

Position Paper on CBD additional voluntary guidance materials to support case-by-case risk assessments of LMOs containing engineered gene drives

Gene drive approaches offer the potential to develop new tools to address important conservation and public health challenges that have not been successfully solved by current methods alone. As research progresses, it has spurred increasing interest in the issue of governance and regulation of these technologies, particularly in the case of gene drive mosquitoes for the control of vector-borne diseases.

In decision [CP-10/10](#), Parties to the Cartagena Protocol on Biosafety agreed on establishing an Ad Hoc Technical Expert Group on Risk Assessment (AHTEG) to develop additional voluntary guidance materials to support case-by-case risk assessments of living modified organisms (LMOs) containing engineered gene drives.

The proposed guidance material is balanced, helpful and consistent with the overall approach of the Convention on Biological Diversity (CBD) to risk assessment, the AHTEG's mandate, and current best practices in the field. It should be adopted at the Sixteenth meeting of the Conference of the Parties (COP 16), becoming a reference for all Parties interested in gene drive research and application. The next step is to ensure that Parties have the capacity to implement the guidance to use and benefit from gene drive tools in the future.



Looking ahead to COP 16 and beyond:

Future CBD work related to risk assessment should prioritize capacity-building to ensure Parties have the necessary expertise and tools to assess the risks and benefits of gene drive approaches.

The guidance represents an important milestone and should be a reference for Parties interested in gene drive research and applications. However, it is equally important that Parties have the capacity to implement this or any other future CBD guidance in this field. While other work on synthetic biology might also be helpful, capacity-building should remain a priority, in line with the [Capacity-building Action Plan for the Cartagena Protocol](#) agreed upon at COP 15. It is crucial to ensure that Parties are able to build and align domestic frameworks with international best practices, and to make informed decisions on whether to research and potentially use gene drive tools.

If Parties decide to develop further guidance materials on self-limiting insects at COP 16, it is necessary to have a clear understanding of what can be classified as such, so to avoid unnecessary overlap with the new guidance on gene drive organisms.

Discussions at COP 16 will consider including self-limiting insects as a new topic for additional risk assessment guidance. To avoid unnecessary duplication with gene drive guidance, it is essential to clearly define self-limiting insects and distinguish them from other LMOs. Understanding these definitions is crucial, as some gene drive insects could fall under this category. Keeping the guidance on self-limiting insects distinct from that on gene drive organisms is important to avoid duplication and unhelpful overlap, as the latter is likely to be adopted at COP 16.

Adoption of the voluntary guidance is recommended by the Network for the following reasons:

The new guidance is science-based, consistent with the principle of case-by-case assessment, and makes provisions for considering both risks and benefits.

The new and voluntary guidance effectively builds upon [Annex III of the Cartagena Protocol](#), providing detailed guidance for assessing the potential adverse effects of gene drive mosquitoes. It also introduces a 'pathway to harm' approach, which represents current best practices in the risk assessment framework for gene drive organisms by providing a method for problem formulation for a specific gene drive transgene or organism. The guidance also carefully makes provisions to consider both potential risks and benefits on a case-by-case basis, including contributions to human health and the impact on vector-borne disease burden, while accounting for the diverse range of gene drive technologies, strategies, and approaches.

The new guidance acknowledges the need for adopting a comparative approach when assessing gene drives' potential benefits and risks.

By comparing the potential benefits and risks associated with gene drives against those posed by existing tools used for the same purpose, experts can undertake a more comprehensive assessment of the technology and make more informed decisions. Experts should also consider the risk of inaction, assessing the potential consequences of maintaining the status quo.

Uncertainty is not a concept unique to gene drive and should not prevent the

use of cost-effective measures to avoid environmental degradation.

The guidance acknowledges the uncertainties surrounding gene drives, but emphasizes that these should not prevent their potential use after a careful analysis of their potential risks and benefits, following the precautionary approach proposed by the [1992 Rio Declaration](#). The guidance also acknowledges that further research is vital to address uncertainties and data gaps, including through field evaluations, which are critical to the development of safe and effective gene drive tools.

The new guidance recognizes national authorities' key role in risk assessment while ensuring an inclusive approach to stakeholder engagement throughout the process.

National authorities are responsible for deciding whether to allow gene drive research and potential future applications of gene drive tools. As highlighted in the new guidance, Parties can always revert to the Convention and its Protocols when seeking additional guidance on key issues surrounding LMOs research and application, such as transboundary movement or liability and redress. It also recognizes that robust engagement is crucial for building and sustaining public confidence, help define priorities and inform gene drive assessment, research design and pathways. Therefore, it acknowledges the need for engaging with Indigenous People and Local Communities (IPLCs) and considering free, prior, and informed consent (FPIC), according to national context and legislation.