PUTTING PRECAUTION INTO ACTION: CONTINUING CBD LEADERSHIP ON SYNTHETIC BIOLOGY GOVERNANCE

BACKGROUND

After a decade of groundbreaking leadership by the Parties to the Convention of Biodiversity (CBD) addressing Synthetic Biology, Decision 15/31 established a "broad and regular" process of multidisciplinary horizon scanning, assessment and monitoring of new developments in Synthetic Biology. The need for this process had been already identified by parties in Decision 14/19. This process provides a practical means for governments to collaboratively track and respond to biodiversity threats and opportunities emerging from modern biotechnology developments in a timely manner.

Following Conference of Parties 15 (COP15), the multidisciplinary Ad Hoc Technical Expert Group (mAHTEG) on Synthetic Biology was formed and followed its mandate to:

- Develop the methodology for this broad and regular process.
- "Road test" the process by undertaking and reporting on a first round of multidisciplinary horizon scanning, assessment and monitoring.
- Identify key areas of developments requiring policy attention.

In early 2024, the mAHTEG issued a set of recommendations to the SBSTTA, outlining a methodology for the broad and regular process. They also articulated proposals for further policy work on priority areas that had been identified as a result.

KEY POINTS

Drawing on the work of the mAHTEG, the Parties at SBSTTA 26 should:

1. **Agree the methodology of the broad and regular process**, as outlined and road-tested by the mAHTEG, and **confirm that the process should occur at least each biennium** (ie; between every COP).

2. **Re-emphasize the importance of multidisciplinarity and precaution** to the functioning of the broad and regular process.

3. **Initiate timely policy formulation processes on priority topics identified by the mAHTEG**, including 1. The Integration of Artificial Intelligence (AI) with synthetic biology and 2. Self-spreading vaccines for wildlife.

4. **Request that assessment guidelines on gene drives also incorporate socioeconomic, cultural, and ethical impacts.**

5. **Address other topics raised by the mAHTEG:** including issues of North-South equity, self-limiting insects, technology facilitation, and capacity-building for horizon scanning, assessment and monitoring activities.

6. **Ensure no release of high risk and unassessed synthetic biology organisms, components, or products takes place.**

The following briefing provides further background details on these aspects.

1 AGREEING THE METHODOLOGY FOR THE BROAD AND REGULAR PROCESS FOR MULTIDISCIPLINARY HORIZON-SCANNING, ASSESSMENT AND MONITORING

In Decision 14/19 (paragraph 3) Parties to the CBD agreed "that broad and regular horizon scanning, monitoring and assessing of the most recent technological developments is needed for reviewing new information regarding the potential positive and potential negative impacts of synthetic biology vis-à-vis the three objectives of the Convention and those of the Cartagena Protocol and Nagoya Protocol". Building on this, paragraph 4 of Decision 15/31 was adopted which formally "establishes a process for broad and regular horizon-scanning, monitoring and assessment of the most recent technological developments in synthetic biology". Paragraph 5 of that decision further "establishes a multidisciplinary ad hoc technical expert group [mAHTEG] on synthetic biology to support the process for broad and regular horizon scanning, monitoring and assessment."

In the past two years, the mAHTEG undertook extensive work to design and test a working methodology for the broad and regular process. This was reported as Annex IV of CBD/SBSTTA/26/4. A review of this methodology was also undertaken by the mAHTEG, as was a peer review. The proposed methodology involves an expert-driven process with multiple steps of information gathering, synthesis, screening, selection, filtration, and analysis. The mAHTEG identified 5 priority topics for assessment: self-spreading vaccines for wildlife, self-limiting insect systems, development of engineered gene drives to control vector-borne diseases and invasive species, integration of artificial Intelligence and machine learning, and inequity in the participation of developing countries in the context of synthetic biology.

It is important to emphasize that at SBSTTA 26 Parties are not being asked to agree on whether the broad and regular process is going ahead. That is already firmly agreed in decision 15/31. SBSTTA is simply being asked to endorse the methodology that was developed by the mAHTEG including the frequency (regularity) of the process.

To address this, Parties may endorse the recommendation of the mAHTEG (from **ANNEX V** of their report) by deciding:
"That the methodology used for the first cycle take into account the review of the process for broad and regular horizon scanning, monitoring and assessment of the most recent developments in synthetic biology conducted by the multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology to Support the Process for Broad and Regular Horizon Scanning, Monitoring and Assessment[1] and serve as a basis for such a process to be conducted in each biennium, while keeping the methodology under review at future meetings of the Group;"

In agreeing the methodology, Parties should emphasize that the broad and regular process should occur every biennium.

Two consecutive COP decisions have now emphasized that the process of horizon scanning, assessment and monitoring should be "regular" (that is "recurring at uniform intervals"). In fact, this conforms with practice since the CBD has already maintained an Ad Hoc Technical Expert Group on Synthetic Biology continuously for a decade, meeting in every intersessional biennium since COP 12. With the establishment of the broad and regular process, it is to be expected that the process maintains at least the same regularity of the past decade.

In its recommendations to the SBSTTA, the mAHTEG specifies that the process be "conducted in each biennium". While the Parties to the CBD always have the option to change arrangements at some future point, it would not be a good use of either COP

or SBSTTA's limited time to continually debate re-authorisation every two years, given that it has already decided that this is to be a "regular" process.

2 RE-EMPHASIZE MULTIDISCIPLINARITY AND PRECAUTION

• The importance of Multidisciplinarity and broad participation.
The need for multidisciplinarity to meet the "broad" nature of the process was already recognized in the terms of reference for the mAHTEG (Decision 15/31) which specified the need for "expertise from a broad range of scientific disciplines, as well as interdisciplinary and intercultural expertise, indigenous peoples and local communities." In the final report of the mAHTEG to SBSTTA 26, the expert group further emphasized the importance of this multidisciplinarity:

"For reasons of equity and precaution, decision-making on synthetic biology applications, including release into the environment, should, wherever possible, be informed by the assessment of potential impacts, including socioeconomic, cultural and ethical impacts, and a multidisciplinary, participatory process for allowing inputs from all affected stakeholders, indigenous peoples and local communities, women, youth and rights holders is important in view of the cross-cutting nature of synthetic biology;"

The mAHTEG reflected that **"The multidisciplinary nature of the Ad Hoc Technical Expert Group has substantially contributed to the overall process for the horizon scanning, monitoring** and assessment by allowing for valuable insights into the potential impacts of synthetic biology on the objectives of the Convention."

These conclusions are in line with previous decisions on synthetic biology that emphasize the participation of Indigenous Peoples and Local Communities (IPLCs) among other forms of interdisciplinary knowledge. At the same time, proper implementation of the procedure for avoiding and managing conflicts of interests in expert groups, adopted in Decision 14/33, is a necessary safeguard for the process to remain robust.

• The process should be Precautionary
The mAHTEG reported that as "[t]he increasing complexity in the range of tools, the fields of applications and the potential for cumulative, synergistic and scaling effects may all result in unpredictability and uncertainty regarding the potential impacts of synthetic biology applications, the application of the precautionary approach is important;" (Annex 1, paragraph 2b).

This emphasis on precaution is consistent with many existing decisions that "urge Parties and invite other Governments to take a precautionary approach in accordance with the preamble of the Convention and with Article 14, when addressing threats of significant reduction or loss of biological diversity posed by organisms, components and products resulting from synthetic biology." See for example paragraph 4 of X/13, paragraph 4 of Decision XI/11/, paragraph 3 of Decision XII/24, paragraph 1 of Decision XIII/17, paragraph 11 of Decision XIV/19 and the preamble of Decision XV/21.

3 INITIATE POLICY FORMULATION PROCESSES ON 1. INTEGRATION OF ARTIFICIAL INTELLIGENCE (AI) WITH SYNTHETIC BIOLOGY AND 2. SELF-SPREADING VACCINES FOR WILDLIFE

As well as providing (and reviewing) a methodology, the mAHTEG also undertook a first run of a **Multidisciplinary Horizon Scanning, Assessment and Monitoring Process (MHSAMP)**. On this basis they issued advice to the SBSTTA for next steps on the following priority topics for more in-depth assessment and policy formulation:

A. Addressing the Integration of Artificial Intelligence (AI) with Synthetic Biology.
The mAHTEG reported that "rapid advances in artificial intelligence (AI) and machine learning have led to a significant increase in their use for the development of organisms, components, and products of synthetic biology".

In particular, big data companies with no previous biosafety experience (eg; Microsoft, NVIDIA, Google, and Salesforce) are now active in the bio-design and re-engineering of new proteins, viruses, and microbes. Additionally, the use of AI and machine learning in digital agriculture is incorporating bioengineered organisms.

Relying upon AI agents and models (including large language models) to alter genomes for commercial use raises a host of serious safety, ethical, intellectual property, and governance questions. Many of the concerns arising from the use of AI to generate images, video, and text may also be applicable in the case of AI-generated life forms or proteins. AI models generated for synthetic biology depend upon extensive use of **digital sequence information (DSI) databases, with special challenges in ensuring benefit sharing**. The combination of AI and synthetic biology is a cross-cutting issue for the DSI negotiations in the CBD and thus, must be addressed to protect the multilateral mechanism and other arrangements addressing DSI benefit sharing from being outdated from its very start.

The mAHTEG advised that "the accelerated development of artificial intelligence and machine learning in the field of synthetic biology may have significant adverse impacts on the objectives, principles and provisions of the Convention and that those potential impacts need further evaluation".

They propose:
- The CBD initiate a policy formulation process.
- "A request to the mAHTEG to undertake a further assessment leading to a report addressing, inter alia, potential impacts on biosafety, the sustainable use of biodiversity, equitable access and benefit-sharing, social, economic and cultural aspects, impacts on traditional knowledge and practices, and other relevant matters."
- The Secretariat develop a technical series publication addressing artificial intelligence and participate in UN system level activities on AI.
- Parties "Consider the development of effective and equitable governance arrangements for artificial intelligence data sets, foundation models, algorithmic biodesign tools, automated science tools and the use of synthetic biology organisms, components and products in cyber physical systems."

B. Engineered self-spreading vaccines for wildlife
Another priority area of concern identified for precautionary action by the mAHTEG is the development of self-spreading engineered viral and bacterial vaccines intended for use in wildlife populations. In these applications, engineered viruses are released to deliberately spread in wild populations intended to prompt an immune response in infected hosts. The mAHTEG noted that "Despite technical feasibility, ethical, ecological and regulatory concerns surround the self-spreading vaccine approach, as releasing genetically engineered organisms with contagious self-spreading capabilities into the environment introduces substantial challenges in risk assessment, monitoring long-term effects and mitigating harm."

The mAHTEG calls for Parties to the CBD to:
- "Conduct an appropriate assessment of the ecological, socioeconomic, cultural, and other impacts of self-spreading vaccines and any potential adverse effects on biological diversity, taking also into account risks to human health."
- "Develop mechanisms to ensure the free, prior and informed consent of all potentially

affected communities, including indigenous peoples and local communities."
- "Examine whether there is an appropriate evidence base on which to justify potential field tests or commercial use has been conducted."

4 COMPLETE THE SOCIO-ECONOMIC ASPECT OF GENE DRIVE ASSESSMENT GUIDELINES

The Convention and its Cartagena Protocol on Biosafety have been addressing the topic of engineered gene drives in several decisions, most notably paragraphs 9 to 11 of Decision 14/19.

As enshrined in the Cartagena Protocol on Biosafety and aligned with previous decisions on organisms containing engineered gene drives, in order to support the the right of Parties to also take into account socio-economic considerations in decision-making on an assessment of living modified organisms, the mAHTEG proposed that current draft guidance materials for risk assessment of Gene Drives (CBD/SBSSTA/26/5/Add.1) should be accompanied by additional advice, to incorporate a wider assessment of the socioeconomic, cultural, and ethical impacts of engineered gene drives, in particular on Indigenous Peoples and Local Communities. Such a process could potentially be undertaken in conjunction with a renewed mandate of the AHTEG on socio-economic considerations under the Cartagena Protocol, and/or through other appropriate processes under the Convention.

5 ADDRESS OTHER PRIORITIES: CAPACITY BUILDING AND KNOWLEDGE SHARING

Additionally the mAHTEG was requested to identify capacity-building, technology transfer, and knowledge-sharing needs on issues related to synthetic biology and in the light of the outcomes of the horizon scanning process. Two particular proposals from the mAHTEG were:

A. Overcoming North/South Inequities and ensuring full and effective participation for Horizon-Scanning, Monitoring and Assessment

The mAHTEG identified inequitable participation of developing countries in the context of synthetic biology as a priority topic and emphasized that the multidisciplinary, broad and regular process itself was an important means to build capacity and share information. A table of options on improving capacity-building, technology transfer, and knowledge-sharing called for support to Indigenous Peoples and Local Communities, Women, Youth and holders of other knowledge systems as essential for enabling multidisciplinary horizon scanning, monitoring and assessment of synthetic biology.

The mAHTEG also pointed to the importance of "ensuring that cultural, social, ethical issues related to synthetic biology are considered in the light of the reality and needs of Indigenous Peoples and Local Communities, their oral ways and a lack of information and knowledge through the use of culturally appropriate tools, including indigenous languages."

B. Establishing an Observatory on new Developments in Synthetic Biology

The mAHTEG recommended that the Parties "Explore options for supporting and establishing appropriate procedures, as well as providing appropriate financial or technical resources, to contribute to the effective monitoring of trends and issues in synthetic biology that need to be considered under any future broad and regular horizon scanning, monitoring and assessment in relation to the three objectives of the Convention".

One specific proposal advanced to improve the broad and regular process was that "consideration should be given to the development of a mechanism, such as an observatory on synthetic biology, for monitoring or facilitating the issues included in the prioritized list or the provisional selection list." Such an observatory function could be held by the Secretariat of the CBD over Synthetic biology (eg; similar to or integrated with the functioning of the Biosafety Clearing House).

6 ENSURE NO RELEASE OF HIGH RISK SYNTHETIC BIOLOGY ORGANISMS, COMPONENTS OR PRODUCTS TAKES PLACE

The assessment of the mAHTEG has exposed significant risks, uncertainties, and knowledge gaps surrounding the use of synthetic biology technologies. The self-spreading vaccines, organisms, components, and products derived from the integration of artificial intelligence with synthetic biology, and engineered gene drives assessed by mAHTEG present unique ecological and societal challenges, including potential unintended consequences such as species extinction, ecosystem disruption, and transboundary impacts. Moreover, uncertainties remain regarding the cumulative effects of these technologies, their long-term persistence in the environment, and potential adverse effects on human health. Given these unresolved concerns, Parties are urged to adopt a precautionary approach and refrain from releasing high-risk synthetic biology organisms, components, or products unless the following gaps are addressed:

1. Establishment of an appropriate evidence base on which to justify potential field test or commercial use.
2. Implementing clear and fully funded risk assessment and monitoring process, in accordance with Decision 14/19 and XII/24.
3. Ensuring Free, Prior, and Informed Consent (FPIC) from all potentially affected Indigenous Peoples and Local Communities, aligned with the UN Declaration on the Rights of Indigenous Peoples (UNDRIP), and active, free, effective, meaningful, and informed participation from potentially affected farmers and individuals in rural areas, in accordance with the UN Declaration on the Rights of Peasants and Other People Working in Rural Areas (UNDROP).
4. Fulfillment of Recommendation 23 of Annex V of the mAHTEG report, which emphasizes the need for socioeconomic, cultural, and ethical impact assessments of gene drives.
5. Addressing liability and redress issues, particularly in cases involving transboundary movements and applications of synthetic biology beyond national jurisdictions of developers or funders.
6. Making decisions for release in alignment with the principle of intergenerational equity.
7. Developing clear, reliable and fully operational methods to effectively contain, reverse or recall the release of gene drive applications and assessing them (including socio-economic and cultural assessment).

THIRD WORLD NETWORK
Dr. Eva Sirinathsinghji, evasinghji@gmail.com
+44 (0)7801 547 859

FRIENDS OF THE EARTH US
Jim Thomas, jim@scanthehorizon.org

ETC GROUP
ECOROPA
ECONEXUS
AFRICAN CENTRE FOR BIODIVERSITY
POLLINIS
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ASIAN CENTRE FOR BIODIVERSITY