Executive summary

This document constitutes the sixth 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 five previous volumes of the series covered documents issued from 1996 to 2012. This Volume 6 contains the consensus documents published during the 2013-15 period.

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 with this work. The Working Group's primary goals are to promote international regulatory harmonisation, to ensure that methods used in 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, saves resources and 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 are also described.

Chapter 1 provides guidance and information on issues relevant to the risk/safety assessment of low-level presence (LLP) situations, which relate to seed containing small amounts of transgenic material that have been authorised for cultivation in an exporting country but not in the country of import. The availability and use of information when facing such cases is explored, with elements to consider and approaches to the management of LLP situations.

Chapter 2 deals with the biology of sugarcane (*Saccharum* spp.). This information can be a useful tool for the biosafety assessment. It contains elements of taxonomy; centre of origin; domestication and cultivation practices; morphological characteristics; reproductive biology; pollination and vegetative growth; genetics; abiotic interactions with nutrients, temperature, water and other stresses; interactions with weeds, pests and pathogens; hybridisation and introgression, and biotechnological developments.

Other crops are similarly considered and their biology described in the following chapters: Chapter 3 relates to cassava (*Manihot esculenta*), Chapter 4 to common bean (*Phaseolus vulgaris*) and Chapter 5 to cowpea (*Vigna unguiculata*). Chapter 6 deals with the biology of eucalyptus tree, being focused on those *Eucalyptus* species and hybrids which are planted commercially and expected to be the subjects of possible genetic modification aiming to improve their performance, resistance and adaptation to stressing conditions.

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 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.