

FOREWORD

Genetically engineered crops (also known as transgenic crops) such as maize, soybean, rapeseed and cotton have been approved for commercial use in an increasing number of countries. During the period from 1996 to 2005, for example, there was more than fifty-fold increase in the area grown with transgenic crops worldwide, reaching 90 million hectares in 2005.¹ 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.

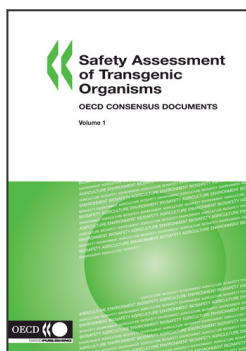
Biosafety Consensus Documents are intended to be a "snapshot" of current information on a specific host organism or trait, for use during regulatory assessments. They are not intended to be a comprehensive source of information on everything that is known about a specific host or trait; but they do address the key or core set of issues that member countries believe are relevant to risk/safety assessment. This information is said to be mutually acceptable among member countries. To date, 25 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.

This book is a compilation of those Biosafety Consensus Documents published before February 2006. It also includes two recently published texts: the first, entitled *An Introduction to the Biosafety Consensus Document of OECD's Working Group for Harmonisation in Biotechnology*, explains the purpose of the consensus 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. The second text is a *Points to Consider for Consensus Documents on the Biology of Cultivated Plants*. This is a structured checklist of "points to consider" for authors when drafting or for those evaluating a consensus document. Amongst other things, this text describes how each point is relevant to risk/safety assessment.

This book 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 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 this book or indeed, OECD's other harmonisation activities. If needed, a short pre-addressed questionnaire is attached at the end of this book that can be used to provide such comments.

The published Consensus Documents are also available individually from OECD's website (<http://www.oecd.org/biotrack>) at no cost.

1. Clive James (2005), International Service for the Acquisition of Agri-biotech Applications (<http://www.isaaa.org/>)



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