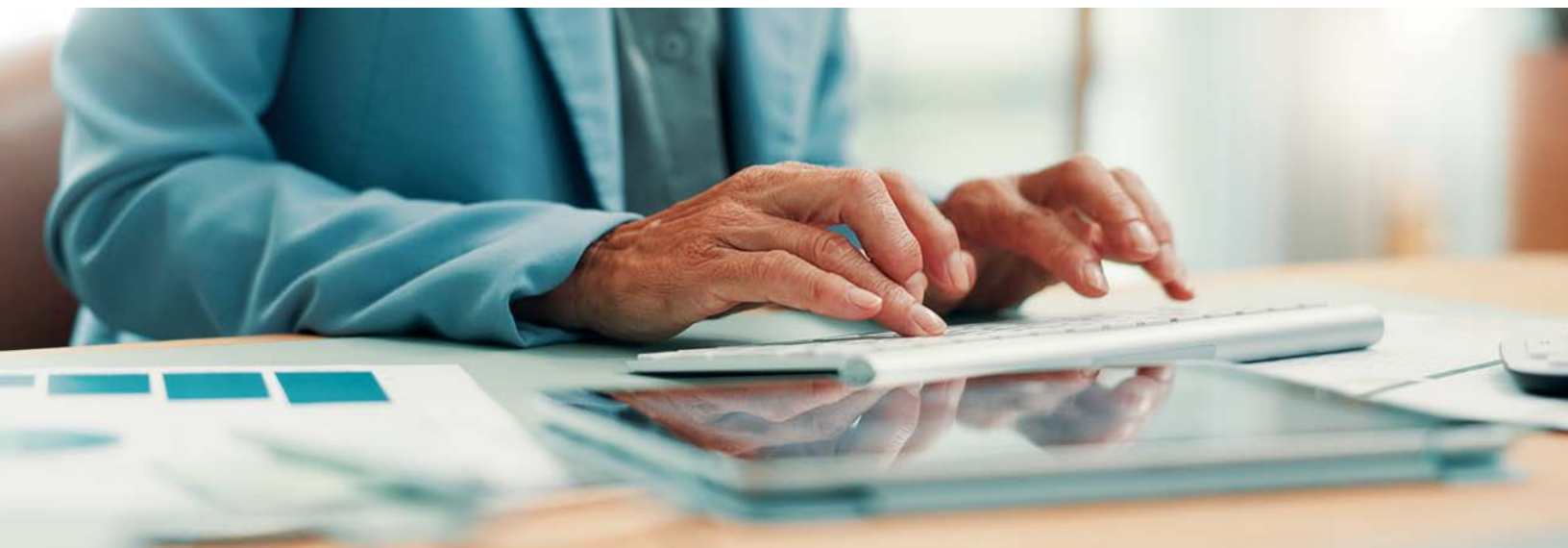


Position Paper on risk assessment and risk management of LMOs

At CP-MOP 11, Parties welcomed the [additional voluntary guidance materials to support case-by-case risk assessments of living modified organisms \(LMOs\) containing engineered gene drives](#). This was an important milestone for responsible research and governance of this rapidly evolving field. It reflects emerging international best practices, offering a valuable foundation for researchers, regulators, and policymakers seeking to ensure that these technologies are developed and used in a scientifically rigorous and context-sensitive manner.

Parties were also tasked under decision [CP-11/7](#) to consider at the Twelfth Meeting of the Parties to the Cartagena Protocol on Biosafety ([CP-MOP 12](#)) whether new risk assessment guidance is needed, and if so, on what topics. It is important that any further guidance material remains scientifically sound, and non-duplicative. CP-MOP 12 is an opportunity for Parties to reaffirm the case-by-case, science-based foundation of risk assessment and to prioritize capacity-building for Parties to put existing and future guidance into practice.

The [development of new guidance materials](#) could offer welcome support for Parties, provided it remains grounded in scientifically sound risk assessment, is clearly differentiated from existing instruments, including the voluntary guidance on LMOs containing engineered gene drives, and avoids inconsistencies. Any new materials developed in the next cycle should be clear in scope and scientifically robust, reflecting the limited time and resources available to the AHTEG. The next and more crucial step is to ensure Parties have the capacity to implement guidance, without which it is of little practical use.



Additional guidance must cover topics and issues not addressed by CBD and its protocols. The rationale for selecting those topics must clearly explain why existing guidance materials are not sufficient.

Some proposed topics are broadly framed and risk overlapping with existing materials, notably the voluntary guidance on engineered gene drives. The topic "LMOs expressing genome-editing machinery for pest or pathogen control" is a clear example. Pest and pathogen control covers a very wide range of organisms and technologies, including gene drive mosquitoes for vector-borne disease control, gene drive approaches to invasive species management, and other genome-edited organisms designed to suppress or modify pest and pathogen populations. Many of these applications are already addressed by the existing guidance on gene drive LMOs, so a new topic framed this broadly risks duplicating that guidance rather than addressing a genuine gap.

The topic "long-term and cumulative effects of genetic constructs and LMOs" raises a similar concern. Consideration of long-term and cumulative effects is already a core part of risk assessment under [Annex III of the Cartagena Protocol](#) and is built into the existing guidance on LMOs containing engineered gene drives, which addresses persistence, spread, and effects over time. Framing this as a distinct new topic risks creating inconsistencies and the false impression that long-term and cumulative effects are not already part of standard risk assessment practice.

Any rationale for a new topic should state explicitly why it is not already addressed by the existing general [guidance on risk assessment of LMOs](#) or by the guidance focused on LMOs containing engineered gene drives.

The AHTEG's work program should focus on a small number of well-defined topics and consider the available time of its members.

AHTEGs face time and resource constraints, and the range of expertise within any one AHTEG is limited. Its scope of work should therefore stay focused on a very limited number of topics to produce practical, scientifically robust outputs. Past experience shows that guidance development is resource- and time-intensive. Selecting concrete, narrowly defined topics from the outset improves the odds of producing

scientifically sound materials that Parties can readily support. Commissioning independent technical experts to prepare initial drafts could also help stretch the AHTEG's limited capacity further, while ensuring that materials draw on the most relevant and current scientific expertise.

The scope and status of any new materials, and their relationship to existing guidance, should be clearly defined.

The current draft text uses two different terms, "technical notes" and "guidance materials," to describe similar prospective output, without clearly distinguishing between them. Recent discussions have shown a preference for the term "guidance materials", since this aligns with the terminology already used. However, this shift has not been fully carried through the draft text.

The term "technical notes" has no precedent and is not defined under the Cartagena Protocol or in any prior CBD guidance, which makes it unclear what form such a document would take, what status it would carry and how it relates to existing guidance. The only guidance formally adopted by Parties is the risk assessment guidance on LMOs containing engineered gene drives: if technical notes are proposed as an annex or appendix, they would, in practice limited in scope to gene drive LMOs.

Without clarity, new materials risk being misapplied, duplicating existing work, or creating unclear expectations.

Capacity-building and international cooperation are essential to foster the practical implementation and benefits of guidance materials, including the existing guidance on gene drive LMOs.

Comprehensive capacity-building programs should be further developed by the CBD to help countries implement the provisions of the Cartagena Protocol, including the technical and regulatory expertise needed to understand and apply new guidance effectively.

Capacity-building is already recognized as a cross-cutting priority under the Convention, and similar discussions are taking place across other areas of CBD work, reflecting the strong and consistent interest Parties have shown in strengthening capacity-building more broadly. As new guidance materials are adopted, many countries will need to develop or strengthen the skills required to adapt and apply them domestically, and this support should be built into implementation planning from the outset rather than treated as an afterthought.

Recognizing and building the capacity of national authorities is essential, as they play a vital role in the risk assessment process and in ensuring domestic gene drive research aligns with local and international standards. This work is consistent with the Capacity-building Action Plan for the Cartagena Protocol agreed at CP-MOP 10. International partnerships should be encouraged to support the exchange of knowledge, expertise, and resources among countries, scientific communities, and other stakeholders.