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, such as invasive alien species and vector-borne diseases, that have not
been successfully solved by current methods alone. 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. The decision requested SBSTTA to make a
recommendation as to “whether additional guidance materials on risk assessment are needed for (a)
living modified organisms containing engineered gene drives” for consideration at CBD COP 15-
MOP 10.

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Tools and guidelines to carry out accurate risk assessments of gene drive already exist

- 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.
- In addition, there is a body of expertise and analysis already at national levels in many countries, as well as efforts already undertaken by other international organizations, such as the World Health Organization (WHO) and the European Food Safety Authority (EFSA) specifically focused on gene drive organisms.
- If Parties were to move forward with the development of new additional guidance, it should build on and be complementary to existing risk assessment resources in order to avoid duplication of efforts and ensure that the work is carried out efficiently.

The CBD must make the most efficient use of its limited resources

- The CBD should ensure that any work undertaken makes the best use of existing resources and responds to a genuine need from Parties.
- Work on further guidance should only proceed if consensus can be reached on the specific scope of the guidance and an adequate process is found to ensure the result is science-based and technically accurate.
- The focus on the additional guidance should not distract from or supersede the existing need for capacity building for risk assessments for all LMOs.

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

- More than developing new guidelines, the priority should remain 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.

• 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.

If Parties choose to proceed, the additional guidance should have a clear scope, respond to specific needs identified by Parties and be based on the principle of case-by-case assessment

• The suggested recommendation for the development of generic “guidance” is problematic given the enormous variation in characteristics and risk profiles among proposed applications of engineered gene drives.

• It is essential that before embarking on the complex and lengthy effort of developing new guidance, there is a clear consensus on what needs this guidance should meet. This can help ensure the guidance is useful and has the support of Parties.

• Further detail should be provided, either in the text of the recommendation itself or in the terms of reference (TORs) of the expert group regarding the specific issues related to risk assessment for gene drive organisms that require the development of further guidance. This will help avoid open-ended and potentially inconclusive discussions on guidance applicable to all gene drive applications in all contexts and ensure that the work of the CBD responds to the actual needs identified by Parties*.

• 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.

• Guidance should avoid creating unnecessary barriers to research and remain in alignment with paragraph 11 of CBD decision 14/19 on the necessary conditions for experimental release of organisms containing engineered gene drives.

*This is in line with COP-MOP decision 9/13 which recognizes that “specific guidance may be useful, to support case-by-case risk assessment” and ss recommended by New Zealand during the informal virtual sessions in preparation for SBSTTA24.
The process for developing the proposed new documents must ensure timeliness and adequate expertise

- Commissioning a dedicated group to prepare a scope and later the guidelines would be a more effective way to prepare the guidelines than relying on the AHTEG process.

- Gene drive research is a rapidly-evolving field, while the usual process of developing and considering outputs through an AHTEG faces constraints with regards to pace and timelines.

- Parties should consider alternative approaches:
  - Composition: Setting up an independent group of risk assessment and regulatory experts, including experts with first-hand knowledge and understanding of gene drive research, would be a more productive way to proceed. It should also include experts who have already participated in assessing RA frameworks for gene drive at a national level.
  - Timeframe: This group could have a time-limited mandate to first identify a reasoned shortlist of topics to address, and then to work on these. It could report to the AHTEG or directly to the SBSTTA and complete its work in a total of 4 years.
  - Basis: The independent expert group could use the report commissioned to Perseus in 2019 and reviewed by the AHTEG, complemented by an appropriate update, to establish the short list. It could be complemented by interviews with regulatory experts amongst Parties and with other experts who have worked on developing existing guidance.

For more information visit: www.genedrivenetwork.org