SYNTHETIC BIOLOGY AND RISK ASSESSMENT AT CBD COP16 ENSURING PRECAUTION, EQUITY AND BALANCE

The fair, equitable and precautionary governance of new developments in modern biotechnology, ('Synthetic Biology') has been at the heart of the mission and decisions of the Convention on Biological Diversity (CBD) for over three decades.

In the past two COPs, parties have committed to pursuing a careful governance for Synthetic Biology: **establishing a 'broad and regular' process for the horizon scanning, assessment and monitoring of new developments in Synthetic Biology supported by a Multidisciplinary Ad Hoc Technical Expert Group.** This carefully designed process is critical to identifying key priority topics for the CBD to address on a precautionary basis.

At COP 16, parties should reaffirm this process and agree on the next steps in the CBD's Synthetic Biology program:

1. **Ensure Multidisciplinary Knowledge in Assessment and Monitoring Synthetic Biology.** The multidisciplinary nature of the mAHTEG should be affirmed, extending its mandate and authorizing it to analyze these developments to guide careful, informed and thoughtful policy decisions.

2. **Exercise precaution: Horizon scanning, assessment and monitoring.** The currently bracketed annexed text directs the mAHETG to undertake a deeper assessment of three priority topics: Integration with Artificial Intelligence, Self-spreading vaccines and gene drives. (See Part B and Annex of draft decision CBD/SBSTTA/REC/26/4.)

3. **Ensure any proposed "Synthetic Biology Action Plan"is aligned with existing decisions** to support precaution, regulation, horizon scanning, assessment and monitoring of synthetic biology. This 'Action Plan" is currently biased towards industrial and technical development of the field of synthetic biology. (Part A, draft decision CBD/SBSTTA/REC/26/4)

4. **Ensure the proposed risk assessment guidance materials on engineered gene drives undergo an independent review.** There should also be guidance on 'LM fish and other potential LM aquatic organisms' and consideration of further guidance for LM self-limiting insect systems. (See Risk Assessment and Risk Management of Living Modified Organisms - CBD/SBSTTA/REC/26/5).

These essential decisions about Synthetic Biology and Risk Assessment and Risk Management of LMOs will ensure that governance and oversight of Synthetic Biology continues to be balanced, fair, equitable and precautionary in line with the aims of the convention.

1 ENSURING MULTIDISCIPLINARY KNOWLEDGE IN ASSESSMENT AND MONITORING SYNTHETIC BIOLOGY (CBD/SBSTTA/REC/26/4 - PART B)

KEY POINTS

- → "Welcome" the mAHTEG report.
- → Extend the tenure of the mAHTEG.

BACKGROUND

Decision 15/31 established a specifically "multidisciplinary" Ad Hoc Technical Expert Group (mAHTEG) that developed an expert-driven methodology, undertook initial assessments and identified key topics for deeper assessments in an intended second round. The mAHTEG conducted its work in 2023-2024, which included conducting assessments of new developments in synthetic biology advancements. It also included setting the priority issues that need to be tackled by the CBD. The outcomes of the work of the mAHTEG were forwarded to SBSTTA-26 in May 2024.

What is needed?

To honor the decisions already made and ensure good governance and precaution, Parties at COP16 should insist on lifting almost all of the brackets imposed on Part B. Parties need to:

- Welcome the outcomes of the process so far (Paragraph 10).
- Extend the tenure of the mAHTEG emphasizing the multidisciplinary expert nature of the process.
- Ensure that the process and AHTEG are multidisciplinary in nature, including providing for the full and effective participation of indigenous peoples and local communities, women and youth.
- Update the literature review to take into account ecological, socioeconomic, ethical and cultural considerations.

What is at stake?

Affirm the multidisciplinary nature of the mAHTEG, extending its mandate and authorizing it to analyze these developments is critical to guide careful, informed and thoughtful policy decisions.

2 EXERCISING PRECAUTION: HORIZON SCANNING, ASSESSMENT AND MONITORING (CBD/SBSTTA/REC/26/4 - PART B)

KEY POINTS

- → Affirm previous COP decisions on the need for broad and regular process of multidisciplinary horizon scanning, assessment and monitoring of new developments in Synthetic Biology.
- → Authorize deeper assessment on SynBio-AI Integration, Self-spreading vaccines and gene drives as key priorities.

BACKGROUND

Modern biotechnology has come a long way since the CBD was first negotiated in the early 1990's. Today's Artificial Intelligence models trained on digital sequence information (DSI) generate designs for highly novel organisms and proteins while engineered viruses and gene drives are designed to be self-spreading in the wild. Keeping abreast of the risks and implications of modern biotechnology requires robust arrangements for horizon scanning, technology assessment and monitoring.

The precautionary principle is now more important than ever. That is why parties established a "broad and regular" process of multidisciplinary horizon scanning, assessment and monitoring of new developments in Synthetic Biology. (Decisions 14/19 and 15/31).

What is needed?
Mandate the mAHTEG to continue with an in-depth assessment of the potential impacts of:
- Integration of artificial intelligence and machine learning into synthetic biology.
- Self-spreading vaccines for wildlife and health.
- Engineered gene drives to control vector-borne diseases and invasive species.

What is at stake?
The continued ability of CBD Parties and other governments to monitor, assess and regulate new biotech developments depends upon precautionary and robust horizon scanning, assessment and monitoring. Otherwise, parties are blindfolded amidst the rush of new technologies and applications. The use of proprietary artificial intelligence for synthetic biology further challenges the safety, equity and reliability of new or altered lifeforms due to 'black box' effects as well as undermining access and benefit-sharing arrangements.The environmental release of self-spreading genetically engineered viruses and gene drives could negatively violate the integrity of ecosystems in unpredictable ways.

3 ENSURING A PRECAUTIONARY "ACTION PLAN" ON SYNTHETIC BIOLOGY (CBD/SBSTTA/REC/26/4 - PART A)

KEY POINTS

- → Ensure the 'Action Plan on Synthetic Biology' includes Horizon scanning, assessment, monitoring, regulation, liability and redress.
- → Delete text proposals to reopen debates on the definition and whether synthetic biology is a new and emerging issue.

BACKGROUND

The topic of Synthetic Biology has been on the CBD agenda for over 15 years and at COP 15 parties decided "not to require further analysis on whether synthetic biology is a new and emerging issue." At least five previous decisions already mandate work on Synthetic Biology under the convention. (See decision 15/31 para 2). Now there is a text proposal for an "Action Plan on Synthetic Biology" - but one that would only support capacity building, technology transfer and knowledge sharing in Synthetic Biology. This partial construction risks being biased towards industry agendas. Surprisingly some Parties also added text requesting the mAHTEG to reopen issues that had already been settled by previous decisions - namely considering the operational definition of synthetic biology and once again assessing whether synthetic biology is a 'new and emerging issue' despite the prior agreement to put aside this question under decision 15/31.

What is needed?
The proposed thematic "Action Plan on Synthetic Biology" is currently unbalanced, since it only emphasizes capacity-building and development, access to and transfer of appropriate technology and knowledge-sharing in the context of enabling synthetic biology applications and omits other key aspects of synthetic biology governance. If left unbalanced in this way, such language comes close to mandating the CBD parties to support industrial development of Synthetic Biology as an industrial field. To be aligned with the aims and objectives of the Convention, an "Action Plan on Synthetic Biology" grounded in the precautionary approach needs to also address regulation, oversight, liability and redress, horizon scanning, assessment and monitoring. Language in Part A of the decision should therefore also include these elements.

Additionally, it would be a large backwards step to reopen settled topics such as the definition of Synthetic Biology or discuss whether this is a 'new and emerging issue.' Such text should be removed.

What is at stake?
For 15 years, Parties to the CBD have evolved a balanced and sensible approach to global governance of Synthetic Biology, grounded in an agreed operational working definition, a precautionary approach and a groundbreaking new process for Horizon Scanning, Assessment and Monitoring. It would be a cardinal error if such an 'action plan' only focused in an unbalanced way on just one or two aspect of Synthetic Biology governance and failed to also reflect the progress that had already been made over the six preceding cycles of negotiations and decisions to establish horizon scanning, assessment, monitoring and regulation. If balanced, an "Action Plan on Synthetic Biology" could help ensure this rapidly changing field is under proper oversight.

4 EVALUATING AND DEVELOPING NEW RISK ASSESSMENT GUIDANCE. (CBD/SBSTTA/REC/26/5)

KEY POINTS

- Note" (rather than "welcome") voluntary guidance on risk assessment of gene drives.
- Request independent evaluation and assessment of the voluntary guidance on risk assessment of gene drives.
- Authorize development of further risk assessment guidance on LMO aquatic organisms and self-spreading insects.

BACKGROUND

Since the last meeting of the Parties to the Cartagena Protocol an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management of Living Modified Organisms was convened. This AHTEG developed a draft voluntary risk assessment guidance for evaluating the biosafety of LMOs containing engineered gene drives (engineered to spread a genetic trait in the wild) with an additional focus on mosquito applications. Despite being a Conflict of Interest, key developers of the technology led drafting voluntary guidance proposals, resulting in sharp disagreements between experts. Civil society sent a letter of complaint to the CBD Secretariat, due to concerns regarding conflict of interest procedures not being enacted, and that the underlying methodological basis of risk assessment of LMOs was being shifted to a less precautionary approach, such as shifting the burden of proof from having to prove safety to now having to prove harm. Moreover, there are questions regarding its alignment with Annex III of the Cartagena Protocol. At SBSTTA 26, many Parties nonetheless supported text that would "welcome" the controversial voluntary risk assessment guidance on gene drives, rather than simply "take note".

At SBSTTA 26, Parties also proposed text to authorize an AHTEG to develop additional Risk Assessment guidance on living modified fish.

What is needed?
Given ongoing concerns that the voluntary guidance materials on gene drives is not sufficiently precautionary; moreover, that conflicts of interest challenge the integrity of the document - It would be appropriate to just "take note" of the outcomes of the AHTEG and to "acknowledge" the guidance materials rather than "welcome" them.

Importantly, there should be a wider independent review of the guidance materials.

The overall work on risk assessment is important to continue; Article 15 of the Cartagena Protocol is central. Thus, the AHTEG should develop additional voluntary guidance materials for living modified fish and also expand the remit to "other aquatic organisms." This additional guidance should not follow the general risk assessment pathway detailed in the current guidance on/for GDOs, but follow Annex III of the protocol and the 'proof of safety' approach as to be true to the precautionary approach.

Additionally, Parties should take up the recommendation from the Synthetic Biology mAHTEG to consider self-limiting insects as a potential topic for further guidance.

What is at stake?

Risk assessment of LMO's is a core part of the Cartagena Protocol on biosafety. The ongoing development of voluntary risk assessment guidance documents is essential to enact the precautionary principle. However, it is also important that the guidance be rigorous, free from bias and clearly founded on precaution and best practice and keep the burden of proof on demonstrating safety. The introduction of a different risk assessment methodology by actors close to biotechnology industrial development is worrying and must be subject to scrutiny. The CBD has agreed procedures on conflict of interest and needs to safeguard these procedures when conservation and protection of biodiversity are at stake.

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