



POSITION PAPER ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS 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, such as invasive alien species and vector-borne diseases. Although research into synthetic gene drives is still at a relatively early stage, with no field evaluations planned in the medium-term, recent scientific progress in developing potential gene drive organisms has spurred increasing interest in the issue of governance and regulation of these technologies.

Decision [CBD/CP/MOP/DEC/9/13](#) established an online forum and an Ad Hoc Technical Expert Group with the purpose of supporting deliberations by countries on the suitability of current guidance for risk assessment of gene drive organisms. Taking into account these deliberations, SBSTTA endorsed the development of additional voluntary guidance materials to support case-by-case risk assessment of LMOs containing gene drives. This SBSTTA recommendation was not the subject of consensus however, as there was insufficient time for discussions during the SBSTTA 24 meeting.

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This recommendation will inform deliberations at COP-MOP 10 of the Cartagena Protocol, which should take into account the following considerations:

New guidance should be part of the Biosafety Technical Series and offer a voluntary and additional set of materials.

- As noted by many Parties, in the study commissioned by the CBD Secretariat, by several participants in the Online Forum, and by experts on the Ad Hoc Technical Expert Group (AHTEG), the current methodologies for risk assessment of LMOs are broadly adequate for organisms containing engineered gene drives.
- To avoid duplication and ensure an effective use of resources, the new guidance materials should thus be additional to the existing CBD Guidance on Risk Assessment of LMOs ([UNEP/CBD/BS/COP-MOP/6/13/Add.1](#)) and could be part of the Biosafety Technical Series.
- The guidance should also be complementary to existing materials outside of CBD, such as the body of expertise and analysis already developed in many countries, as well as efforts specifically focused on gene drive organisms already undertaken by other international organizations, such as the

World Health Organization (WHO) and the European Food Safety Authority (EFSA).

To ensure the guidance brings added value, the materials should focus on issues that are clearly specific to gene drive organisms.

- Developing new guidance requires significant time and resource commitments. Rather than focusing on a specific species, the guidance should focus on a set of issues that will be relevant and useful for an extended period, and applicable to a broad range of possible gene drive organisms. This approach would avoid the need to develop new guidance in short order for other species.
- The guidance should focus on the specific topics that arise in risk assessment of gene drive organisms and which may be different or additional to those considered in the risk assessment of other LMOs, as described in the CBD's 2012 guidance document.
- This could encompass issues related to the temporal and spatial spread of gene drive organisms (persistence, spread, predictability), molecular characterisation, and monitoring.
- The outputs from this effort should be science-based, consistent with the principle of case-by-case assessment and make provisions for the consideration of both risks and benefits.

The process for developing the proposed new documents must ensure timeliness and adequate expertise.

- Given the complexity and technicality of the topics to be addressed by the guidance, commissioning a technical



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consultant (or several consultants) to develop drafts on the agreed issues would provide a technically and scientifically-sound basis for Parties to consider draft elements of a guidance at the next SBSTTA.

- The AHTEG mechanism does not allow for the necessary time and expertise needed to develop a robust set of considerations on these technical topics. A consultant could ensure a timely report, as was the experience on Digital Sequence Information.
- At its next meeting, SBSTTA could then consider the reports and work on draft guidance based on the input provided. This may include narrowing down the set of topics to be addressed by the guidance materials.

Capacity-building for risk-assessment is a priority for Parties.

- The development of new guidelines should not overshadow the need to support Parties that request assistance to build their understanding of gene-drive approaches and of their capacity to assess a regulatory dossier. This dovetails with the broader need to ensure implementation of the Cartagena Protocol for all LMOs, not just gene-drive organisms.
- In submissions on their experiences, challenges and needs regarding LMOs

containing engineered gene drives, the need for increased capacity-building was highlighted repeatedly by Parties to the Cartagena Protocol. Although Parties may acknowledge that adequate methodologies for risk assessment exist, many expressed the concern that they lack the adequate resources and/or expertise (legal, scientific, procedural, or otherwise) to implement them.

- As the foremost international organization dealing with biodiversity and conservation, the CBD is centrally placed to facilitate this capacity-building among Parties. Knowledge-sharing, training, and other capacity-building activities should therefore be prioritized in its work. This capacity-building should be done as part of an overall effort to build capacity for LMOs generally, including through the proposed capacity building plan for biosafety post-2020, to be considered by COP-MOP 10 ([CBD/SBI/3/18](#)).
- Equal weight should be placed on inviting Parties and other stakeholders to submit information on how capacity-building for risk assessment among Parties can be strengthened. In particular, Parties should be encouraged to consider how capacity-building can help address perceived gaps in the resources at their disposal to effectively assess the risks associated with gene drive organisms.

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The only way to address existing uncertainties and data gaps is through further research.

- As mentioned above, data gaps remain that may hamper the ability of Parties to carry out accurate risk assessments. The only way to address these gaps and other uncertainties is by fostering further research on gene drives.
- Any policies or measures that unnecessarily restrict gene drive research or prevent it from being carried out responsibly could undermine the ability of Parties to conduct risk assessments. They would therefore be counterproductive in ensuring that gene drives are investigated, evaluated, and potentially deployed safely.

For more information visit:
www.genedrivenetwork.org

