

Executive summary

This document constitutes the tenth 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”. The Series collate individual “consensus documents” published by the Working Party on the Harmonisation of Regulatory Oversight in Biotechnology. The nine previous volumes covered documents issued from 1996 to 2022. The current volume contains the Consensus Document on Environmental Considerations for Risk/safety Assessment for the Release of Transgenic Plants, published in 2023.

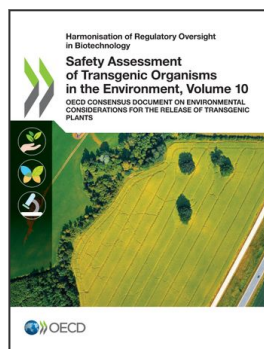
Modern biotechnologies are applied to plants (crops, flowers, trees), animals and micro-organisms. The safety of the resulting transgenic organisms, when released in the environment for use in agriculture, forestry, fishery, the food and feed industry, biofuel production or other applications, represents a challenging issue. Genetically engineered products are rigorously assessed by their developers and by governments 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.

The OECD offers long-standing recognised expertise in biosafety and contributes to facilitating a harmonised approach. The OECD consensus documents identify information of relevance to the environmental risk/safety assessment of genetically engineered organisms. These publications are considered worldwide as sustainable references for use in biosafety evaluation.

This document deals with the environmental risk/safety assessment of transgenic plants at a broad level. Its purpose is to describe an approach and provide illustrative examples for planning and structuring risk/safety assessments for the release of transgenic plants into the environment. It provides general information on key concepts and important points that risk/safety assessors should focus on when planning such assessments. These key features include the comparative approach, the familiarity with the biology of the unmodified plant species, the general protection goals, the assessment endpoints, the potential adverse effects associated with the environmental release, the pathways to harm and corresponding risk hypotheses, relevant information elements, and the use of environmental considerations in planning such assessment.

Annexes A to G of the document describe seven examples of environmental considerations routinely examined by assessors and taken from actual experience gained during risk/safety assessment of transgenic plants intended for environmental release. These environmental considerations are: Invasiveness and weediness; Vertical gene flow; Organisms (animals); Soil functions; Plant health; Crop management practices; and Biodiversity (protected species and habitats/ecosystems).

The set of science-based information and data contained in this volume, previously agreed by consensus and published by the OECD, constitutes a solid reference and a practical tool for use during the biosafety assessment planning process. This publication should be of interest to regulators and assessors from national authorities 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.



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