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Position Paper on Synthetic Biology

Synthetic biology offers unprecedented opportunities to develop biological systems for a multitude of applications, ranging from healthcare and agriculture to environmental remediation and renewable energy. Although much of the research in this field is still at an early stage, many tangible positive applications are already emerging from synthetic biology techniques. Gene drive technologies are one possible use of synthetic biology approaches being explored to contribute to addressing specific conservation and public health challenges that current methods are not able to solve.

In decision [CBD/COP/DEC/15/31](#), Parties to the Convention on Biological Diversity (CBD) established a multidisciplinary Ad Hoc Technical Expert Group (mAHTEG), tasked over a two year period with identifying and prioritizing synthetic biology trends and issues, as well as identifying gaps in capacity-building, technology transfer, and knowledge-sharing.

Next steps on synthetic biology under CBD:

- Capacity-building should be the priority focus of the next cycle of work, as it did not receive adequate time and attention in the work of the current mAHTEG.
- The analysis of the mAHTEG can be noted, but the methodological issues and inconsistencies that characterize the current outcomes should be recognized. An external peer-review of the methodology and outcomes should be sought to inform any subsequent horizon scanning.
- If the horizon scanning process is renewed, it should be at a four- or six-year interval to allow for sufficient new developments and the approach for such horizon scanning should be revised to ensure adequate expertise.
- Rational for additional assessments of technologies that are not new and emerging, and which are already subject to assessments at the national level, such as gene drive, should be provided before any decision is made to pursue such assessments.
- The work under synthetic biology should remain focused on identifying new trends and technologies, and not evolve into technological assessments which require expertise and time that is not available under the Convention, and which could be more effectively done by other organizations.

The horizon scanning process is intended to help raise awareness of advancements in synthetic biology, facilitating informed decision-making regarding developments in this rapidly evolving field. A methodical and evidence-based approach is vital to achieving this goal. The process should also avoid duplicating discussions on topics already tackled by CBD to help streamline resources.

Further work on synthetic biology should focus on capacity building to help countries carry out the assessments they deem necessary and to benefit from the research.

Many countries face significant challenges in capacity-building, technology transfer, and knowledge-sharing, contributing to further inequity in the synthetic biology field. The mAHTEG was mandated to explore ways to facilitate, promote and support these, but discussions have not advanced since COP-15.

Despite being priorities for many countries, the issues of capacity-building, technology transfer, and knowledge-sharing have received little attention in this cycle.

To ensure any future process of horizon scanning is robust and useful, it should follow a clear methodology and focus on novel developments that have not yet been examined or discussed by the previous AHTEGs and SBSTTAs.

A robust horizon scanning should be based on an established and vetted methodology, using available evidence and a documented process. The ranking and prioritization of the 17 issues and trends by the mAHTEG were inconsistent with the outcomes of the literature review carried out by the CBD Secretariat. In addition, the current horizon scanning managed to review only 5 out of 17 issues and trends, with no clear explanation of the criteria for earmarking these 5 issues for detailed assessment.

Two of the top issues and trends identified – gene drive organisms and genetically modified insects – have already been discussed at length under CBD and other UN bodies and are governed by multiple international and national frameworks. Gene drives have been under discussion under the Convention for almost a decade. Decision [CBD/COP/DEC/14/19](#) already offers a cautious but supportive approach to developing these technologies. The additional voluntary guidance materials for risk assessments of LMOs containing engineered gene drives, currently under development by another AHTEG, also demonstrate that gene drives are not new on the CBD agenda.

The assessment of gene drive (and synthetic biology, at large) should be balanced, acknowledging both potential risks and benefits.

The assessment of any technology should offer concrete and clear information based on sound evidence, weighing both potential positive and negative impacts ([CBD/COP/DEC/14/19](#)). It is also vital to consider the ability of existing tools to address the identified challenges and the consequences of inaction. Only by following this path can a complete picture of the role a technology could play in supporting the objectives of the Convention be offered.

Every year, malaria kills over 608,000 people and infects over 249 million people. Most of them are children under the age of five. We are also facing an unprecedented environmental crisis, where more than 3,500 of the 37,000 alien species

introduced by human activity worldwide have become invasive and pose major threats to nature, the economy, food security and human health. Gene drive is one of the tools under development that could help to address the current health and environmental crisis.

The mAHTEG should acknowledge the limitations of current methods to address these challenges, acknowledging the importance of innovation and research. Gene drive approaches, along with many tools currently used to control vector-borne diseases and invasive species, may not address the root causes of these issues. However, this is not different from most tools currently in use (rodenticides, insecticides, bednets, etc) and should not imply that gene drive tools are intrinsically less valuable or should not be considered for development and possible use.

The assessment of potential social, cultural, and economic impacts is an important consideration in weighing the use of any synthetic biology tool, including gene drives. However, a new mAHTEG is not the most appropriate mechanism for conducting this assessment, given its limited resources and expertise and the fact that it would be detached from the specific socio-economic and cultural contexts in which different technologies may be proposed for use. There are established processes and methodologies for such assessments, which are often required by national authorities as part of the review of regulatory dossiers. In several countries, Social-Economic and Health Impact Assessments (known as either ESHIA or ESIA in different national jurisdictions) are already considered a requirement in the assessment of gene drive technologies ([learn more at "Environmental, Socio-economic, and Health Impact Assessment \(ESHIA\) for Gene Drive Organisms"](#)). At a

broader level, Strategic Impact Assessments (SIA) or Strategic Environment Assessments (SEA) are also well-established approaches that contributes to assessing possible social, cultural, economic, and health impacts.

Science takes time to evolve. Instead of having a horizon scanning process each biennium, international organizations should facilitate information exchange on synthetic biology's latest developments.

Research progress and scientific breakthroughs take time, not justifying an open-ended mandate for repeated horizon scanning every two years. During this interval, CBD and other international organizations working on synthetic biology should increase cooperation and information-sharing to facilitate Parties' access to relevant information in the field. Many organizations, such as OECD and the African Union, are working on synthetic biology and horizon scanning and could contribute to this dialogue.

If further horizon scanning work is agreed upon, it could occur every two to three bienniums and be carried out by an organization or body with specific experience and knowledge of horizon scanning methodologies. Under these circumstances, issues that have already been considered by the Convention and its protocols, such as gene drives, should not be subject to continuous assessment to optimize resource allocation and produce insightful outcomes.

