## Foreword

From their first commercialisation in the mid-1990s, genetically engineered crops (also known as transgenic crops) have been increasingly approved for cultivation and for entering in the composition of foods or feeds by a number of countries. To date, genetically engineered varieties of at least 33 different plant species (including agricultural crops, ornamental plants and flowers, as well as trees) have received regulatory approvals in OECD countries and other economies from all regions of the world. However, the vast majority of plantings remains for soybean, maize, cotton and rapeseed (canola), the four species having covered together more than 99% of the global area of transgenic crops in 2018. Over the 23-year period from 1996 to 2018, the surface cultivated with genetically engineered crops has drastically raised worldwide, resulting in a significant increase of their harvest in human food and animal feed (often designated as "novel" foods and feeds). Analyses and statistics from several sources, despite some differences in total estimates, concur in highlighting the same following trends:

- 1. general rising in volumes of genetically engineered commodities produced
- 2. still a limited number of producing countries (they were 26 in 2018) compared to those having granted some approvals for food or feed consumption (70 countries in 2018, including the 28 members of the European Union)
- 3. growth potential for genetically engineered crops at a global level in future years, in particular if a wider range of species are brought into cultivation.

For instance, the *Global Status of Commercialized Biotech/GM Crops in 2018*, issued by the International Service for the Acquisition of Agri-Biotech Applications, reports a record 191.7 million hectares of genetically engineered plants grown, representing a growth rate of 1% from the previous year. According to this study, the five main producers in 2018 were in ranking order the United States, Brazil, Argentina, Canada and India covering together more than 91% of the total area. Interestingly, developing countries grew more global transgenic crops (54%) than industrial countries (46%). Among the 26 countries having planted transgenic crops in 2018, only 7 of them were OECD countries, listed by decreasing area as follows: the United States, Canada, Australia, Mexico, Spain, Chile and Portugal. However, an additional group of countries does not produce transgenic crops but imports the produced commodities, for use in their feed industry in particular, as is the case in most jurisdictions of European Union member states and several other economies worldwide. Important volumes of genetically engineered commodities are already subject, every year, to international trade.

Information on these transgenic crops which have been approved for commercial release in at least one country (for planting and/or for use in 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, as well as information on approvals in countries.

In parallel to the expansion of genetically engineered crops developed for their resistance to pests and diseases, varieties are being developed by breeders for new types of traits: adaptation to climate change, improved composition (biofortification), enhanced meat productivity, easier processing and many other applications. The range of biotechnology applications to agricultural plant breeding is widening and it seems that this trend will continue. Consequently, the volume of novel foods and feeds available on the market and exchanged internationally is expected to increase in the coming years.

Consumers from all over the world are requiring a high level of safety and full confidence in the products they eat. This is particularly important for the products of modern biotechnology, which are sometimes questioned and subject to diverse levels of acceptation among countries. The approvals of transgenic crops follow a science-based risk/safety assessment regarding their potential release in the environment (biosafety) and their use in foods or feeds (novel food and feed safety). The OECD has undertaken activities related to environmental safety aspects since the mid-1980s, while the development of scientific principles for food safety assessment was initiated in 1990. The OECD helps countries in their risk/safety assessment of transgenic organisms by offering national authorities a platform to exchange experience on these issues, identify emerging needs, collate solid information and data, and develop useful tools for risk assessors and evaluators.

The Working Group for the Safety of Novel Foods and Feeds (previously named the "Task Force") is composed of delegates from OECD member countries, other economies, international bodies and observer organisations involved in these matters, from all regions of the world. National participants and experts come from government ministries and agencies that have responsibility for the risk and safety assessment of novel foods and feeds in the respective countries. The main outputs of the working group are the "consensus documents", practical tools for helping with food and feed safety assessment, which compile science-based information and data relevant to this task. These publications address compositional considerations of crops subject to plant breeding improvement with modern biotechnologies. The key composition elements (nutrients, anti-nutrients, toxicants and, sometimes, other constituents) that they contain can be used to compare novel foods and feeds with conventional ones. These documents are published after consensus is reached among countries, providing a science-based set of information and data designed for use in the comparative approach as part of the safety assessment.

To date, 24 OECD "consensus documents" relating to the safety of novel foods and feeds have been published. They provide solid information commonly recognised by experts and collate the reliable range of data available in the scientific literature at the time of the publication. In addition, reports on key events and documents of a broader nature aiming to facilitate harmonisation have been developed, for instance: animal feedstuffs derived from transgenic commodities (2003), designation of an OECD "Unique Identifier" for transgenic plants (2002, revised in 2006), molecular characterisation of transgenic plants (2010), proceedings of the OECD Workshop on High-throughput DNA Sequence in the Safety Assessment of Genetically Engineered Plants (2016).

Volume 3 of this series compiles the four consensus documents of the OECD Series on Safety of Novel Foods and Feeds issued between 2015 and 2019, dealing with the composition of common bean, rice (revising the original version of 2004), cowpea and apple. The presentation of the OECD work, originally published in 2006 and updated in 2014 with the previous compendia, was used as a basis for the introduction section that explains the purpose of the consensus documents, their relevance to risk/safety assessment and their preparation by the working group.

The consensus documents constituting the four chapters of this Volume 3 were approved by the OECD Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology (the "Joint Meeting") under written procedure and prepared for publication by the OECD Secretariat. The consensus document on the composition of common bean was approved on 18 December 2015 [ENV/JM/MONO (2015)49], the document on the composition of rice on 3 November 2016 [ENV/JM/MONO(2016)38], the document on the composition of cowpea on 7 December 2018 [ENV/JM/MONO(2018)36], and the document on the composition of apple on 12 July 2019 [ENV/JM/MONO(2019)23].

The present series (Volumes 1 to 3) offers ready access to those documents which have been published thus far. This set of science-based information and data, agreed by consensus and published by the OECD, constitute a solid reference recognised internationally. It is already widely used in comparative approach as part of the risk/safety assessment of transgenic products. As such, this publication should be of value to applicants for commercial uses of genetically engineered crops, to regulators and risk assessors in national authorities in charge of granting approvals to transgenic plant products for their use as foods or feeds, as well as to the wider scientific community.

Each of the consensus documents may be updated in the future as new knowledge becomes available. Three of them dealing with key crops (canola, soybean and rice) have already been revised and recently updated in order to maintain their full relevance to risk assessors using them. Users of this book are therefore encouraged to provide information or an opinion regarding the contents of the consensus documents or any of the OECD's other harmonisation activities. Comments can be sent to <u>ehscont@oecd.org</u>.

The published consensus documents are also available individually from the OECD Biotrack website (<u>www.oecd.org/biotrack</u>) at no cost.

## Acknowledgements

This book is the result of the common effort of the participants in the OECD Working Group for the Safety of Novel Foods and Feeds. Each chapter is composed of a "consensus document" which was prepared under the leadership of one or several countries, as listed at the end of this volume. During the preparation of their successive drafts, useful input and suggestions for the documents were provided by a number of delegates and experts from the working group, whether from OECD member countries, other economies or observer organisations.

Each 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 Safety of Novel Foods and Feeds. This volume, containing the consensus documents issued from 2015 to 2019, was prepared by Eleonore Morena, with the contribution of Yoko Takasu. It was edited by Bertrand Dagallier, under the supervision of Peter Kearns, at the EHS Division of the OECD Environment Directorate.

The OECD is grateful to the scientists, regulators and authorities who participated in the development of these consensus documents on compositional considerations for new varieties of crop species and wishes to thank each of them.



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