IUCN

Synthetic biology in relation to nature conservation

Briefing document

IUCN is pleased to acknowledge the support of its Framework Partners who provide core funding: Ministry of Foreign Affairs, Denmark; Ministry for Foreign Affairs, Finland; Government of France and the French Development Agency (AFD); Ministry of Environment, Republic of Korea; Ministry of the Environment, Climate and Sustainable Development, Grand Duchy of Luxembourg; the Norwegian Agency for Development Cooperation (Norad); the Swedish International Development Cooperation Agency (Sida); the Swiss Agency for Development and Cooperation (SDC) and the United States Department of State.

To date, generous contributions towards funding the development of the IUCN policy on synthetic biology and nature conservation have been provided by the Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection of the Government of Germany, and the Gordon and Betty Moore Foundation. More generally, the IUCN Council has endorsed a request for financial support in implementing the Resolution, sent by the IUCN Director General to IUCN Government Members and philanthropic foundations. This solicitation remains open to ensure sufficient resource mobilisation, with the anticipation that a draft IUCN Policy on Synthetic Biology and Nature Conservation is ready for consideration by the IUCN Membership at the 2025 IUCN World Conservation Congress. Importantly, IUCN is not approaching private sector and campaigning organisations for financial support, to reduce any risk of perceived conflict of interest.

Published by: IUCN, Gland, Switzerland

Recommended citation: *IUCN (2024). Synthetic Biology in Relation to Nature Conservation: Briefing Document.* Gland, Switzerland: IUCN

DOI: https://doi.org/10.2305/UGAT2818

Layout by: Lera Balashova

Table of contents

Summary

- In 2021, IUCN adopted Resolution 123, mandating the development of a synthetic biology policy, complemented by inclusive guidance.
- The biodiversity crisis, driven by human activities, affects genetic diversity, species extinction and ecosystems, impacting human well-being.
- Synthetic biology, although lacking a universal definition, presents potential positive and negative impacts on nature conservation.
- Synthetic biology applications extend beyond nature conservation, impacting agriculture, public health and industry, with potential positive, negative and neutral consequences.
- Case-by-case risk assessment is crucial in the regulation of synthetic biology applications, considering the diversity of potential impacts. It requires a balanced approach, incorporating not only biosafety considerations but also socioeconomic impacts in evaluating potential risks.
- Governance challenges arise due to the absence of a comprehensive international regulatory framework, leading to a polarised debate within international organisations.
- Access and Benefit-Sharing principles, rooted in the Convention on Biological Diversity, are crucial for regulating synthetic biology, particularly concerning Digital Sequence Information.
- Inclusive decision-making in synthetic biology governance must consider social, economic and cultural factors, with the Free, Prior, and Informed Consent of affected communities playing a central role.

Established 75 years ago, IUCN is a global Union, convening a Membership of national and sub-national governments, together with civil society and Indigenous Peoples' organisations for nature conservation. IUCN has significant roles in establishing conservation policies, developing and advancing targeted management actions and addressing underlying drivers to conserve nature around the world.

In 2021, IUCN Members adopted IUCN Resolution 123[1], mandating the development of an IUCN policy on synthetic biology in relation to nature conservation. This briefing document has been prepared to support the policy development process and to complement the Guidance on the inclusive and participatory process supporting "Towards development of an IUCN policy on synthetic biology in relation to nature conservation"[2]. In this context, the document is also informed by the Citizens' Assembly[3] recommendations regarding the stockpiling of resources and filling of knowledge gaps, the definition of synthetic biology, the policy scope to encompass both intended and unintended impacts on people and nature, the characteristics of methodologies for assessing risks and benefits; the recognition of the aspirations and rights of Indigenous Peoples and local communities, awareness-raising such that IUCN is recognised as a trusted expert at all levels, and advocating the application of Access and Benefit-Sharing. The briefing document is therefore structured so that Part A provides an overview of key issues concerning nature conservation and synthetic biology, and recalls progress on addressing these topics to date within IUCN, in order to assist IUCN constituents in providing feedback pursuant to the inclusive and participatory process. Subsequently, Part B elaborates on these issues relevant to synthetic biology in relation to nature conservation and is intended to provide IUCN stakeholders with additional context and a common understanding to inform their feedback in the IUCN policy development process.

1 https://portals.iucn.org/library/sites/library/files/resrecfiles/WCC_2020_RES_123_EN.pdf
2 https://www.iucncongress2020.org/motion/075
3 https://engage.iucn.org/topic/recommendations-iucn-citizens-assembly-synthetic-biology-relation-nature-conservation

Part A

Overview of synthetic biology in relation to nature conservation

The biodiversity crisis

1 The world faces a biodiversity crisis driven by human activities. This encompasses widespread reductions and disruptions across all levels of ecological organisation. It includes declines and disruptions in genetic diversity, a severe exacerbation of the risk of species extinction (with >40,000 species assessed as threatened out of >150,000 assessed to date), and detrimental impacts on the extent and integrity of natural ecosystems. In addition to this erosion of the intrinsic value of life on Earth, these losses have pervasive negative impacts on human well-being. The urgency for nature conservation is compounded by interrelated global challenges relevant to the environment and sustainable development, including climate change, health, poverty, and justice.

2 The primary drivers of the biodiversity crisis are agriculture, unsustainable harvesting and invasive alien species. Global, regional, and national conservation measures promoting biodiversity conservation have resulted in some notable successes, but biodiversity continues to decline globally. Conservation responses such as protecting important sites and incentivising sustainable use are successful in mitigating many such threats. However, other drivers – for instance, many invasive species and diseases – have no effective responses; and much biodiversity will be irreversibly lost unless such responses are developed.

The promise and perils of technology

3 Advances in science and technology give rise to an ever-increasing range of new tools that have the potential to contribute towards nature conservation, including amelioration of threats for which effective responses are currently lacking. Synthetic biology is potentially one such new tool, or perhaps better considered as a new toolbox, amongst a range of emerging interventions better able to address those threats. However, recognising that synthetic biology is developing rapidly and largely independently of the field of biodiversity conservation, it is notable that it has the potential to be beneficial and to pose risks to biodiversity and people.

4 Synthetic biology encompasses a field of rapidly evolving and cross-cutting disciplines. It does not have a universally agreed definition or scope, which creates challenges for discussions about its potential implications and governance, including in relation to nature conservation. The Convention on Biological Diversity uses a working definition as "a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems". Non-scientists and scientists alike find it difficult to readily distinguish synthetic biology from other disciplines, such as genetic engineering or modern biotechnology.

5 Like all technologies, synthetic biology can have direct positive, negative and neutral impacts when applied for nature conservation purposes. It can also have indirect positive and negative impacts on nature conservation when applied in other sectors such as agriculture. Such direct and indirect impacts have implications not only for biodiversity loss and nature conservation but also for local communities and their livelihoods, including their ability to share in economic and other benefits from nature. While aiming for reliable and predictable results in cost-benefit analyses, the challenge arises from the complexity of the various factors involved. The intricate impacts of synthetic biology on biodiversity, local communities and economic benefits contribute to difficulties in consistently predicting the outcomes of these analyses.

Governance, regulation of synthetic biology and inclusive policy development

6 No international, regional or national legal framework comprehensively regulates synthetic biology applications. Such applications are governed by scientific norms and practices interacting with a patchwork of statutory, religious, customary, indigenous and other governance systems.

7 Some harmonised international norms and treaty frameworks are relevant to the governance of synthetic biology, particularly concerning environmental risk assessment and management. Potential governance elements could also address liability for harm, access and benefit-sharing including equitable access to technologies arising from the utilisation of genetic resources, intellectual property and ownership, the precautionary principle, and Free, Prior, and Informed Consent by Indigenous Peoples and local communities. These different elements create the potential for diverging priorities and trade-offs in issues of governance.

8 Whether synthetic biology has a place in nature conservation, either to guide potential direct conservation applications or to ensure a voice for nature in applications beyond conservation, ignites passionate debate and divergent views. This polarity is evident in the discussions surrounding Resolution 123[4] and its predecessor Resolution 086[5] within the IUCN constituency. To navigate these diverse perspectives, inclusive discussions across the entire spectrum of the IUCN constituency in all its diversity are therefore essential for reconciling these varied perspectives for finding common ground.

4 https://portals.iucn.org/library/node/49795
5 https://portals.iucn.org/library/node/46503

Part B

Elaboration of synthetic biology in relation to nature conservation

Synthetic biology in the context of the biodiversity crisis

The biosphere, the foundation for human and all life on Earth, is undergoing massive alteration, with biodiversity declining at an unprecedented rate. The IUCN Red List of Threatened Species™[6] documents that approximately 25% of species in assessed animal and plant groups face extinction. The Golden Toad (*Incilius periglenes*) from Costa Rica, for example, became extinct in 1989 due to the fungal disease chytridiomycosis. Without immediate action, the global rate of species extinction, already approaching a thousand times higher than the background rate normal over Earth's history, will escalate. At least 10% of genetic diversity has been lost to date: a classic example is the Black-footed Ferret (*Mustela nigripes*) from the USA which suffered a severe loss of genetic diversity as a result of a population bottleneck in the 1980s caused by disease outbreaks. Moreover, some entire ecosystems have already collapsed, such as the Aral Sea ecosystem in Kazakhstan and Uzbekistan which dried up between 1985 and 2006 due to water extraction for irrigation in cotton agriculture.

Key direct drivers of change with substantial global impact include alterations in land and sea use together with the conversion of natural habitats for agriculture, urbanisation, transport and industry, as well as unsustainable exploitation of organisms, invasive alien species, climate change, and pollution[7]. These direct drivers result from indirect drivers such as production and consumption patterns, human population dynamics, trade, technology and governance, influenced in turn by social values and behaviours.

These losses and disruptions have severe negative impacts on people. As one specific example, in the 1990s, the Oriental White-backed Vulture (*Gyps bengalensis*) population suffered a 90% population crash across Asia due to poisoning by the veterinary drug Diclofenac. This in turn has allowed an increasing abundance of scavenging feral dogs and resulting outbreaks of rabies, as well as impacting the cultural heritage of the Farsi people. Putting such examples together, the Intergovernmental Platform on Biodiversity and Ecosystem Services[8] found pervasive declines for 14 of 18 categories of Nature's contributions to people.

The biodiversity crisis therefore demands urgent attention. The gravity of biodiversity loss has elevated the issue to the global policy agenda, for example with the inclusion of Sustainable Development Goals for Life in Water (#14) and Life on Land (#15) within the United Nations 2030 Agenda for Sustainable Development[9]. More recently, these commitments have been refined through the adoption of the Kunming-Montreal Global Biodiversity Framework in 2022[10]. Establishing four outcome goals for 2050 supported by 23 action targets for 2030, this framework aims to achieve a comprehensive vision for biodiversity conservation.

Meanwhile, conservation action has been mobilised around the world by government agencies, civil society and other sectors. These efforts have yielded substantial positive impacts in abating many threats, exemplified by notable successes like the reintroduction into protected areas in Tunisia and Chad of the Scimitar-horned Oryx (*Oryx dammah*), declared Extinct in the Wild since 2000. Without these conservation actions, the rates of mammal and bird extinction rates over the last three decades would have been three or four times higher.

Looking ahead, modelling scenarios for the coming century also provides some optimism. While business-as-usual scenarios project continuing declines, they reveal that improvements in the status of biodiversity are possible

6 https://www.iucnredlist.org
7 https://doi.org/10.5281/zenodo.3831673
8 www.ipbes.net
9 https://sdgs.un.org/2030agenda
10 https://www.cbd.int/gbf

under most scenarios which advance conservation and tackle drivers. However, no effective conservation responses are yet available for addressing some drivers of loss, as in the case of the endemic birds of Hawai'i, USA, for which the prevalence of avian malaria has been increasing over recent decades as the invasive mosquito vector has spread upslope, facilitated by climate change.

The promise and perils of synthetic biology applications across nature conservation and other sectors

Synthetic biology represents a paradigm shift in modern biotechnology, described as a further development and new dimension of modern biotechnology that combines science, technology, and engineering to facilitate and accelerate the understanding, design, redesign, manufacture, and/or modification of genetic materials, living organisms, and biological systems[11]. This interdisciplinary field holds promise for addressing global challenges related to food security, healthcare and environmental sustainability. At the same time, it raises concerns about potential impacts, including on biodiversity and people.

The rapid development of synthetic biology relies on a repertoire of supporting technologies, some of which are borrowed from traditional genetic engineering. Recent technological advances have significantly broadened the scope of synthetic biology applications, leading to advances in plant and animal engineering. For example, the use of the gene editing technology CRISPR-Cas demonstrates potential benefits, such as increased crop yield, improved quality, enhanced disease resistance and stress tolerance. In addition, technologies such as engineered gene drives are offering ways to spread desirable traits across populations. These transformative tools and areas of research represent a spectrum of applications that, in the context of nature conservation, can be categorised according to their potential direct or indirect impacts on biodiversity[12].

Against a backdrop of a range of emerging interventions under development, certain applications of synthetic biology hold promise for nature conservation purposes directly, with potential applications in addressing drivers for which conservation responses are currently lacking. Examples could include control of many alien invasive species and diseases, and building resilience in response to global changes like climate change and ocean acidification. The risks of such applications could include effects on non-target species, on non-target populations of the same species and unanticipated impacts on the ecological community. These need to be considered relative to the risks of not intervening, for example failing to halt species extinctions.

However, the majority of synthetic biology applications are designed for other sectors, with a global market estimated to reach US$ 63.8 billion by 2030[13] and with potential indirect impacts on nature in turn[14]. Notably, synthetic biology interventions in agriculture, already a key sector driving biodiversity loss, could have further negative impacts through, for example, allowing crops to grow in areas currently unsuitable for cultivation. They could also have positive impacts, for instance in allowing sustainable agricultural intensification to meet demands for human consumption with a smaller footprint of land. In public health, investments in disease vector control through synthetic biology could impact biodiversity. Similarly, in industry, synthetic biology is being used to modify production methods or to switch from petroleum-based to bio-based inputs. This transition is particularly relevant for environmental sustainability, reducing reliance on finite resources and lessening the ecological footprint associated with traditional production processes.

Given the diversity of potential impacts, generalisations across all applications of synthetic biology are impossible. Each application demands case-by-case consideration. The lack of consensus on which technologies and applications fall within the scope of synthetic biology adds complexity to the definition and application of regulatory approaches. Moreover, the cross-cutting nature of synthetic biology

11 https://www.cbd.int/doc/publications/cbd-ts-100-en.pdf
12 http://doi.org/10.1016/j.isci.2022.105423
13 https://www.verifiedmarketresearch.com/product/global-synthetic-biology-market-size-and-forecast/
14 https://doi.org/10.2305/IUCN.CH.2019.05.en

involves a wide range of stakeholders in governance[15], making it difficult to reach consensus on the boundaries of the field.

The current governance landscape relies on international treaties, laws, processes and initiatives, considering factors such as products, processes, purposes and transboundary impacts. However, this regulatory framework is fragmented, with the risk of regulatory gaps and overlaps. While increased oversight could strengthen governance, there is also a countervailing risk that creating an overly complex or stringent environment could stifle innovation in the sector.

The current governance arena emphasises science-based risk assessment as the cornerstone of regulation. However, it is recognised that this is only one element of a broader decision-making process due to the diversity of potential impacts and perspectives[16,17]. Integrating and coordinating the governance of synthetic biology, going beyond biosafety to encompass social impacts, ethical principles and social justice, emerges as an imperative.

The transformative potential of synthetic biology to contribute towards addressing global challenges – including biodiversity loss – underscores the need for sound research guidelines, robust governance methods, integration with the social sciences, and community engagement. Striking a balance between scientific innovation and responsible development while respecting legal, ethical and societal values is the key challenge as synthetic biology moves forward.

Relevance of Access and Benefit-Sharing, including Digital Sequence Information, for synthetic biology in relation to nature conservation

Access and Benefit-Sharing is a concept established under the Convention on Biological Diversity that aims to ensure the fair and equitable sharing of benefits arising from the utilisation of genetic resources (i.e. plants, animals, microorganisms and their DNA or genetic material) and which possess valuable traits or characteristics for research, development or commercial purposes[18]. The rationale behind Access and Benefit-Sharing is to ensure that the benefits resulting from the commercialisation of genetic resources are shared in a fair and equitable manner, particularly with the countries or communities that have conserved and managed these resources and possess traditional knowledge associated with their use[19]. It is important both from an ethical standpoint and in providing an incentive for continued conservation action. Benefits can take various forms, including monetary payments, technology transfer, capacity-building initiatives or the sharing of research results.

Different countries have different approaches to ensuring fair and equitable benefit-sharing associated with the utilisation of genetic resources. Moreover, there is an evolving discussion in international treaty frameworks governing as to how Access and Benefit-Sharing principles developed for traditional innovation in life sciences and biotechnology, should be applied to innovation approaches which are increasingly reliant on genetic information. Digital sequence data generated from the analysis of nucleotide or amino acid sequences often underpins the development of synthetic organisms as well as technologies and tools developed using synthetic biology. Accordingly, the development of regulatory frameworks for synthetic biology is closely linked to such Access and Benefit-Sharing discussions.

Establishing clear guidelines and agreements on Access and Benefit-Sharing in synthetic biology is therefore a complex task that requires the involvement of multiple stakeholders, including governments, scientists, industry and Indigenous Peoples and local communities. A recent decision by the Convention on Biological Diversity[20] to establish a multilateral mech-

15 https://www.cbd.int/doc/publications/cbd-ts-100-en.pdf
16 https://www.cbd.int/doc/publications/cbd-ts-100-en.pdf
17 https://doi.org/10.2305/IUCN.CH.2019.05.en
18 https://portals.iucn.org/library/node/10258
19 https://portals.iucn.org/library/node/10258
20 https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-09-en.pdf

anism for benefit-sharing from the use of digital sequence data is anticipated to include discussions regarding its application to synthetic biology given its inherent use of digital sequence data.

Inclusive decision-making regarding synthetic biology and nature conservation, including social, economic, cultural and other considerations

The current governance landscape relies on international treaties, laws, processes and initiatives, considering factors such as products, processes, purposes and transboundary impacts. However, this regulatory framework is fragmented with the risk of regulatory gaps and overlaps. While increased oversight could strengthen governance, there is also a countervailing risk that creating an overly complex or stringent environment could stifle innovation in the sector.

The current governance emphasises science-based risk assessment as a regulatory cornerstone, acknowledged as one element due to diverse potential impacts and perspectives[21,22]. The imperative is to integrate and coordinate synthetic biology governance, extending beyond biosafety to encompass social impacts, ethical principles and social justice.

The transformative potential of synthetic biology to contribute towards addressing global challenges – including biodiversity loss – underscores the need for sound research guidelines, robust governance methods, integration with the social sciences and community engagement. Balancing scientific innovation with responsible development while respecting legal, ethical and societal values is the key challenge.

Despite the absence of a cohesive or unified international regulatory framework for synthetic biology, the fragmented regulatory landscape for biosafety and the transboundary movement of genetically modified organisms under the Convention on Biological Diversity may provide learnings to inform the regulation and governance of synthetic biology. For example, the current governance approach for genetically modified organisms emphasises the ‘precautionary approach’, such that “where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimise such a threat” and science-based risk assessment, offering lessons for the regulation and governance of synthetic biology products.

However, many stakeholders consider that the regulation and governance of synthetic biology should involve a more comprehensive cost-benefit analysis which looks beyond biosafety and environmental risk assessment. Consideration of a broader range of issues focusing on inclusive decision-making and reconciliation of trade-offs may strengthen public acceptance, minimise indirect harms and allow the precautionary approach to take into account the consequences of inaction and opportunity cost.

A more robust regulatory approach might include a systematic evaluation of the social, economic, cultural and other impacts that may arise from the release of synthetic biology products. Such considerations may impact communities differently, for example, concerning livelihoods or belief systems. As inclusive decision-making can bring into tension benefits and costs which may not be homogenous across affected communities and which may not be readily capable of reconciliation, trade-offs and compromise are important in decision-making when assessing factors beyond environmental risk.

The Free, Prior, and Informed Consent of communities which stand to be affected by the public release of synthetic biology products is central to inclusive decision-making. The Akwé: Kon Voluntary Guidelines provide a collaborative framework for implementing Free, Prior, and Informed Consent in the assessment of the cultural, environmental and social impact of proposed developments on sacred sites and on lands and waters traditionally occupied by Indigenous Peoples and local communities. Free, Prior, and Informed Consent in the context of Indigenous Peoples and local communities is expected to be recognised in all discussions concerning inclusive decision-making and not be limited to those focussed on science-based risk assessment in the context of synthetic biology.

21 https://www.cbd.int/doc/publications/cbd-ts-100-en.pdf

22 https://doi.org/10.2305/IUCN.CH.2019.05.en