each Consensus Document was issued individually, as soon as finalised and agreed for declassification, by the OECD Environment, Health and Safety Division in the *Series on Harmonisation of Regulatory Oversight in Biotechnology*. Volumes 3 and 4 of this publication, containing the 2006-2010 Consensus Documents, were prepared and edited by Bertrand Dagallier and Carina Arambula, under the supervision of Peter Kearns, at the EHS Division, OECD Environment Directorate.

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