

Executive summary

This document constitutes the fifth 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 collating in a single volume the individual “consensus documents” published by the Working Group on the Harmonisation of Regulatory Oversight in Biotechnology. The four previous volumes of the series covered the documents issued during the 1996-2010 period. This volume contains the consensus documents issued in 2011 and 2012, while Volume 6 will collate those published in 2013, 2014 and 2015.

Modern biotechnologies are applied to plants, and also trees, animals and micro-organisms. The safety of the resulting transgenic organisms when released in the environment for their use in agriculture, food and feed industry, or for other applications, represents a challenging issue. This is true nowadays with the increasing cultivation of genetically engineered crops, and might become more crucial with future biotechnology developments widening to new species (e.g. insects, algae) and new targets such as crops adapted to climate change, plants of improved composition (biofortification), products for easier processing, renewable biofuels, insects modified to prevent diseases, biofertilisers and other applications. Genetically engineered products are rigorously assessed by their developers during their elaboration, and by governments when ready for release, to ensure high safety standards for the environment, human food and animal feed. Such assessments are felt essential for a healthy and sustainable agriculture, industry and trade. The growing number of novel organisms will also need to be assessed through a scientifically sound approach to risk assessment that will inform biosafety regulators and support the decision concerning their release.

The OECD Working Group on Harmonisation of Regulatory Oversight in Biotechnology was established in 1995. It gathers national authorities responsible for the environmental risk/safety assessment of products of modern biotechnology in OECD countries and in other economies which are key stakeholders in their production and use. Observer international organisations and experts involved in biosafety are associated to this work. The Working Group’s primary goals are to promote international regulatory harmonisation, to ensure that methods used is the risk assessment of genetically engineered products are as similar as possible, therefore opening the way to possible recognition and even acceptance of information from other countries’ assessments. The benefits of harmonisation are multiple: it strengthens mutual understanding among countries, avoids duplication and saves resources, increases the efficiency of the risk assessment process. Overall, it improves safety, while reducing unnecessary barriers to trade.

The consensus documents constitute the main output of the Working Group. They offer practical tools which compile science-based information relevant to the risk/safety assessment of transgenic organisms intended for release in the environment. They are publicly available and considered worldwide as solid references for biosafety.

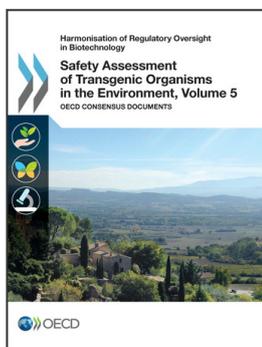
In this volume, the introduction to the biosafety consensus documents presents the OECD Working Group, the key background concepts, principles and common approach prevailing in risk/safety assessment of transgenic organisms. The purpose of the consensus documents and how they are developed, is also described.

Chapter 1 provides guidance on issues relevant to the risk/safety assessment of commercial environmental applications involving genetically engineered micro-organisms, especially bacteria. It explores the important aspects in bacteria for causing adverse human health effects, and how this knowledge can be used in biosafety regulatory assessment. It contains information on bacterial pathogenicity (general considerations, factors and determinants, molecular aspects), and other elements on assessing potential for bacteria-mediated adverse human health effects.

Chapter 2 deals with the biology of squashes, pumpkins, zucchinis and gourds (*Cucurbita* species). This information can be used as a useful tool for the biosafety assessment. It contains elements of taxonomy, centres of origin and distribution, morphological characters, reproductive biology, genetics, hybridisation and introgression, crop production, interactions with other organisms, pests and pathogens, and biotechnological developments.

Chapter 3 relates to the biology of *Brassica* species which include oilseed rape, turnip rape, mustards, cabbages and other oilseed crops. Taxonomy for a range of *Brassica* species is described, their centres of origin and distribution, reproductive biology, genetics, hybridisation and introgression, crop production, interactions with other organisms, pests and pathogens, breeding methods and biotechnological developments, common pathogens and pests.

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. It is already widely used as part of the biosafety assessments. As such, this publication should be of value to applicants for commercial uses of transgenic organisms, to risk assessors and regulators in national authorities in charge of granting approvals to their release in the environment, as well as the wider scientific community.



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