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. Most of these productions to date 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 are increasingly grown, and other traits 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 plants, 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, trees), 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.

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 transgenic products in OECD countries and partners. Other international organisations 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 opens the way to recognition and possible 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 (or “biosafety”) are already being used worldwide. Biosafety consensus documents are major outputs of its work, addressing the key elements and core set of science-based issues that countries believe are relevant to biosafety assessments. Being publicly available, these documents can also benefit other countries around the world wishing to use these tools following the same principles.

In addition, information on the transgenic plants approved for commercial release in at least one country for use in agriculture and/or in foods and feeds processing can be found in the OECD BioTrack Product Database (https://biotrackproductdatabase.oecd.org). Each transgenic product is described, with information on approvals in different countries. To date, this database covers 393 varieties from 26 plant species approved in 18 countries/regions and continues to expand.

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 offers the relevant platform for it (e.g., see the proceedings of the OECD conference "Genome Editing: Applications in Agriculture – Implications for Health, Environment and Regulation" held in 2018).

More than sixty consensus and guidance documents have been published by the WP-HROB to date. Their scope is growing in line with the new biotechnological developments and wider applications to new fields. The list shown in Annex H of the publication summarises the extent of the species or subjects currently covered and in which volume of the series to find them. In the area of plants, these science-based publications deal with the biology of crop and tree species, selected traits introduced into plant species, and other biosafety issues arising from modifications made to plants. They are available at www.oecd.org/biotrack.

This Volume 10, containing the OECD Consensus Document on Environmental Considerations for Risk/safety Assessment for the Release of Transgenic Plants, is of different content, dealing with environmental risk/safety assessment at a broader level. The document contains general information on points that risk/safety assessors should focus on when planning assessments for the release of transgenic plants into the environment. The annexes describe seven examples of environmental considerations routinely examined by assessors and taken from actual experiences gained during risk/safety assessment of transgenic plants.

The purpose of this document is not to elaborate new terminology or to describe how to undertake an actual risk/safety assessment, but rather to describe an approach and provide illustrative examples for planning and structuring an environmental risk/safety assessment. The set of science-based information contained in this Volume, previously agreed by consensus and published by the OECD, constitute a solid reference recognised internationally, and a tool for use during the environmental risk and safety assessment process. The document should be of interest to regulators and assessors in charge of evaluating the risk/safety of transgenic plants prior to environmental release, as well as to plant breeders and the wider scientific community.

Complementing the biosafety work developed at OECD, the programme on the safety of novel foods and feeds develops guidance and consensus documents on the composition of foods and feeds derived from transgenic plants that can be used in a comparative approach. More information on the novel food and feed safety programme can be found on the OECD BioTrack website (www.oecd.org/biotrack).

The consensus documents published in Volumes 1 to 10 of the Series are also available individually free of charge on the OECD BioTrack website. The WP-HROB endorsed this document, which is published under the responsibility of the Chemical and Biotechnology Committee of the OECD.