OECD Publishes Consensus Document on Environmental Considerations for the Release of Transgenic Plants

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On July 27, 2023, the Organization for Economic Cooperation and Development (OECD) published a new document in its Series on Harmonization of Regulatory Oversight in Biotechnology, *Safety Assessment of Transgenic Organisms in the Environment, Volume 10: OECD Consensus Document on Environmental Considerations for the Release of Transgenic Plants*. The document addresses environmental risk/safety assessment at a broader level than previous consensus and guidance documents from the Working Party on the Harmonization of Regulatory Oversight in Biotechnology (WP-HROB). The purpose of the document 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 on which risk/safety assessors should focus when planning such assessments. According to OECD, 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 through G 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. **OECD states that 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).

According to OECD, the set of science-based information and data contained in the volume

"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. The consensus documents published in Volumes 1 to 10 of the Series are available individually free of charge on the <u>OECD Bio Track</u> <u>website</u>.

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