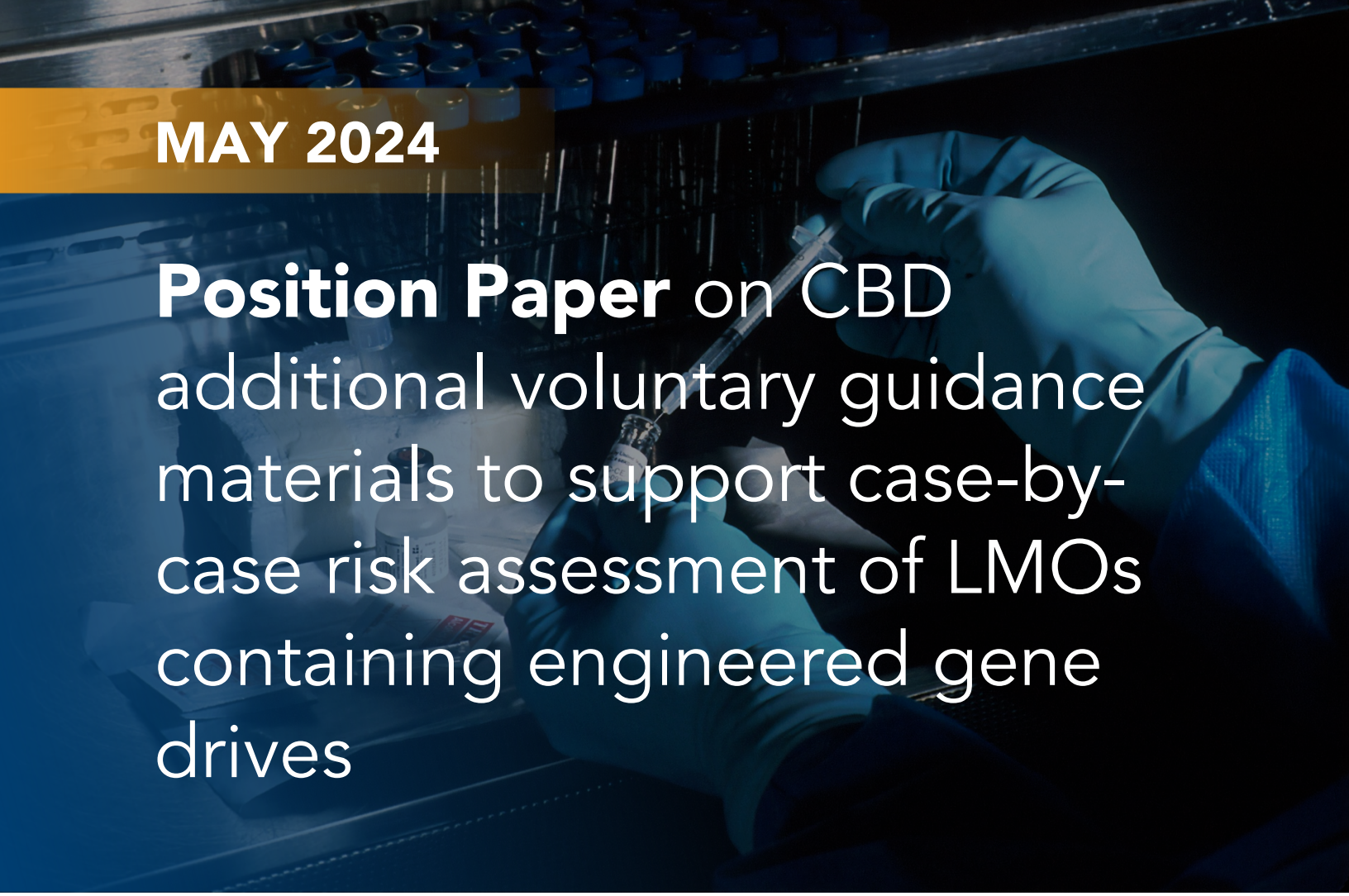

MAY 2024

Position Paper on CBD additional voluntary guidance materials to support case-by-case risk assessment 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 CBD's overall approach to risk assessment, the AHTEG's mandate, and current best practices in this field. It should be endorsed at the Twenty-sixth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA26) and recommended for adoption at the Sixteenth Conference of the Parties (COP16), becoming a reference for all Parties interested in gene drive research and application.

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 material recognises that there are many different types of gene drive constructs, for many different uses and contexts. As a result, a case-by-case approach will be needed to determine the possible risks and benefits of each application. Risks and benefits associated with each gene drive approach should take into account the type of modification made, the species it is applied to, and the ecosystem and geography where the organism with the drive system will be used, rather than on the gene drive mechanism itself.

The guidance carefully makes provisions to consider both potential risks and benefits, including contributions to human health and the impact on vector-borne disease burden, for a diverse range of gene drive technologies, strategies, and approaches. The text ensures thorough evaluations tailored to the specific characteristics of each application.

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 have 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.

The choice of comparators will depend on the risk hypothesis to be tested and other factors,

such as the availability of appropriate comparators. In the case of gene drive mosquitoes, the guidance suggests risk assessors consider comparator activities such as large-scale insecticide applications, the release of *Wolbachia*-infected, self-limiting mosquitoes, or the release of a predator species.

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.

Ultimately, national authorities are responsible for deciding whether to allow gene drive research and possible 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.

Robust engagement is important not only because it is crucial for building and sustaining public confidence, but also because it can help define priorities and inform gene drive assessment, research design and pathways. The new guidance acknowledges the importance of engaging with indigenous people and local communities and considering free, prior, and informed consent (FPIC), according to national context and legislation.

Modeling plays an essential role in gene drive's risk assessment process, helping to build a bridge between laboratory studies and natural conditions.

The new guidance recognizes the importance of modeling in answering some of the scientists' questions on the predictability, spread, persistence, and impact of gene drive organisms. Risk assessments of gene drive tools need to draw from various sources of data to offer a picture that is as complete as possible, and are likely to combine both probabilistic (quantitative) and qualitative information elicited through multiple methods, from stakeholder interviews to laboratory studies. Modeling can help address uncertainties by predicting the effects inside and outside laboratory conditions and at spatial-temporal scales too large to study empirically prior to release.

Future CBD work related to risk assessment should focus on capacity-building implementation to ensure Parties have the necessary expertise and tools to research, and potentially use and benefit from gene drive approaches.

The guidance represents an important milestone and should be a reference for countries interested in gene drive research and applications. However, countries must receive support for implementing this new voluntary guidance and other relevant guidance for the assessment and management of LMOs. Recognizing and building the capacity of national authorities is essential as they are responsible for ensuring that domestic gene drive research and applications align with local and international standards and best practices.