Executive summary

This Volume 8 contains the "OECD consensus document on the biology of mosquito *Aedes aegypti*". It is published in the Series on Harmonisation of Regulatory Oversight in Biotechnology which relates to the environmental risk/safety assessment of transgenic organisms, also called "biosafety" assessment. This new publication provides a useful tool to national authorities and scientists involved in the evaluation of the safety of genetically-engineered mosquitoes when released in the environment.

The mosquito *Aedes aegypti* is of major public health concern, being the main vector of viruses responsible for diseases such as yellow fever, dengue fever, Zika fever and chikungunya. Its development in tropical and sub-tropical areas is intrinsically linked to human habitats and activities that offer the insect its adequate living conditions and the blood meal it needs for reproduction. This mosquito species is subject to biotechnological research and applications (including genetic engineering), aiming to contribute to the control of its population and thus limiting its drastic impact on human health.

Considering the rising spread of related epidemics in many parts of the world, together with the development of genetically-engineered mosquitoes contemplated for use in integrated control management, the OECD Working Group on Harmonisation of Regulatory Oversight in Biotechnology (WG-HROB) decided to develop this document on *Aedes aegypti* biology. The project, launched in 2014, was co-led by Mexico, Brazil and the ILSI Research Foundation, with additional expertise provided by Australia, France, India, Kenya, the United States and the industry sector. Other countries and observer organisations involved in the WG-HROB activities also participated in the preparation of the document.

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 their use in agriculture, forestry, the food and feed industry or for 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. This remains essential with new biotechnology developments using insects to fight against disease outbreaks: engineered mosquitoes need to be evaluated through a scientifically sound approach to risk/safety assessment that will inform biosafety regulators and support the decision concerning the release of these novel organisms in the environment.

The OECD offers a long-standing recognised expertise in biosafety and contributes to facilitating an 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, and the intended use of the organism. The OECD Biosafety consensus documents elaborated by the WG-HROB identify parts of this information which 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.

To conduct biosafety assessment of *Aedes aegypti*, a deep knowledge of the mosquito species is required to fully consider its potential interaction with the environment of release. Useful information can go from accurate taxonomic nomenclature, the origin of the species and its current distribution in the world, up to the life cycle of the mosquito in its successive forms (eggs, larvae, pupae and male/female adults). The reproductive biology is also essential to understand its behaviour: what are its breeding sites and reproduction features (mating, physiological aspects, fecundity), and the potential effect of *Wolbachia* bacteria. The *Ae. aegypti* genetics is also of great value, including genetic linkage map, population genetics and phylogeography, susceptibility to insecticides and resistance mechanisms, as well as genetic variability in the mosquito competence to transmit virus infection. Then, it is crucial for biosafety assessors to acquire extensive knowledge of the ecology of this mosquito, i.e. its interactions with the other species in the environment: ecological niche it occupies; the climatic parameters influencing its development; its anthropic habitats in strong connection with human population; the abiotic requirements in terms of water and food availability; and the fitness to local conditions including its dispersal, population distribution and modelling.

To prepare this publication, experts have summarised in this single document key elements from a vast range of solid science-based publications, selected for their potential interest during biosafety assessment and carefully referenced. This information is intended to benefit-risk assessors that may need to consider potential effects on the environment when releasing engineered *Aedes aegypti* in the context of mosquito control programmes, and therefore may contribute in facilitating the decision-making process.

Opening Volume 8, the introduction to the Biosafety consensus documents provides additional information on the key background concepts, principles and common approach prevailing in risk/safety assessment of transgenic organisms. The purpose of the OECD consensus documents are described in detail, as well as the process by which they are developed. These publications address the biology of crops, trees and micro-organisms, as well as specific traits introduced in engineered plants, with a recent scope extension to animal species.

Another mosquito, *Anopheles gambiae*, is currently considered by the WG-HROB for developing a similar biology document. The *A. gambiae* complex of species includes the most important vectors of malaria disease, and biotechnological solutions for its control are being explored. The future document will constitute a useful complement to this publication by enlarging the scope of insects covered by the OECD Biosafety consensus documents.