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 or for entering in the composition of foods and feeds, or use in industrial processing. Up to now, the large majority of these agricultural productions remain for soybean, maize, cotton and rapeseed (canola), as outlined in *The Bioeconomy to 2030: Designing a Policy Agenda* (OECD, 2009). Despite some differences in total estimates, all analyses and statistics concur in underlining the general increasing trend in volumes produced and traded, number of countries involved and growth potential. For instance, James reports in the *Global Status of Commercialized Biotech/GM Crops: 2014, ISAAA Brief No. 49* that the surface area of transgenic crops worldwide constantly increased over the 19-year-period from 1996 to 2014, to reach 181.5 million hectares grown in 28 countries. To date, genetically engineered varieties of over 25 different plant species (including crops, flowers and trees) have received regulatory approval in OECD and non-OECD countries from all regions of the world. 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 2014 were the United States, followed by Brazil, Argentina, India and Canada, covering together almost 90% of the total area. Interestingly, developing countries grew more of global transgenic crops (53%) than industrial countries, at 47%. Among the 28 countries having planted those crops in 2014, only 9 of them were OECD countries, listed by decreasing area as follows: the United States, Canada, Australia, Mexico, Spain, Chile, Portugal, the Czech Republic and the Slovak Republic. In addition, some countries do not grow genetically engineered plants but import the produced commodities, for use in their feed industry in particular, as it is the case in several jurisdictions of Europe as well as some other economies worldwide.

Information on the transgenic crops which have been 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* (*www2.oecd.org/biotech*). Each transgenic product and its Unique Identifier are described, with information on approvals in countries. To date, this database covers about 240 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, and also trees, animals and micro-organisms. The safety of the resulting genetically engineered organisms when released in the environment for their use in agriculture, food and feed industry, as biofuel or for other applications represents a challenging issue.

This is already true nowdays with the increasing cultivation of transgenic crops. It 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. Among the ongoing developments of modern biotechnology, crop varieties modified for gaining adaptation features such as the resistance to certain biotic/abiotic stresses, result in better resilience to climate change. "Bio-fortification" (applied to rice, tuber crops and other species) develop varieties with enhanced content in some constituents, 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 contemplated as potential biofuels to provide renewable energy; among them algaes, with photosynthetic cyanobacteria, are of special interest as they can be cultivated year round on non-arable land, alleviating the pressure on agricultural land and freshwater resources that would be exerted by crops growng for biofuel purposes. Less anticipated, genetically engineered mosquitos are used in few places since 2014 to control the insect population and fight tropical diseases transmitted by them. Other biotechnology developments, and in particular applied to micro-organisms, might lead to other products such biofertilizer 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. Other exploratory fields may comprise bioremediation by using of living organisms for removing contaminants from the environment such as polluted land, or the development of detergents containing micro-organisms.

Even if it is difficult to predict which of these new biotechnology developments would lead to large applications in a 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 the 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 a 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, 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 (the "Working Group") 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 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 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 the OECD community and beyond in other juridictions wishing to use them during their assessment process.

As of December 2015, a total of 53 consensus and guidance documents on biosafety have been published by the Working Group. They include documents which address the biology of plants, 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 harmonisati-on have been developed.

The volumes of this publication published in 2016 contain a compilation of those biosafety consensus documents issued in 2011 and 2012 (Volume 5), and from 2013 to 2015 (Volume 6). Both of them contain the "Introduction to the biosafety consensus documents" published earlier (and slightly updated since Volumes 3 and 4 of 2010). 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 previous Volumes 1-4 (OECD, 2006a; 2006b; 2010a; 2010b) the present publication offers ready access to those consensus documents published on the OECD BioTrack website thus far. As such, Volumes 5 and 6 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 of the activities of the OECD programme on novel food and feed safety, in particular to the consensus documents developed on the composition of foods and feeds derived from transgenic organisms, which detail 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.

As each of the consensus documents may be updated in the future when 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 from the OECD's Biotrack website, at no cost (*www.oecd.org/biotrack)*. Some updates have been made to data and citations in this edition.

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 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 in 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. Volumes 5 and 6 of this publication, containing the 2011-15 consensus documents, were prepared by Jennifer Allain and edited by Bertrand Dagallier, under the supervision of Peter Kearns, at the EHS Division, OECD Environment Directorate.