Foreword

From their first commercialisation in the mid-1990s, genetically engineered crops (also known as "transgenic" or "genetically modified" plants) have been approved for commercial release in an increasing number of countries, for planting, entering in the composition of foods and feeds, or use in industrial processing. Up to now, the majority of these agricultural productions remain for soybean, maize, cotton and rapeseed (canola) bearing pest resistance and/or herbicide tolerance traits aiming to improve yields and reduce the costs of production, as outlined in the OECD study *Farm Management Practices to Foster Green Growth*. Other engineered crops might gain importance and come into play in the short to medium term. Despite differences in total estimates, all analyses and statistics concur in underlining the general increasing trend in volumes produced and traded, and growth potential for agriculture productivity. For instance, the International Service for the Acquisition of Agri-biotech Applications reports in its annual *Global Status of Commercialized Biotech/GM Crops* survey that the surface area of transgenic crops worldwide has constantly increased since the first commercial planting in 1996 to reach 185.1 million hectares grown in 26 countries in 2016. To date, genetically engineered varieties of over 25 different plant species (including crops, flowers and trees), and more recently of two animal species, have received regulatory approval in OECD and non-OECD economies alike. Such approvals for release in the environment usually follow a science-based risk/safety assessment before being granted.

The five main producers of genetically engineered crops in 2016 were the United States, Brazil, Argentina, Canada and India, covering together almost 91% of the total area. Interestingly, developing countries grew more of global transgenic crops (54%) than industrial countries, at 46%. Among the 26 countries having planted those crops in 2016, only 9 of them were OECD countries, listed by decreasing area as follows: the United States, Canada, Australia, Spain, Mexico, Chile, Portugal, the Slovak Republic and the Czech Republic. This represents, however, a significant part of the total agricultural acreage in OECD countries: the *OECD Compendium of Agri-environmental Indicators* estimates that about 18% of the total OECD arable and permanent cropland area was sown to transgenic crops on average for the 2008-10 period. In addition, some countries do not grow genetically engineered plants but import commodities derived from them, for use in their feed industry in particular. This is the case in several European countries and some other economies worldwide: according to the ISAAA, from 1992 to 2016, a total of 40 countries gave approvals for such commodities to be used as food or feed, and/or cultivation.

Information on the transgenic crops approved for commercial release in at least one country for use in agriculture and/or foods and feeds processing can be found in the OECD *Biotrack Product Database* (https://biotrackproductdatabase.oecd.org). Each transgenic product and its Unique Identifier are described, with information on approvals in countries. To date, this database covers about 255 approved genetically engineered plant varieties, and will be extended in future years to include additional species and information from a larger group of countries.

Modern biotechnologies are applied to plants, but also to trees, animals and micro-organisms. The safety of the resulting genetically engineered organisms when released in the environment for their use in agriculture, the food and feed industry, as biofuel or for other applications represents a challenging issue. This is already true for transgenic crops, and will be even more critical in the future as applications of biotechnologies widen to new species and new areas: a growing number of novel organisms will have to be assessed before their possible use and market release. Recent examples include animal species: since 2014, genetically engineered mosquitos have been used in several areas to control insect populations and contribute to fighting the diseases transmitted by them; an Atlantic salmon strain, modified for fast growth, was approved in a few countries in 2015-16 for production in confined environments and commercial use.

Among biotechnology developments, some crops (maize, sugarcane) have been modified for adaptation features such as resistance to certain biotic/abiotic stresses including drought tolerance, leading to better resilience to climate change. “Bio-fortification” (applied to rice, tuber crops and other species) involves varieties with enhanced content in some of their food and feed components (e.g. vitamins or minerals). Plants with reduced lignine or with increased oil content are examples of products sought to facilitate industrial uses of the commodities and decrease the production costs. As highlighted in the proceedings of the OECD Conference “Biosafety and the Environmental Uses of Micro-organisms” held in 2012, a range of new species are being contemplated as potential biofuels to provide renewable energy. This includes algae such as photosynthetic cyanobacteria, which are of special interest as they can be cultivated year round on non-arable land, alleviating the pressure on agricultural areas and freshwater resources that would be exerted by crops grown for biofuel purposes. Other biotechnology developments, applied in particular to micro-organisms, might lead to other products including biofertiliser organisms living in symbiosis in crop roots and optimising the nitrogen fixation, or biocontrol agents acting as plant protection products to control disease and attack by insects or other invertebrates. Other exploratory fields may involve bioremediation by using living organisms for removing contaminants from the environment such as polluted land, or in the development of detergents containing micro-organisms.

The fast development and increasing use of a range of new breeding techniques, including “genome editing”, will allow for quicker development of applications at lower cost. These techniques are being reviewed by regulators, risk assessors, researchers and plant developers, including at the OECD, for discussing their potential impact on risk assessment (see the report of the OECD “Workshop on Environmental Risk Assessment of Products Derived from New Plant Breeding Techniques” held in 2014).

Even if it is difficult to predict which of these biotechnology developments would lead to large applications in the medium term, it is expected that some of the products will have important impacts in their respective economic sectors. A scientifically sound approach to their risk assessment should inform biosafety regulators and support national decisions regarding their potential release. Genetically engineered products are rigorously assessed by their developers during their elaboration, and by governments when ready for commercial use, to ensure high safety standards for the environment, human food and animal feed. Such assessments are felt essential for healthy and sustainable agriculture, industry and trade.

An environmental safety/risk assessment of transgenic organisms is normally based on the information on the characteristics of the host organism, the introduced traits and the environment into which the organism is introduced. The interaction between these elements and the intended application are also of importance. At its first session held in June 1995, the OECD's Working Group on Harmonisation of Regulatory Oversight in Biotechnology decided to focus its work on identifying parts of this information which could be commonly used in countries for environmental safety/risk assessment, in order to encourage information sharing and prevent duplication of efforts. The biosafety consensus documents are one of the major outputs of its work.

The biosafety consensus documents constitute 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 OECD member countries believe to be 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 OECD countries and beyond in other juridictions wishing to use them during their assessment process.

As of November 2017, a total of 56 consensus and guidance documents on biosafety have been published by the Working Group. They include documents which address the biology of plants, animals (one species to date), trees and micro-organisms, as well as those dealing with specific traits that are used in genetically engineered crops. In addition, documents of broader nature aiming to facilitate harmonisation have been developed.

This volume contains a compilation of those biosafety consensus documents issued in 2016 and 2017. It also includes the "Introduction to the biosafety consensus documents" published earlier (and slightly updated from the previous volumes). The introduction 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.

Along with the previous six volumes, the present publication offers ready access to those consensus documents published on the OECD BioTrack website thus far. As such, Volume 7 should be of value to applicants for commercial uses of transgenic organisms, regulators in national authorities, breeders, risk assessors as well as the wider scientific community.

This biosafety work is complementary to the activities of the OECD programme on the safety of novel foods and feeds, in particular to the consensus documents developed on the composition of foods and feeds derived from transgenic organisms. These documents describe the key nutrients, anti-nutrients, toxicants and other constituents that can be used in a comparative approach. More information on this programme can be found in the introduction to this volume.

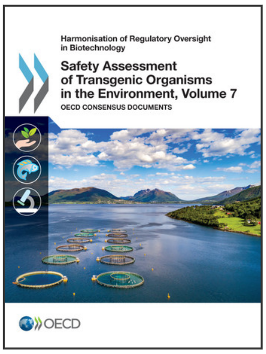
As each of the consensus documents may be updated in the future as new knowledge becomes available, users of this book are encouraged to provide any information or opinions regarding the contents of the consensus documents or indeed, the OECD's other harmonisation activities. Comments can be provided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

The published consensus documents are also available individually free of charge on the OECD's Biotrack website (www.oecd.org/biotrack). Please note, however, that there have been updates to some statistical production data and citations in the current edition.

Acknowledgements

This book is the result of the common effort of the participants of the OECD's Working Group on Harmonisation of Regulatory Oversight in Biotechnology. Each chapter is composed of a "consensus document" which was prepared under the leadership of one or several countries and observer delegations, 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 from the working group, whether from OECD member countries, non-member economies or observer organisations.

Each consensus document was issued individually, as soon as it was finalised and agreed on declassification, by the OECD Environment, Health and Safety (EHS) Division in the Series on Harmonisation of Regulatory Oversight in Biotechnology. This volume, containing the 2016-17 consensus documents, was prepared by Jennifer Allain and edited by Bertrand Dagallier, under the supervision of Peter Kearns, at the EHS Division, OECD Environment Directorate.



From:

Safety Assessment of Transgenic Organisms in the Environment, Volume 7

OECD Consensus Documents

Access the complete publication at:

https://doi.org/10.1787/9789264279728-en

Please cite this chapter as:

OECD (2017), “Foreword and Acknowledgements”, in *Safety Assessment of Transgenic Organisms in the Environment, Volume 7: OECD Consensus Documents*, OECD Publishing, Paris.

DOI: https://doi.org/10.1787/9789264279728-1-en

This work is published under the responsibility of the Secretary-General of the OECD. The opinions expressed and arguments employed herein do not necessarily reflect the official views of OECD member countries.

This document and any map included herein are without prejudice to the status of or sovereignty over any territory, to the delimitation of international frontiers and boundaries and to the name of any territory, city or area.

You can copy, download or print OECD content for your own use, and you can include excerpts from OECD publications, databases and multimedia products in your own documents, presentations, blogs, websites and teaching materials, provided that suitable acknowledgment of OECD as source and copyright owner is given. All requests for public or commercial use and translation rights should be submitted to rights@oecd.org. Requests for permission to photocopy portions of this material for public or commercial use shall be addressed directly to the Copyright Clearance Center (CCC) at info@copyright.com or the Centre français d’exploitation du droit de copie (CFC) at contact@cfcopies.com.