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The Importance of Technology Assessment in Synthetic Biology Governance

Barbara Ntambirweki, ETC Group & The African Technology Assessment Platform (AfriTAP)

Synthetic biology is advancing faster than most government systems can manage. Regulatory frameworks, scientific review processes and international governance mechanisms were largely designed for slower-moving technologies and many are struggling to keep pace with a field defined by rapid iteration and cross border research networks. After two decades of research investment, synthetic biology actual contribution to biodiversity conservation remains largely unproven in practice. Promised applications restoring degraded ecosystems, engineering disease resistance, replacing biodiversity-derived products with synthesized alternatives are still mostly theoretical or in early trials. For example gene drives or engineered organisms released into open environments can have irreversible ecological effects; once released, these present biosafety, socio-economic, ethical, and cultural risks. In addition, the conclusions of the AHTEG report clearly show that current benefits of synthetic biology to biodiversity are lacking, illustrating the speculative nature of synthetic biology. 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.

Given this combination of unproven benefit and unresolved risk, a robust, ongoing process of technology assessment is essential rather than optional. Technology assessment is a range of practices used by people across the world to evaluate new and emerging technologies through a deliberate, systematic process. To be effective, technology assessment must be partici-

patory: it has to involve people who might be affected, or who have expertise through their life experience people in all their diversity, including indigenous peoples, farmers, and fisher folk, who are often part of popular and social movements. The aim of technology assessment is to look forward, anticipate and prevent damage before new technologies are introduced.

Technology assessment allows Parties to track the pace of development of synthetic biology techniques are advancing faster than regulatory and scientific capacity to evaluate them, so horizon scanning and periodic review help governance keep pace. It also allows Parties to apply the precautionary approach in a structured way: in the absence of conclusive evidence on ecological, health, and socio-economic outcomes, technology assessment weighs potential benefits against potential harms before large-scale deployment, rather than allowing de facto adoption to outpace evaluation. And it allows Parties to address risks that are not purely biosafety-related: synthetic biology intersects with access and benefit-sharing, intellectual property, food security, traditional knowledge, and the rights of Indigenous Peoples and local communities, requiring dedicated, ongoing scrutiny of its socio-economic, cultural, and ethical dimensions.

The governance of synthetic biology requires continuous, rigorous assessment before and as it develops. Where technology assessment is rigorous, governance can be proactive. Where it is weakened, governance risks becoming reactive managing harms that earlier scrutiny could have anticipated and prevented.

Engineering Nature: A Paradigm Shift for Conservation?

Joann Sy, Pollinis

As Parties began discussions on synthetic biology under SBSTTA agenda item 5, the opening statements serve as a timely reminder that debates about synthetic biology reflect a deeper discussion about the future direction of biodiversity conservation, and are not limited to technical risk assessment or governance.

At its heart, the debate reflects a broader shift in the conservation framework. Traditionally, conservation has focused on restoring and maintaining the ecological and evolutionary processes that enable nature to recover, adapt, and sustain biodiversity. This has involved protecting species and ecosystems, restoring degraded habitats and addressing the drivers of biodiversity loss through measures such as habitat protection, sustainable resource management, and ecosystem restoration. Synthetic biology introduces a different paradigm: rather than protecting and supporting the natural processes through which ecosystems and evolution shape biodiversity, it proposes actively redesigning living organisms, populations and ecological interactions to achieve very specific outcomes. While proponents' instrumental assessment lead to the assumption that synthetic biology is a neutral tool to address challenges such as invasive species, wildlife diseases, and declining populations; a comprehensive assessment unveils the paradigm shift that changes our relationship with the world and the questions about ecological uncertainty, reversibility, ethics, governance, Indigenous Peoples' rights, local communities and equitable benefit-sharing.

As SBSTTA continues its consideration of synthetic biology, the challenge is not only how to assess individual technologies, but also how to ensure that conservation policy remains guided by the precautionary approach enshrined in the CBD and reflected in the Cartagena Protocol on Biosafety. In this regard, the conversation is ultimately about more than technology. It is about determining the role that increasingly powerful biotechnologies should, or should not, play in shaping the future of nature conservation.

Synthetic Biology and Biodiversity Conservation: A Case for Precaution

Dana Perls, Friends of the Earth USA

Under the Convention on Biological Diversity (CBD), synthetic biology is increasingly promoted as a potential tool for biodiversity conservation. Proposed applications include species restoration, genetic rescue, invasive species control, and climate adaptation. High-profile initiatives, such as efforts to engineer grey wolves with traits associated with the extinct dire wolf, have contributed to narratives that synthetic biology could help address biodiversity loss. Other examples include genetically engineered American chestnut trees designed to resist chestnut blight, climate-adapted corals intended to withstand ocean warming, and gene drives proposed to suppress invasive Province of Como, Lombardy, Italy species populations.

However, most of these applications remain at an early stage of development and have not been demonstrated as effective conservation tools in natural ecosystems. Many have been tested only in laboratories, contained environments, modelling exercises or limited field trials. There is little evidence regarding their long-term ecological performance, safety, reversibility or ability to achieve intended conservation outcomes at scale. As a result, significant uncertainties remain about how engineered organisms may interact with complex and dynamic ecosystems over time.

These uncertainties raise important questions regarding ecological interactions, containment, transboundary movement, evolutionary responses, and the potential for unintended or cascading effects. For example, gene

drives designed to alter or suppress invasive species could affect food webs or ecosystem functions in unforeseen ways, while engineered trees, corals, or proxy organisms modelled on extinct species may behave differently from expectations once released into the environment.

Concerns extend beyond ecological risks. Synthetic biology also raises socio-economic, cultural, ethical and governance issues, including questions of participation, equity, liability, benefit-sharing, and the rights and knowledge of Indigenous Peoples and Local Communities. Assessments must therefore consider not only environmental impacts but also broader societal implications.

Consistent with the precautionary approach embedded in the CBD and the Cartagena Protocol on Biosafety, decisions regarding synthetic biology should be guided by comprehensive, participatory, and case-by-case assessment. Given the limited evidence base and remaining uncertainties, precaution is essential to ensure that emerging technologies do not create new and potentially irreversible challenges for biodiversity and the communities that depend upon it.