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Briefing Note for UN Biodiversity Conference 2024 – Synthetic Biology (COP 16, October 2024)

Horizon scanning, monitoring and assessment: Fundamental in ensuring equity and precaution in synthetic biology development

SUMMARY OF KEY RECOMMENDATIONS

Incorporate the principles and elements of horizon scanning, monitoring and assessment, within the proposals for capacity building and development, access to and transfer of technology and knowledge sharing:

* Ensure that capacity building and development efforts equip developing countries with the capacity to horizon-scan, monitor and assess synthetic biology technologies, so that they do not inequitably bear the brunt of any risks.
* Ensure that technologies that are accessed and transferred are locally appropriate and environmentally-sound, through robust technology assessment, to prevent unfair 'technology dumping' on developing countries.
* Prepare the proposed thematic action plan to support capacity building and development, access to transfer of technology and knowledge sharing in the context of horizon scanning, monitoring and assessment of synthetic biology.
* Implement the proposed action plan in accordance with relevant articles of the Convention: Article 7, Article 14, Article16 and Article19, paragraph 4.
* Stipulate modalities to operationalize the outcomes of the horizon scanning, monitoring and assessment process within the proposed action plan.

Continue broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology in a precautionary and multidisciplinary manner:

* Extend the broad and regular horizon scanning, monitoring and assessment process.
* Welcome the outcomes of the multidisciplinary AHTEG on Synthetic Biology.
* Re-establish the multidisciplinary AHTEG to continue to support the process of horizon-scanning, monitoring and assessment.
* Task the multidisciplinary AHTEG to conduct in-depth assessment of living modified organisms containing engineered gene drives, 'self-spreading vaccines', as well as the integration of artificial intelligence and machine learning with synthetic biology.
* 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.

Introduction

Novel technological applications, such as living modified organisms (LMOs) developed through the use of new genetic engineering and synthetic biology technologies, pose challenges for risk assessment and biosafety regulations. There is a diversification of such technologies, (e.g., from novel genome editing techniques across to integration of artificial intelligence (AI) with genetic engineering), increased depth of interventions (e.g., self-spreading or expansion into wild ecosystems), and applications intended for new sectors (e.g., from public health to conservation). These developments will have broad implications that would span ecological, health, socio-economic, cultural and ethical dimensions.

Crucial for decision-makers are also the risks related to the potential failure of synthetic biology products and applications. Huge promises are being made, with significant hype, including in interrelated fields such as AI, which is now increasingly integrated with synthetic biology. However, numerous flagship ventures have faced stumbling blocks and consequent financial woes in the face of bottlenecks in product development and downturns in investor interest, falling "fast and hard" to bankruptcy[1].

This significant hype requires careful scrutiny to discern fact from fiction. Detailed analyses are required to enable decision-makers to choose between the appropriate actions required to address issues: whether experimental synthetic biology technologies, or other safer and proven approaches. Lessons can be learnt from the parallel situation with LMO crop technologies that have largely failed to move beyond the two dominant traits of herbicide resistance and insecticide tolerance. Their long-term viability is increasingly challenged by declining utility in the face of efficacy and suitability challenges.

The deployment of potentially risky, irreversible, ineffective or unsuitable technologies warrants a precautionary approach. There is an urgent need for broad horizon scanning and in-depth, multidisciplinary assessments of their potential impacts on biodiversity, human health and well-being.

CBD discussions to date

In 2018, Parties to the Convention on Biological Diversity (CBD) agreed in Decision 14/19 that broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology is needed. Such a process was established by Decision 15/31 in 2022. A multidisciplinary Ad Hoc Technical Expert Group (AHTEG) was also established by the same decision, to support the process.

The multidisciplinary AHTEG carried out its work in 2023-2024, which included conducting assessments of new synthetic biology advancements. The assessments produced several outcomes, including on the prioritised topics of LMOs containing

[1] Synthetic biology, once hailed as a moneymaker, meets tough times. *Science Insider,* 22nd August 2024 https://www.science.org/content/article/synthetic-biology-once-hailed-moneymaker-meets-tough-times

engineered gene drives (EGD-LMOs), 'self-spreading vaccines' which are live LMO viruses designed for spread in wild populations, self-limiting LMO insect systems, the integration of artificial intelligence and machine learning with synthetic biology, and the inequity in the participation of developing countries in the context of synthetic biology.

The recommendations of the multidisciplinary AHTEG were forwarded to the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), which met in May 2024. Difficult and unresolved discussions there resulted in a heavily bracketed text.[2] The SBSTTA recommendation will be taken up at the Sixteenth Conference of the Parties (COP16), under the agenda item on synthetic biology.

The draft decision for COP16 comprises two operational sections: (A) capacity-building and development, access to and transfer of technology and knowledge-sharing in the context of synthetic biology, and (B) broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology.

Currently, however, the balance between Section A and Section B is skewed. Most of Section B is in square brackets with the biosafety functions of horizon scanning, monitoring and assessment at risk of being deleted or watered down. Regrettably, there are some Parties, largely the few that have adopted and/or those that develop and export LMOs, that do not want to continue the horizon scanning, monitoring and assessment process.

These Parties instead attempted to refocus the discussion towards the benefits of synthetic biology technologies. They strongly promoted the issue of capacity-building and development, access to and transfer of technology and knowledge-sharing.

While these issues are key for developing countries, given the barriers they face in this regard, the delicate balance in the text between the two parts has shifted. Restoring balance to the text would require reestablishing equity and precaution, through the horizon scanning, monitoring and assessment process.

Capacity for horizon scanning, monitoring and assessment and appropriate technology transfer are key to ensuring equity

Critical to the efforts for capacity building and development is the need to also ensure that developing countries have the capacity to horizon-scan, monitor and assess novel and potentially risky synthetic biology technologies. Developing countries largely lack the capacities to do so, yet may bear the overwhelming brunt of any risks, a situation which is highly inequitable.

The capacity to assess any synthetic biology technology is necessary to prevent the potential 'dumping' of risky, unsuitable or ineffective technologies on developing

[2] Discussions on multidisciplinary assessments of synthetic biology falter, Third World Network, 31 May 2024, https://www.twn.my/title2/biotk/2024/btk240515.htm

countries. Technology dumping has a long history, including within the fields of biotechnology applications, with direct implications for the CBD's objectives.

Neither should industry interests and profit motives drive a technology transfer agenda without adequate oversight. Developing countries need to be able to horizon-scan, monitor and assess risks, so that they are not left bearing the burden of risk management, clean up, liability and costs associated with any damages or technology failures incurred.

In the first place, any technologies that are accessed and transferred should not negatively impact the environment or peoples, and must be locally appropriate and cost-effective. This means that synthetic biology applications should undergo robust technology assessment prior to any deployment.

As such, the draft decision needs to **incorporate the principles and elements of horizon scanning, monitoring and assessment** (currently limited to Section B), **within Section A** dealing with capacity building and development, access to and transfer of technology and knowledge sharing. This will better link Sections A and B, and rationalizes the language in Section A that stipulates that capacity-building and development, technology transfer and knowledge-sharing is also relevant for the assessment and regulation of synthetic biology.

The proposed **thematic action plan** to support capacity building and development, access to transfer of technology and knowledge sharing should therefore be specifically prepared **in the context of horizon scanning, monitoring and assessment of synthetic biology**. Current language in paragraphs 5 and 7 of the draft decision referring to the action plan "in the context of synthetic biology" is too broad and general.

The proposed action plan should also be **implemented in accordance with relevant articles** of the Convention, which could be recalled in the chapeau of paragraph 7 of the draft decision:

- **Article 7** (identification and monitoring), functions which include horizon scanning and monitoring,
- **Article 14** (impact assessment and minimizing adverse impacts),
- **Article16** (access to and transfer of technologies, as essential elements for the attainment of the CBD's objectives, and that do not cause significant damage to the environment), and
- **Article19, paragraph 4** (information on use and safety regulations, and on potential adverse impacts of LMOs resulting from biotechnology).

The proposed thematic action plan should further include an additional paragraph stipulating **modalities to operationalize the outcomes of the horizon scanning, monitoring and assessment process** contained in Section B. This will again better link Sections A and B of the decision, and allow Parties to take forward appropriate precautionary and multidisciplinary action in a holistic action plan.

Precaution warrants continuation of horizon scanning, monitoring and assessment process, and in-depth assessments

The precautionary approach is an underlying principle of the CBD, and should be the basis of discussions on synthetic biology. In this regard, the **extension of the broad and regular horizon scanning, monitoring and assessment process**, would help operationalize precaution. Parties would be able to stay abreast of novel technologies that are on the horizon, allowing for effective oversight to assess the risk, suitability and efficacy of the organisms, products and components developed through the use of synthetic biology, and act to prevent adverse effects even in the absence of full scientific certainty.

The precautionary approach is also a key element of a human-rights based approach, as determined, for example, by the Inter-American Court of Human Rights[3]. The Court asserted that States must act to protect the "rights to life and to personal integrity" in cases where there are plausible indications of severe and irreversible damage to the environment, even in the absence of scientific certainty. This is in keeping with the precautionary approach. Relevant to the CBD, Section C of the Kunming-Montreal Global Biodiversity Framework (KMGBF) states: "*Implementation of the Framework should follow a human-rights based approach, respecting, protecting, promoting and fulfilling human rights. The Framework acknowledges the human right to a clean, healthy, and sustainable environment*."

Without thorough horizon-scanning, monitoring and assessment processes, there is a risk that developing countries, particularly those who are recipients of synthetic biology technologies, would be subject to a technology transfer agenda that pushes for innovations to be accepted without access to information regarding risk, efficacy and suitability of technological applications. Precaution is thus also a key element to an equitable approach that protects against technology dumping.

The **re-establishment of the multidisciplinary AHTEG** is essential to continue the process of horizon-scanning, monitoring and assessment. Moreover, the outcomes and recommendations from the previous multidisciplinary AHTEG need to be carried forward into **in-depth assessments**, ensuring that its recommendations are not ignored.

Outcomes of the multidisciplinary AHTEG should thus be **welcomed** to ensure that they are taken on by Parties. The issues identified for in-depth assessment are: **living modified organisms containing engineered gene drives**, **'self-spreading vaccines'**, as well as **the integration of artificial intelligence and machine learning with synthetic biology**. These elements are reflected in paragraph 3(c) of the terms of reference contained in the Annex to the draft decision and should be retained.

[3] Inter-American Court of Human Rights. Advisory Opinion OC-23/17, The Environment and Human Rights, 15 November 2017, https://www.corteidh.or.cr/docs/opiniones/seriea_23_ing.pdf

Multidisciplinary assessments can help operationalize precaution and equity

Multidisciplinarity is required to produce holistic assessments that can complement, and not duplicate, the LMO risk assessment processes under the Cartagena Protocol on Biosafety. Such assessments allow for socioeconomic, ethical and cultural issues to be duly considered alongside scientific information. It can also include interrelated issues such as fair and equitable benefit sharing arising from the use of digital sequence information on genetic resources.

A broader, scientific assessment can also go beyond biosafety risks assessed on a case-by-case basis, taking into account, for example, long-term and/or cumulative risks, potential efficacy limitations, the veracity of claims of benefits and suitability of technologies. For example, after three decades of LMO crop commercialisation, there is an accumulation of evidence linking these to a range of impacts, including adverse socioeconomic impacts on farmers' livelihoods, repeated technology failures, increased pesticide use and associated health impacts, and potential biodiversity loss. Technology failures experienced in India and Burkina Faso by smallholder farmers cultivating LMO 'Bt' insecticidal crops have been largely documented by social scientists, civil society and farmers' organisations, which may fall outside the narrow sphere of scientific peer-reviewed journals. Failures in India have prompted calls for holistic assessments that can protect smallholder farming communities from damage.

It is thus important that information and expertise are broadened in order to adequately assess risks. This requires interdisciplinary and intercultural expertise, including from **indigenous peoples and local communities, women and youth**. Their **full and effective participation** is needed in the multidisciplinary AHTEG and discussions on synthetic biology.

Updating the literature review to take into account **ecological, socioeconomic, ethical and cultural considerations** can also assist in this regard, drawing also on reports from civil society. However, a literature review cannot be considered as an alternative to an assessment process, but instead a tool that can facilitate the process.

The determination of the suitability and safety of technologies within national contexts further requires a broad range of expertise that is locally relevant. Otherwise, nations may rely largely on external information, including from private industry, where profits may take precedence over national development goals. Marketing and lobbying prowess is no substitute for sovereign checks and balances needed to ensure that resources are not wasted and/or harm is not inflicted.

Multidisciplinarity can thus assist in operationalising a precautionary and equitable approach to synthetic biology, providing holistic assessments for decision-makers. References to multidisciplinarity in the draft decision therefore need to be retained.