Third World Network Briefing Note (July 2026)

Assessment and regulatory capacity: A prerequisite for evidence-based and precautionary decision-making, sovereignty and equity in synthetic biology

Summary of key recommendations

The following elements, drawing also from the report of the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology, are key for the draft decision:

* Focus the thematic action plan on the **assessment**, **governance and regulation of synthetic biology, especially for developing countries**:

- The thematic action plan should be responsive to broader cross-cutting issues, including **biosecurity and biosafety concerns, the need for robust regulatory frameworks, liability and redress for damage, equity considerations, environmental and social safeguards, the importance of strengthening public sector research for public good, technology transfer of environmentally sound and appropriate technologies,** and **data sovereignty.**

- **Research collaborations and capacity-building efforts should be independent and free of conflicts of interest**, so that such efforts are not driven by profit incentives.

* Re-emphasise the need for a process that is flexible and forward looking with respect to future developments, with **anticipatory horizon-scanning and monitoring mechanisms for timely identification and assessment** of potential positive and potential negative impacts**.** Parties should be able to benefit from such mechanisms to identify appropriate and realistic applications and emerging developments, while applying a **precautionary approach.**

* **Implement evidentiary standards for claims of benefits** and their relevance to their potential contributions to the Kunming-Montreal Global Biodiversity Framework (KMGBF) and the three objectives of the Convention. This is because the **current and potential benefits of synthetic biology have yet to be verified or proven.**

*** Assess the potential positive and potential negative impacts** of the identified topics of artificial intelligence and computation biology; bioremediation and waste reduction applications; artificial cells, synthetic genomes and artificial biochemical pathways; applications for conservation use, and microbiome engineering.

*** Ensure that assessment is on a multidisciplinary and inclusive basis to contribute to participatory decision-making**, in accordance with the precautionary approach and national priorities and circumstances, and in consultation with indigenous peoples and local communities, women and youth, with their free, prior and informed consent.

* **Extend the procedure for avoiding or managing conflicts of interests in expert groups,** adopted in decisions 14/33 and 16/26, to consultants.

1. Background

CBD Parties in decision 16/21 decided to devlop a thematic action plan to support capacity-building, technology transfer and knowledge sharing in the context of synthetic biology, building on the needs and priorities of Parties, especially for developing country Parties, for the implementation of the three objectives of the CBD and the KMGBF.

The decision further established an AHTEG to, among other things, identify current and potential benefits of synthetic biology, and the potential positive and negative impacts of most recent technological developments; and provide advice on ways to take into account capacity-building and development, access to and transfer of technology and knowledge-sharing in synthetic biology with respect to the draft thematic action plan.

2. Thematic action plan: Assessment and regulatory capacity key to precaution and equity

The thematic action plan needs to be appropriately balanced if it is to support Parties in the implementation of the three objectives of the CBD and the KMGBF. This means that the thematic action plan must **incorporate precautionary safeguards, including ensuring that capacity is built for independent and sovereign assessment, governance and regulation of synthetic biology.** It should not be tilted towards promoting technology research or an enabling environment for deployment of unproven and potentially risky applications lacking a robust evidence-base.

Critical to the efforts is **the need to ensure that developing countries have the capacity to horizon-scan, monitor and assess** novel and potentially risky synthetic biology technologies, **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. Developing countries largely lack the capacities to do so, yet may bear the overwhelming brunt of any risks, a situation which is highly inequitable. Safeguards are also needed to protect from the practice of 'technology dumping', corporate capture, extractive practices and biopiracy, and the undermining of scientific and data sovereignty.

Moreover, **equitable participation in research and development in the field should not automatically equate to an enabling environment for the deployment of synthetic biology applications**, given the vast majority of applications relevant to the Convention have yet to be commercialised or widely deployed, remaining unproven. This issue is exemplified by many Parties with high levels of capacity for R&D, that nonetheless take a precautionary approach to applying it, particularly with regard to environmental release, given the potential risks and uncertainties**.**

While access to and transfer of technology are crucial means of implementation for developing countries, 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.

It is thus vital to ensure the process of capacity building remains independent, with processes to avoid or manage conflicts of interests, or to prevent an industry-driven agenda from taking hold. **External actors cannot be left to determine technology development trajectories, which may not be aligned with national needs and priorities.**

3. **Anticipatory horizon-scanning and monitoring, and multidisciplinary assessment**

The precautionary approach is an underlying principle of the CBD, and should be the basis of discussions on synthetic biology. In this regard**, anticipatory and timely horizon-scanning and monitoring** can assist Parties in staying abreast of novel developments within the field. This can allow for **effective oversight to assess safety, suitability and efficacy of novel technologies**, including biosafety, socio-economic, cultural and ethical dimensions.

Assessment processes are further critical, in order to provide sufficient quality of evidence for determining which technologies may provide benefits or cause harm to biodiversity. This means that there must be **holistic, evidence-based determination** of the relevance of synthetic biology to the KMGBF, both in terms of contributions as well as challenges to the achievement of its targets (see Annex for a summary of the potential negative impacts of recent developments in synthetic biology that present challenges to the KMGBF).

Without in-depth multidisciplinary assessment processes, there is a risk that countries, particularly developing countries who are recipients of synthetic biology technologies, would be subject to technology transfer agendas 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.

An **inclusive, multidisciplinary assessment** process would broaden information and expertise 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 necessary for robustly assessing the potential positive and negative impacts of synthetic biology.

4. **Evidentiary standards for claimed current or potential benefits and potential positive impacts**

Assessing the veracity of claimed benefits is also foundational to sovereign scientific development, and thus necessary to address inequities between countries. Currently, commercial interests have led to significant hype within the field, including for entirely theoretical or speculative technologies. Promotion of unproven technologies risks undermining locally-developed innovations, instead promoting applications originating from countries that are already highly active in this regard. Hype also drives up the opportunity costs associated with diverting finite resources away from local, already proven or less risky alternatives.

The AHTEG report (CBD/SYNBIO/AHTEG/2026/1/3) clearly shows that **demonstrable current benefits of synthetic biology to biodiversity are lacking**, illustrating the speculative nature of synthetic biology. Further, the list of current benefits was disputed by some members of the AHTEG and highlights the need for a more robust and precautionary assessment process.

Relying on developer information alone, such as press releases, media articles or early-stage research is not sufficient for evidence of benefits. Not least given that of the seven purported current benefits on the list, some do not appear to exist yet (e.g. synthetic biology cultured meats made directly from animal cells); are not in production (e.g. semi-artificial artemisinin); are almost completely lacking in

commercialisation or preceding trial performance evidence (e.g. LM genome edited trees); or whose evidence-base entirely derives from extremely limited and short-term developer publications (e.g. microbes engineered to produce ethanol from industrial emissions).

A stark illustration of the lack of current benefits is the continuation of herbicide-tolerance as a lead trait being commercialised for new LMOs developed via synthetic biology techniques such as genome editing. After decades of unmet promises regarding the future of new and useful LM crop plant traits, the vast majority of such crops are still dominated by this single trait, which is continuing with the development of herbicide-tolerant edited LMOs, including for staple crops such as rice.

Further deficiencies were noted by the AHTEG in relation to the potential benefits of synthetic biology, including that: (i) links to the targets of the Framework may require further verification and consideration; and (ii) that links to indicators in the monitoring framework for the KMGBF have yet to be established.

Assessing the validity of claimed current and potential benefits is thus foundational to an evidence-based approach required for assessing the relevance of applications in contributing towards the KMGBF and the three objectives of the Convention, and to assessing socio-economic considerations. It would further serve as a quality control mechanism, critical to preserving the integrity and legitimacy of the process overall.

5. Extending the conflicts of interest procedure to consultants

Ensuring independence within all aspects of synthetic biology discussions and work under the Convention is key to the ability to make evidence-based decisions in order to ensure credibility in the process and outcomes. Maintaining independence from profit-driven agendas can help to ensure that sovereign development within the field is not undermined.

The commissioning of the scientific study to support the work of the AHTEG exemplifies the importance of independence in maintaining evidentiary standards, scientific rigour, and unbiased information. Unfortunately, the objectivity of the entities selected to conduct the study was questioned, as their aims are to promote the business and profit interests of the companies they represent. Such conflicts-of-interest concerns, raised by civil society, had implications for the quality of the study. These limitations are documented in the AHTEG report.

Extending the conflicts of interest procedure adopted under the Convention to consultants would provide a necessary quality control mechanism. This can help ensure that studies are independent and provide credible, evidence-based and balanced information for taking decisions**.**

Annex: Potential Challenges of Select Recent Developments in Synthetic Biology to the Targets of the Global Biodiversity Framework

Recent developments in synthetic biology pose potential negative impacts that could present challenges to the achievement of the targets of the Kunming-Montreal Global Biodiversity Framework. The table below lists select recent developments and some examples of their potential negative impacts, and the GBF targets they challenge. All the information has been directly extracted from: **https://www.cbd.int/documents/CBD/SYNBIO/AHTEG/2026/1/2**

Synthetic biology recent developments	***GBF targets challenged by potential negative impacts***	***Select identified examples of relevant potential negative impacts**** * The full list of potential negative impacts for each recent development is available at https://www.cbd.int/documents/CBD/SYNBIO/AHTEG/2026/1/2
Applications for conservation use	**4, 6, 7**	• Unintended spread across ecosystems • Replacement of wild populations (for engineered wild organisms introduced into the environment when the introduced traits confer fitness advantages or there is competition in the same ecological niche) • Erosion of genetic diversity due to unintended gene flow or transboundary movements • Unintended adverse effects of modification process (e.g. chronic health problems) • Altered host-pathogen dynamics due to viral mutation (for transmissible vaccines) • Spillover due to mutations or recombination events (for transmissible vaccines) • Opportunity costs (e.g. diversion of funds away from conventional conservation projects) • Genetic restoration of endangered species could lead to unintended changes to endangered populations and compromise alternative restoration approaches • Inability to grant free, prior and informed consent or opt-out, and cause liability and redress issue
Artificial intelligence and computational biology	**1, 4, 6, 8, 10, 13, 14, 15, 17, 19, 21**	• Obscured equitable benefits-sharing from the utilization from genetic resources (e.g. bio-piracy, sovereignty over genetic resources, cultural heritage) • Access to traditional knowledge without free, prior and informed consent • Unavailability of information regarding design process (referred to as a 'black box'; e.g. decisions taken by algorithms may be unavailable, sources of information unclear) • Hallucinations and/or lack of human oversight may lead to unexpected side effects • Lower barrier for misuse of technology for the design of harmful organisms or products (e.g. intentional alteration to increase virulence, genetic elements or pathways designed to evade detection) • Energy and water consumption needs of data centres could place pressure on fragile ecosystems, deserts and agricultural regions • Increased mineral extraction for computational infrastructure could have negative impacts on biodiversity and human rights, such as access to water • Inability to predict harm of novel or new-to-nature sequences (e.g. organisms and components whose biological, ecological and biosafety properties are not well understood)
Engineered gene drives and biocontrol applications	**4, 6, 9, 11, 17, 22**	• Engineered wild organisms may have increased invasiveness or express harmful substances in natural habitats • Loss of genetic diversity due to population reduction • Disruption of ecosystem functions that support culturally important or valued species • Unintentional disruption or destabilization of food webs by removing a key prey species or a competitor that naturally regulates other invasive organisms (e.g. predator-prey dynamics) • Niche replacement by another invasive species due to population suppression • Failure to address systemic causes of vector-borne diseases • Dual-use (e.g. targeting beneficial insects during armed conflicts)
Genome-edited plants	**7, 10, 13**	• Increased use of chemical herbicides and pesticides (may have negative impacts on biodiversity and human health or promote the development of herbicide-tolerance) • Yield depression in modified crops

		• Lack of control for adverse effects, unintended changes or modification of non-target organisms if genetic engineering or genome editing are applied in the field • Increased weediness through hybridization between engineered crops and compatible plant species in the environment • Concentration of intellectual property rights in a limited number of companies (may subsequently reduce food security, compromise food sovereignty and have negative socioeconomic impacts)
Microbiome engineering	**6, 7, 8, 11, 13, 17**	• Potential to become invasive, rapid replication, capacity to evolve • Unintentional transboundary movements and large scale spread through diverse dispersal routes (e.g. air/aerosols, water, leaf litter, pollen, seeds, insects or soil-associated animals or fungi) • Altered ecosystem functions and services and microbial population dynamics due to shifts in microbial communities (e.g. pollination or soil health), unintended interactions with native microbiota or disrupted host–microbiome relationships • Altered pathogen dynamics as bees are vectors for numerous viruses and pathogens and disease transmission is not well understood, leading to reduced pollination and cascading impacts on ecosystems and their functions (for engineered bee microbiomes) • Lack of risk management measures (i.e. lack of control for adverse effects, unintended changes or modification of non-target organisms if genetic engineering or genome editing are applied in the field) • Lack of benefits sharing due to concentration of development in startup economies and high-profile laboratories
General considerations (potential negative impacts that may be broadly applicable to many applications)	**1, 2, 3, 4, 6, 7, 8, 9, 10, 11, 13, 14, 17, 20, 21, 22**	• Reduced genetic diversity through cross breeding with modified organisms • Loss or alteration of wild populations due to intended or unintentional releases • Altered ecosystem functions and population dynamics (e.g. pollination or soil health) • Adverse impacts on populations due to horizontal gene transfer from modified organisms to wild relatives (e.g. reduced fitness, increased invasiveness, ecological disruption, negative long-term resilience of ecosystems, persistence of traits) • Change of engineered traits due to mutation and natural selection (e.g. leading to resistance, such as herbicide-tolerance) • Unintended harm when tools or applications are used at scale (e.g. in the environment, targeting multiple species at once) • Generation of cumulative ecological effects affecting species interactions, ecosystem structure and biodiversity patterns from large-scale releases • Unintended exposure of humans and animals from environmental use or large-scale deployment of synthetic biology applications and the potential for adverse health outcomes • Environmental monitoring, governance systems and regulatory oversight are challenged in keeping pace with rapid technological by the speed of development • Reduced benefits-sharing if mechanisms for fair and equitable sharing are not clearly defined or effectively implemented due to reliance on digital sequence information for design of synthetic biology applications • Unequal distribution of benefits and costs (e.g. benefits accrued to those with the funds [to] utilize the technologies, concentration of patenting and restricted access to technologies, costs disproportionately borne by small-scale farmers, beneficial and adverse effects occurring simultaneously to different populations, negative impacts on livelihoods and agricultural systems) • Further reliance on unsustainable practices instead of addressing root causes or investing in alternatives (e.g. climate change, deforestation, use of agrochemicals, fossil fuel use, mining, monocultural agricultural systems) • Diversion of resources away from potentially effective alternative measures (i.e. opportunity costs) • Technological dependence (e.g. use of patented agricultural applications over agroecological ones, need for multiple agrochemical applications) • Socioeconomic considerations (e.g. losses for farmers in cases of failure of technology or if application has not been locally adapted, biocultural heritage of valued crops)