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. The majority of these productions are for soybean, maize, cotton and rapeseed (canola) bearing pest resistance and herbicide tolerance traits, aiming to improve yields and reduce the costs of production. Other transgenic crops that are increasingly grown to date comprise lucerne (alfalfa), sugar beet, sugarcane, papaya, safflower, potato, eggplant, as well as pumpkin, apple and pineapple in smaller areas. Other traits are increasingly introduced in engineered plants, adapting them to biotic or abiotic stress, such as resistance to drought or tolerance to salt in the growing environment, or changing a characteristic, e.g. modified oil content, reduced lignin content, non-browning or nutritional quality (biofortification). Thus, transgenic crops, where adopted and available on the market, enlarge possibilities for farmers, industry and consumers. They can play a part in addressing global concerns such as the rising need for food and feed in the growing population context or the necessary adaptation of agriculture for better resilience to climate change.

Modern biotechnologies are applied to plants (crops, flowers and trees) but also animals and micro-organisms. The safety of the resulting genetically engineered organisms, when released in the environment for their use in agriculture, forestry, fishery, the food and feed industry, biofuel production or other applications, represents a challenging issue. A scientifically sound approach to their risk assessment should inform biosafety regulators and support national decisions regarding their possible market 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 considered essential for healthy and sustainable agriculture, industry and trade.

In 2019, according to the annual report of the International Service for the Acquisition of Agri-biotech Applications, the five main producers of genetically engineered crops were the United States, Brazil, Argentina, Canada and India (listed by decreasing area) covering a combined 170 million hectares representing more than 90% of the global transgenic crop area. Among the 29 countries having grown genetically engineered crops in that year, 9 of them were OECD countries, listed by decreasing area as follows: the United States, Canada, Australia, Mexico, Spain, Colombia, Chile, Portugal and Costa Rica, representing 45% of the global transgenic crop acreage. This rate might increase significantly in future, with Argentina and Brazil being candidates to OECD membership and for whom discussions in the accession process started in 2022.

In addition, a higher number of countries do not grow genetically engineered plant varieties but import commodities derived from them, in particular for their feed industry. In 2019, a total of 72 countries dealt with transgenic organisms for production and/or consumption purpose: 29 countries planted them, while 43 additional economies imported their products for use as novel food or feed ingredients.

The OECD offers long-standing recognised expertise in biosafety and contributes to facilitating a harmonised approach. Since 1995, the OECD Working Party on the Harmonisation of Regulatory Oversight in Biotechnology (WP-HROB) has brought together national authorities responsible for the environmental risk/safety assessment of products of modern biotechnology in OECD countries and other economies. International organisations and experts involved in biosafety activities are associated with this programme.

The primary goals of the WP-HROB are to promote international regulatory harmonisation and ensure that methods used in the risk/safety assessment of genetically engineered products are as similar as possible. This may open the way to possible recognition and even acceptance of information from the assessments of other countries. The benefits of harmonisation are multiple: it strengthens mutual understanding among countries, prevents duplication of efforts, saves resources and increases the efficiency of the risk assessment process. Overall, it improves safety while reducing unnecessary barriers to trade.

Guidance and tools developed by the WP-HROB to help the environmental risk/safety assessment of transgenic organisms are already being used worldwide. Biosafety consensus documents are major outputs of its work. These publications address the key elements and core set of science-based issues that countries believe are relevant to biosafety assessments. This information is said to be mutually acceptable among OECD members and other economies associated with the work. Because these documents are publicly available, they can also benefit other countries around the world wishing to use these tools following the same principles.

A total of 60 consensus and guidance documents have been published by the WP-HROB. They mainly address the biology of crops, trees, animals and micro-organisms, as well as specific traits introduced in engineered plants. Their scope is growing in line with the new biotechnological developments and wider applications to new fields. The list shown in Annex A of the publication summarises the extent of the species or subjects currently covered and in which volume of the series to find them.

In addition, 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 different countries. To date, this database covers 387 approved genetically engineered varieties from 24 plant species and will be extended in future years to include additional species and information from a larger group of countries.

The fast development and increasing use of a range of new breeding techniques, including “genome editing”, allows for quicker and more efficient development of applications at a lower cost. These techniques are being reviewed by regulators, risk assessors, researchers and developers for their potential impact on risk/safety assessment while favouring a coherent policy approach to facilitate innovation, and the OECD including the WP-HROB offers the relevant platform for it (see for instance the proceedings of the OECD conference “Genome Editing: Applications in Agriculture – Implications for Health, Environment and Regulation” held in 2018).

This Volume 9 contains a compilation of those biosafety consensus documents issued between 2019 and 2021 dealing with the biology of apple, safflower and rice. The chapter on rice revises and replaces the original document issued in 1999 and published in Volume 1. Also included here are the “Revised points to consider on plant biology consensus documents”, originally published in 2006 and revised in 2020, updating the related section of Volume 3. The plant species covered by this volume are three major agricultural crops of different nature and uses. All of them are traded internationally as raw commodities and transformed products, and are subject to biotechnology developments with novel varieties proposed on the market. Apple is a well-known fruit cultivated throughout temperate areas, entering in industrial food processing and being consumed worldwide; safflower is an important oilseed plant mostly cultivated for oil production; while rice is an essential staple cereal crop, cultivated mainly in Asia but also in other regions of the world, easy to store and cook, and commercialised everywhere.

Along with the previous volumes, the introduction section explains the purpose of these documents, their relevance to risk/safety assessment, and the process by which the consensus documents are drafted, using a “lead country(ies)” approach. Australia (safflower), Belgium and Germany (apple), Japan (rice) and the United States (points to consider) led or co-led the preparation of the respective chapters.

The set of science-based information and data contained in Volume 9, previously agreed by consensus and published by the OECD, constitute a solid reference recognised internationally, and a tool for use during the biosafety assessment process. As such, this publication should be of value to applicants for commercial and public uses of engineered varieties of safflower, apple or rice, to risk assessors and regulators from national authorities responsible for granting approvals for their release in the environment as well as to 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.

The consensus documents published in Volumes 1 to 9 of the series are also available individually free of charge on the OECD BioTrack website (www.oecd.org/biotrack). Please note, however, that there have been minor updates to some statistical production data and citations in the current edition.

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Each guidance or consensus document was issued individually, as soon as 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 documents issued from 2019 to 2021, was prepared by Eleonore Morena. It was edited by Akihiro Kagoshima under the supervision of Bertrand Dagallier, at the EHS Division of the OECD Environment Directorate.

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