Why is risk assessment and risk management on the agenda at SBSTTA-26?

SBSTTA-26 will consider the outcomes of the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and to make a recommendation for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its eleventh meeting. The report of the AHTEG on Risk Assessment contains the additional voluntary guidance materials to support the case-by-case risk assessment of living modified organisms containing engineered gene drives and the list of prioritized topics on which further guidance materials on risk assessment may be needed. The Secretariat has prepared a note and an addendum to support the deliberations at the SBSTTA-26.

What are living modified organisms (LMOs)?

A "living modified organism" is defined in the Cartagena Protocol on Biosafety as any living organism that possesses a novel combination of genetic material obtained using modern biotechnology.

What is a risk assessment?

Risk assessment is used by competent authorities to make informed decisions regarding LMOs. It aims to identify and evaluate the possible adverse effects of LMOs on the conservation and sustainable use of biological diversity, taking also into account risks to human health. The Cartagena Protocol requires Parties to make decisions on import of LMOs for intentional introduction into the environment in accordance with scientifically sound risk assessments (Article 15) and sets out principles and methodologies on how to conduct a risk assessment (Annex III). It also requires Parties to adopt measures and strategies for preventing adverse effects and for managing and controlling risks identified by risk assessments (Article 16).

What is an engineered gene drive?

An engineered gene drive refers to genetic elements that are transferred to subsequent generations at a frequency greater than the 50% (as expected by Mendelian inheritance). Due to this preferential inheritance, engineered gene drives may rapidly spread through a population. They are designed to suppress or reduce interbreeding target populations or to modify them with an altered genotype. Thus, engineered gene drives have gained attention as a potential novel genetic intervention to control invasive species or vector-borne diseases and due to their potential adverse effects.

Background

In decision CP-10/10, the Conference of the Parties serving as a meeting of the Parties to the Protocol, endorsed the recommendation to develop additional voluntary guidance materials by the AHTEG. It was agreed that the materials will be developed in accordance with Annex III of the Protocol and a specific focus of the material should be on engineered gene drive mosquitos, taking into account current experience with the organism, the type of engineered gene drive and

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specific issues of risk assessment. An AHTEG was established and met twice to develop these materials. In addition, Parties were invited to submit information on their needs and priorities for further guidance materials on specific topics on risk assessment of living modified organisms, including a rationale following criteria in decision CP-9/13.

Further, discussions on risk assessment and risk management will contribute directly to Goal A.5 ("Parties carry out scientifically sound risk assessments of LMOs, and manage and control identified risks to prevent adverse effects of LMOs on the conservation and sustainable use of biological diversity, taking also into account risks to human health") of the Implementation Plan and the Capacity-Building Action Plan for the Cartagena Protocol on Biosafety.

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Important links:
https://bch.cbd.int/protocol