Executive summary

This document constitutes the seventh 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 six previous volumes of the series covered documents issued from 1996 to 2015. The current volume contains the consensus documents published in 2016-17.

Modern biotechnologies are applied to plants, as well as trees, animals and micro-organisms. The safety of the resulting transgenic organisms when released in the environment for their use in agriculture, the 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 (such as animals or algae). In addition, new breeding objectives can lead to obtaining crops with new traits adapted to climate change, plants of improved composition (biofortification), products for easier processing, renewable biofuels, fast-growing fish, insects modified to fight 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. International organisations and experts involved in biosafety are associated with this work. The primary goals of the working group are to promote international regulatory harmonisation, to ensure that methods used in the risk assessment of genetically engineered products are as similar as possible. This opens the way to possible recognition and even acceptance of information from the assessments of other countries. 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 working group's main deliverables. 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.

The introduction to the biosafety consensus documents presents the OECD working group, key background concepts, principles and common approach prevailing in risk/safety assessment of transgenic organisms. The purpose of the consensus documents are described as well as the process by which they are developed.

Chapter 1 deals with the biology of sorghum (*Sorghum bicolor*), an important crop used as staple food or as livestock feed and forage in many countries. This information can be a useful tool for the biosafety assessment of transgenic varieties. It contains elements of taxonomy; morphological characteristics; centre of domestication, geographic distribution and cultivation practices; reproductive biology; genetics; outcrossing and gene flow; ecology; common pests and pathogens; and biotechnological developments.

The biology of tomato (*Solanum lycopersicum*), another key cultivated plant which is consumed globally, is similarly considered in Chapter 2.

Chapter 3 addresses the biology of Atlantic salmon (*Salmo salar*). It is the first OECD publication of this series to deal with an animal species, in this case a commonly cultured, domesticated fish reared for food production but also present in oceans and rivers as undomesticated populations. The biology and ecology of wild Atlantic salmon is described including: classification; life stages; reproduction; centres of origin; geographical distribution; population dynamics; and interaction with other organisms. Similarly, aspects of the farmed form are considered such as: domestication; aquaculture rearing practices; biocontainment; and interactions with the external environment. It also provides elements of genetics and research on genetically engineered salmon, and suggests bibliographic resources for its risk assessment.

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 from national authorities responsible for granting approvals to their release in the environment, as well as the wider scientific community.