OUTREACH NETWORK FOR
GENE DRIVE RESEARCH

Outcomes of CBD SBSTTA 22

on issues related to gene drive organisms

Key takeaways

- **Discussions highlight a growing understanding of gene drive by Parties, but differences remain on how responsible research and evaluation of gene drive-based technologies can best be carried out.**
- **Decisions at COP will set up a multi-year process of work relevant to gene drive. How this impacts existing and future research should be at the forefront of Parties' deliberations at COP.**
- **Some of the proposals could result in moratorium or moratorium-like measures on research (including small-scale field releases), hindering the capacity of researchers to provide answers to the questions raised by Parties.**

Overview of SBSTTA 22

1- On synthetic biology

On gene drive, the discussions focused on how to ensure gene drive research is carried out safely and responsibly, and whether such research poses challenges that cannot be managed. The differences in views on this topic are still clearly identifiable in the outcome document from SBSTTA. For example paragraph 10, in which one of the two options proposes to ban small scale releases of gene drive organisms for the purpose of research[1]. Many Parties noted that experimental releases are a key part of the research process, and while each should be assessed carefully on a case-by-case basis, "refraining from" would amount to putting a moratorium on gene drive research.

Parties also discussed whether language proposed (for example in paragraph 11[2]) offers a fair consideration of new technologies derived from gene drive research, including weighing both potential positive and potential negative impacts in decision-making. Several emphasised the importance of ensuring the key principle of case-by-case assessment is reflected in the text to avoid generalisations across potentially very diverse technologies.

The question of the engagement of indigenous people and local communities in decisions about gene drive research was also raised (paragraph 12). Further clarification on this topic will be important to those researching gene drive, as it will shape their stakeholder engagement programmes as well as national decision-making processes. A lack of clarity could potentially create high uncertainty and be a deterrent to activities.

On other issues more broadly related to synthetic biology, there were persistent and significant differences of views between Parties about whether synthetic biology constitutes a "new and emerging issue" under the CBD, and hence whether it should be discussed. Similarly, many Parties noted that there are an increasing number of issues being added in alongside the topic of synthetic biology, such as genome-editing, which they do not see as falling in the scope of synthetic biology.

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[1] "*Calls upon Parties and other Governments, taking into account the current uncertainties regarding engineered gene drives, to apply a precautionary approach, in accordance with the objectives of the Convention, [with regard to] [refrain from] the release, including experimental release, of organisms containing engineered gene drives*."

[2] "*Recognizes that, as there could be potential adverse effects arising from organisms containing engineered gene drives, before these organisms are considered for release into the environment, research and analysis are needed, and specific guidance may be useful,3 to support case-by-case risk assessment*;"

2- On risk assessment

The discussions under risk assessment in part mirrored the discussions under synthetic biology, with the inclusion of genome editing in the text also the subject to diverging views.

The risk assessment and management negotiations were focused on whether and when CBD should develop further guidance on selected topics. Most of the discussions were around how to identify and prioritise topics that may need further guidance (and whether that was necessary).There were strong differences in views between the Parties. Some noted that the lengthy process to develop the most recent guidance on risk assessment of LMOs had been cumbersome and drawn out, yielding a long and complex document that was not endorsed at COP13. Others argued that some issues need new guidance and such guidance should be provided if a Party has identified the topic as important.

Many Parties pushed back against the notion that CBD should immediately proceed to develop new guidance on gene drive organisms, emphasising that there was no consensus that there were gaps in this area, or what these might be. They stressed instead the need to first assess whether there are clearly identified gaps.

In addition, several Parties pointed out that for new guidance to be useful, it would need to be specific to a well-defined issue, a challenge given how wide and complex the current proposed topics for new guidance are. For example, on gene drive, given the very different possible applications of this approach, an assessment of potential risks may only offer broad generalisations, resulting in a long list of scenarios that are not related to specific applications of the technology. They also noted that work is underway in a number of other venues, in particular at national level, so duplication of efforts should be avoided.

What could Parties decide at COP14?

Depending on how the decisions by Parties at COP are framed, they could either create high uncertainty and impose overwhelming barriers to research, or offer a useful platform for knowledge sharing and to build capacity of Parties to guide research on and evaluation of gene drive technologies.

On both synthetic biology and on risk assessment, the texts call for several activities to take place in the coming years that would create an ongoing workstream related to gene drive. Each of the recommendations call for a new online forum, and each calls for a new expert group (AHTEG) to be formed, as well as for studies and reports to be prepared. The multiplication of activities creates risks of both duplication and divergence, and challenges experts to provide meaningful engagement.

Beyond decisions on the specific activities mandated, Parties will need to agree on how issues should be framed. Language in the decision text will impact the lens through which the issue is considered. For example, Parties will need to decide on whether potential positive impacts of gene drive are taken into account, and on how to apply or interpret the application of the precautionary principle to research.

Decisions at COP will set up a multi-year process of work relevant to gene drive. How this impacts existing and future research should be at the forefront of Parties' deliberations at COP.

What is SBSTTA?

The Subsidiary Body on Scientific, Technological and Technical Advice to the Convention on Synthetic Biology (SBSTTA 22) met in July 2018 in Montreal. SBSTTA is tasked with providing advice to the Conference of the Parties on issues relating to the implementation of the Convention on Biological Diversity (CBD). It can consider any of the topics being discussed under the CBD or its Protocols and is open to participation by all Parties as well as observers. During its

meetings, Parties draft recommendations that are then forwarded to the COP for consideration and which are the basis for negotiations at the COP.

Summary of the process to date

In 2016, at the 13th meeting of the Conference of the Parties to the CBD, gene drive was introduced as a new topic of discussion under synthetic biology. Synthetic biology itself had been discussed before, but gene drive was a new element brought to the attention of Parties just before the start of the COP. Discussions at COP 13 resulted in more work being mandated on synthetic biology, including gene drive, in order to enable Parties at COP14 to consider this topic further.

In 2017, an online forum on synthetic biology was convened by the CBD Secretariat. The online forum is an open online discussion forum where experts can register to participate in discussions. The report from the online forum was then shared with an expert group, called an 'AHTEG' or Ad Hoc Technical Expert Group, which met in December 2017. The AHTEG considered several topics related to synthetic biology and produced its own report, which was then open for peer review comments. The AHTEG report was then shared with Parties. Before SBSTTA 22, the CBD Secretariat prepared a draft set of recommendations on synthetic biology, drawing from the reports. The draft recommendations then formed the basis for the discussions at SBSTTA and they included several references specific to gene drive.

At SBSTTA, gene drive was also included under the agenda item on risk assessment and risk management, which was a novel addition to this area of negotiations.

Outcome documents

Synthetic biology: https://www.cbd.int/doc/recommendations/sbstta-22/sbstta-22-rec-03-en.pdf

Risk Assessment: https://www.cbd.int/doc/recommendations/sbstta-22/sbstta-22-rec-02-en.pdf