Executive summary

This document constitutes the ninth volume of the OECD Series on Harmonisation of Regulatory Oversight in Biotechnology, which relates to the environmental risk/safety assessment of transgenic organisms, also called “biosafety”. It is a compendium of individual “consensus documents” published by the Working Party on the Harmonisation of Regulatory Oversight in Biotechnology. The eight previous volumes of the series covered documents issued from 1996 to 2018. The current volume contains the consensus documents published in 2019-21 on the biology of apple, safflower and rice, preceded by the “points to consider” section providing guidance to authors of draft consensus documents.

Modern biotechnologies are applied to crop plants as well as trees, animals and micro-organisms. The safety of the resulting transgenic organisms, when released in the environment for use in agriculture, forestry, fishery, the food and feed industry or other applications, represents a challenging issue. Genetically engineered products are rigorously assessed by their developers during their elaboration and by governments when ready for release, to ensure high safety standards. These risk/safety assessments, conducted through a scientifically sound approach, inform biosafety regulators and support the decision concerning the release of novel organisms in the environment. 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. The environmental risk/safety assessment of transgenic organisms is usually based on the information collected on the characteristics of the host organism, the introduced traits, the environment into which the organism will be released, the interaction between these factors and the intended use of the organism. The OECD consensus documents identify parts of this information that could be commonly used in countries when conducting environmental risk/safety assessment, aiming to encourage information sharing and prevent duplication of effort among countries. They offer practical tools which compile science-based information relevant for this purpose. They are not a substitute for national requirements and locally available data should also be taken into account, but they can contribute to the risk/safety assessment process. These documents are publicly available and considered worldwide as sustainable references for use in biosafety evaluation.

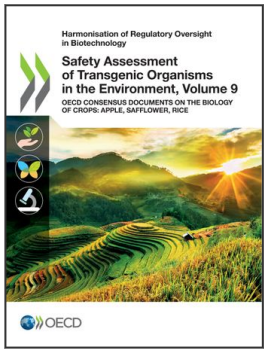
Opening Volume 9, the introduction to the biosafety consensus documents provides additional information on the key background concepts, principles and common approaches prevailing in risk/safety assessment of transgenic organisms. The purpose of the OECD consensus documents is described, as well as the process through which these documents are developed.

Chapter 1 deals with the “Revised points to consider on plant biology consensus documents”, originally published in 2006 and revised in 2020. It offers a structured explanatory checklist of relevant points to consider when preparing or evaluating a consensus document on the biology of a cultivated plant species, in relation to biotechnology and environmental risk/safety assessment of novel varieties.

Chapters 2, 3 and 4 deal with the biology of three major agricultural plants whose products are traded internationally, subject to diverse transformations and uses, and consumed worldwide. These cultivated plant species are respectively: a fruit tree, apple (*Malus domestica*); an oilseed crop, safflower (*Carthamus*

tinctorius); and a staple cereal, rice (*Oryza sativa*). The final section on rice revises the original publication of 1999 contained in Volume 1. The information contained in the three biology chapters provides, for each of the crops, key insights into the regulatory assessment of the environmental safety of genetically engineered varieties: taxonomy, centres of origin, geographic distribution, reproductive biology, genetics, hybridisation and introgression, as well as ecology. Chapter annexes then present the common diseases and pests for the concerned plant and its current biotechnological developments.

The set of science-based information and data contained in this volume, previously agreed by consensus and published by the OECD, constitute a solid reference recognised internationally and already widely used as part of biosafety assessments. As such, this publication should be of value to applicants for commercial uses of transgenic organisms, 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.



From:

Safety Assessment of Transgenic Organisms in the Environment, Volume 9

OECD Consensus Documents on the Biology of Crops: Apple, Safflower, Rice

Access the complete publication at:
https://doi.org/10.1787/e49bd2e8-en

Please cite this chapter as:

OECD (2022), "Executive summary", in *Safety Assessment of Transgenic Organisms in the Environment, Volume 9: OECD Consensus Documents on the Biology of Crops: Apple, Safflower, Rice*, OECD Publishing, Paris.

DOI: https://doi.org/10.1787/9a3d8dd6-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, as well as any data and 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. Extracts from publications may be subject to additional disclaimers, which are set out in the complete version of the publication, available at the link provided.

The use of this work, whether digital or print, is governed by the Terms and Conditions to be found at http://www.oecd.org/termsandconditions.