087 IUCN policy on synthetic biology in relation to nature conservation

RECOGNISING that 'synthetic biology', as defined by the Convention on Biological Diversity (CBD), is developing rapidly and may have significant positive and negative impacts on the integrity and diversity of nature, relevant for the conservation of biodiversity, sustainable use of its components, and equitable sharing of benefits;

RECALLING Resolution 7.123 *Towards development of an IUCN policy on synthetic biology in relation to nature conservation* (Marseille, 2020) and Resolution 6.086 *Development of IUCN policy on biodiversity conservation and synthetic biology* (Hawai'i, 2016), which mandate development of an IUCN policy on synthetic biology in relation to nature conservation;

ACKNOWLEDGING the IUCN Council Decisions C108/2 and C109/8 on the process and terms of reference for implementation of Resolution 7.123;

COMMENDING the inclusive and participatory process carried out to implement Resolution 7.123, including:

a. IUCN constituency-wide responses to the call for information;

b. establishment of the first IUCN Citizens' Assembly, yielding 80 Recommendations;

c. IUCN constituency receipt of multiple resources in support of effective participation, and invitation to two introductory webinars; and

d. two IUCN constituents-wide invitations to provide feedback into the inclusive and participatory process;

ALSO COMMENDING the drafting process carried out as mandated by Resolution 7.123, including:

a. IUCN constituency-wide nominations and comments on the provisional appointment of the IUCN Res 123 Policy Development Working Group;

b. IUCN constituency-wide peer review of the first and second drafts of the policy;

WELCOMING the invaluable work undertaken by the different IUCN constituents who engaged in the development of this policy; the CBD Secretariat for engaging as observers to the Policy Development Working Group; and the generous funding granted by the Government of Germany and the Gordon and Betty Moore Foundation; and

RECOGNISING the deliberations on synthetic biology under the CBD, particularly decision COP/16/L.21; and under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), the World Health Organization, among others;

The IUCN World Conservation Congress 2025, at its session in Abu Dhabi, United Arab Emirates:

1. ADOPTS the IUCN Policy on Synthetic Biology in Relation to Nature Conservation, attached herewith as Annex 1;

2. CALLS ON all IUCN constituents to follow this policy if engaging with synthetic biology in relation to nature conservation;

3. RECOMMENDS that IUCN Members, Council, Commissions and Director General share knowledge, guidance and contribute to build capacities to assist with the implementation of this policy, collaborating as appropriate with other organisations working in this field, including through participation in international policy discussions on the subject;

4. ENCOURAGES IUCN constituents to report on their implementation of this Resolution; and

5. INVITES the Parties to the CBD, CITES and to other relevant multilateral environmental agreements to take this IUCN policy into account when considering synthetic biology in relation to nature conservation.

Annex 1 IUCN policy on synthetic biology in relation to nature conservation

A. Problem definition

Life on Earth faces multiple challenges. Approximately, a quarter of Earth's species are facing a high risk of extinction in the wild in the coming decades, and there is ongoing loss and disruption of genetic diversity and ecosystems. This crisis is primarily driven by unsustainable human activities, including in the context of agriculture, harvest of wild species, built infrastructure, invasive alien species, diseases, pollution, and climate change. Nature conservation, in the context of this policy, is understood as the human activity dedicated to averting the loss of the integrity and diversity of nature and advancing its recovery. These conservation efforts have resulted in some notable successes, but biodiversity continues to decline globally. There is thus an urgent need to continue to strengthen efforts to address drivers and causes of biodiversity loss and support its recovery.

The field called 'synthetic biology', as defined by the Convention on Biological Diversity (CBD) (see section D), is developing rapidly and largely independently of nature conservation efforts. Different applications of synthetic biology may have significant positive and negative impacts on the integrity and diversity of nature. This is relevant for the conservation of biodiversity, sustainable use of its components, and equitable sharing of benefits arising from the utilisation of genetic resources.

Synthetic biology is not to be seen to replace ongoing and future efforts to address biodiversity loss. Synthetic biology could be complementary to these efforts.

There are divergent views on synthetic biology in relation to nature conservation. While research is ongoing, there remain significant data and knowledge gaps about synthetic biology and its potential ecological, ethical, economic, social, and cultural impacts. There is a need for a policy to inform decision-making on the application of synthetic biology in relation to nature conservation. IUCN has a unique role to foster dialogue by convening governments, non-governmental organisations, and Indigenous Peoples' organisations, and to build knowledge on this topic. IUCN, therefore, has decided to develop a policy on synthetic biology in relation to nature conservation. This policy should not be interpreted as supporting or opposing synthetic biology, per se.

B. Audience

The audience for this policy is all constituent parts of IUCN, including Members, Commissions, Secretariat, and National, Regional, and Interregional Committees, including in their interactions with other stakeholders involved in synthetic biology in relation to nature conservation. This policy is intended to guide the work of the IUCN Secretariat, Commissions, and Member organisations and could be informative to a wider audience.

C. Goal

The goal of this policy is to provide a basis to inform decision-making:

- on whether or not to use a synthetic biology application for nature conservation, and on the responsible use of synthetic biology for nature conservation; and
- on how to address the implications for nature conservation of the use of synthetic biology in other sectors.

This policy is intended to harmonize with international instruments, goals, and guidelines, as referenced in the Appendix.

D. Scope

This policy covers synthetic biology in relation to nature conservation; specifically, synthetic biology, whether applied for the purpose of nature conservation, or applied in other sectors, for example, industry, agriculture, or medicine, with potential direct or indirect impacts in relation to nature. The table below illustrates this scope, recognising that there may be cases that span more than one of these categories.

SECTOR / IMPACTS	Conservation	Other (e.g. industry, agriculture, medicine)
Ecological	*In scope*	*In scope*
Social, economic, cultural	*In scope*	*Not in scope*

This policy applies to all applications of tools and technology of synthetic biology, as well as associated research and development, in relation to nature conservation. Synthetic biology is understood according to the operational definition of the Convention on Biological Diversity (CBD) (Decision XIII/17): "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."

This policy does not specify particular applications or technologies of synthetic biology in order to avoid implying an overly narrow scope, while aiming to ensure that the policy is future-proof given the rapidly evolving field.

This policy provides general guidance and is not intended as a detailed implementation guide.

E. Principles

Recognizing the plurality of values of nature and its benefits, the following principles, and any interconnections among them, should be considered in discussions and decision-making on synthetic biology in relation to nature conservation. The first ten principles are adapted from the IUCN Resolution 123 (2020) “Towards development of an IUCN policy on synthetic biology in relation to nature conservation”, with their order unchanged. The order of the principles presented does not imply priority.

- Protect and restore integrity and diversity of nature.
- Advance intergenerational equity.
- Foster gender equity.
- Respect rights, beliefs, and cultures.
- Uphold the right to Free, Prior and Informed Consent.
- Practice inclusion of knowledge holders and rights-holders.
- Facilitate stakeholder and rights-holder participation.
- Take into account multiple sources of types of knowledge and expertise.
- Practice trans-, inter- and multidisciplinarity.
- Ensure that decision-making is science-based; encompasses other authoritative information, including traditional knowledge; and considers ethical principles and a plurality of values.
- Promote fairness, including equitable sharing of benefits, and appropriate provisions for liability and redress; minimize bias and conflict of interest; and ensure transparency and broad accessibility.
- Apply a case-by-case approach as included in the Cartagena Protocol on Biosafety to the CBD.
- Apply the precautionary principle, such as articulated in the 1992 Rio Declaration. Given that all life depends on nature, and the scope of this policy is in relation to nature conservation, the application of the precautionary principle should consider the In Dubio Pro Natura principle.

F. General considerations

The General considerations I-V, presented below, should be interpreted and applied consistently with this policy in its entirety and in accordance with international instruments, national and subnational legislation, and customary law.

I. General considerations for decision-making

This subsection addresses decision-making in relation to synthetic biology. Such decision-making should be guided by the above-mentioned principles, in particular taking a science-based approach and considering other knowledge systems, feedback and perspectives from diverse stakeholders and rights-holders including Indigenous Peoples and local communities, and gender and intergenerational equity. Governance contexts are also an important consideration.

Decision-makers should be able to access information on relevant synthetic biology research, development, and applications in relation to nature conservation. This is particularly important given

that synthetic biology is a fast-developing field, the intricate web of interactions in nature, significant knowledge gaps, and research to better understand these dynamics is ongoing.

Regulatory and other frameworks to evaluate and manage research on, development, and applications of synthetic biology in relation to nature conservation should, as appropriate:

a) Follow a clear process, or processes, for consistent and transparent decision-making, including criteria on whether or not to proceed with any stage of research, development or application. Decision-making processes should include provisions for stakeholders and rights-holder involvement, and, if applicable, further instruments and processes enabling broad public participation.

b) Adopt a case-by-case assessment approach. When relevant, a timely, context-sensitive, inclusive, and participatory problem formulation and feedback process should also be followed.

c) Assess risks and assess benefits in accordance with section F. II. Consideration should also be given to the desirability of independent review of risk assessments and benefit assessments.

d) Be guided by the principle of Free, Prior and Informed Consent, as referred to in section F. III.

e) Provide project plans that include a staged approach, including staged consultation with relevant stakeholders and rights-holders that might lead to reassessments and adaptive management.

f) Ensure that when risk management plans are necessary, they include clear and enforceable conditions relating to containment, monitoring of effects, reporting, contingency plans, and responses to address effects.

g) Consider cross-jurisdictional risks and benefits and call for collaboration among relevant entities across jurisdictions, in line with agreements such as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, and the Convention on International Trade of Endangered Species of Wild Fauna and Flora (CITES).

h) Ensure the proponent of a synthetic biology development or application, along with any relevant authorities, be responsible for appropriate public engagement, transparency, and sharing of information relevant for decision-making.

i) Assess and impose conditions relating to liability and redress, including as provided for in the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, when necessary.

In addition, regulatory frameworks should establish rules providing that those who fail to comply with those frameworks are to be held responsible for any harm caused by their unauthorized use or release of synthetic biology applications.

All relevant entities are encouraged to apply the above provisions, and seek comment or advice from independent relevant expert bodies, particularly in jurisdictions where there are no applicable legislative, administrative, or policy measures.

II. General considerations for risk assessments and benefit assessments for decision-making

This subsection addresses assessments of risks and assessments of benefits in relation to nature conservation.

The assessment of risks and the assessment of benefits should occur independently. Decision-making should then consider both, recognising that risks and benefits are not necessarily proportionally related. Both assessment and decision-making processes should consider the precautionary principle and other principles as set out in section E.

Risk assessments and benefit assessments should:

a) Be enacted on a case-by-case basis.

b) Be rigorous, comprehensive, and transparent, and include such details as correspond with the significance of the risks and benefits. These should include assessing intended and unintended impacts, short-term and long-term effects, multiple interactions, the ability to remediate undesirable consequences, and cumulative effects of synthetic biology whether applied directly for nature conservation or with implications for nature conservation. Risk assessments and benefit assessments should also consider alternatives, including non-synthetic biology approaches and the implications of inaction, and recognise knowledge gaps.

c) Have regard to the characteristics of the organism or technology and the proposed conditions of use, the characteristics of the receiving environment, and whether the application is for research, contained use, semi-field or field trials, commerce, or conditioned or unrestricted release.

d) Recognise differences in national policies, respect national sovereignty, and align with relevant international instruments.

e) As appropriate, incorporate ecological, cultural, socioeconomic, and animal welfare considerations.

f) In accordance with international instruments and national legislation, as appropriate, incorporate feedback and perspectives from relevant stakeholders and rights-holders, including Indigenous Peoples and local communities; build upon past experience; respect knowledge systems; be established in a participatory and anticipatory approach; and recognize the potential scale and complexity of introducing new technologies and their applications to nature.

III. General considerations for Free, Prior and Informed Consent

This subsection addresses the principle of Free, Prior and Informed Consent in decision-making by Indigenous peoples and local communities about synthetic biology in relation to nature conservation, when relevant. Free, Prior and Informed Consent should be applied consistent with relevant national legislation and international instruments, including the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) and the CBD. The United Nations Declaration on the Rights of Peasants and Other People Working in Rural Areas (UNDROP) is also relevant.

In line with the preceding paragraph, to enable Indigenous Peoples and local communities potentially impacted by a synthetic biology application to make informed decisions, the proponents of such applications should: provide relevant information, emphasizing both the potential positive and negative impacts of the activity, presented in a language and format understood by the community, respecting customary laws and protocols; and acknowledge the right of communities to agree or not agree through all stages of the applications.

In order to implement the principle of Free, Prior and Informed Consent effectively, capacity building and communication to encourage mutual understanding, trust, and knowledge exchange between the proponents of a synthetic biology application and the potentially impacted Indigenous Peoples or local communities should be encouraged.

IV. General considerations for fair and equitable sharing of benefits

This subsection addresses the fair and equitable sharing of benefits associated with the potential application of synthetic biology in relation to nature conservation.

Access and Benefit Sharing (ABS) principles, as established in international instruments, including the CBD, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the CBD, and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), as well as national legislation, may apply to synthetic biology applications in relation to nature conservation. ABS principles and rules may also apply to Digital Sequence Information (DSI) in relation to synthetic biology applications in accordance with relevant international instruments and national legislation.

The application of ABS rules to synthetic biology in relation to nature conservation should incorporate gender and inter-generational equity.

Intellectual property rights may influence access to, and use of, applications of synthetic biology, and should not run counter to the objectives of nature conservation. Furthermore, processes and requirements to apply for, and grant intellectual property rights on, applications of synthetic biology in relation to nature conservation should respect the rights of Indigenous Peoples and local communities in relation to genetic resources and associated traditional knowledge, as established by customary laws and international and national legislation.

V. General considerations for communication, education, and public awareness

This subsection addresses the need for increased understanding of synthetic biology in relation to nature conservation. This requires communication, education, and public awareness to be timely, comprehensive, inclusive, open, and balanced.

All relevant governmental and other entities should make an effort to foster trust, be transparent, respect diverse views, and encourage accessibility of information and public engagement. All relevant stakeholders should seek to be aware of the most up-to-date and relevant information about synthetic biology research, development, and applications.

All governmental and other entities are encouraged to be transparent with information about synthetic biology in relation to nature conservation, such as outlined in the United Nations Educational, Scientific and Cultural Organization (UNESCO) Recommendation on Open Science, and according to international instruments and national legislation. These efforts should recognize potential sources of bias and conflicts of interest, and be transparent about those sources and the rationale for decision-making. All governmental and other entities should be encouraged to publicise results and findings, and to provide equitable access to tools, knowledge, and capacity building.

In considering the use of synthetic biology in relation to nature conservation, the full range of views of stakeholders and rights-holders should be sought, understood, and respected.

Information about synthetic biology in relation to nature conservation should be communicated in an accessible manner, including by using open source platforms, and using clear, easy to understand language and technology with which the target audience can engage.

Consistent with their scope, responsibilities, and capabilities, all governmental and other entities engaged in synthetic biology are encouraged to offer accessible capacity building, in particular for stakeholders and rights-holders, including adequate training and technical expertise to support better engagement, understanding, policy making, implementation, monitoring, and impact assessments.

Appendix: Relevant foundational decisions and reference materials

This appendix lists instruments referenced in the text of the policy under each relevant section where they appear. It also includes selected policies and technical documents (marked with an asterisk (*)) that, while not explicitly mentioned in the policy, are particularly relevant to provide additional context.

Section A. Problem Definition

Operational definition of Synthetic Biology: Convention on Biological Diversity: "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."

- Convention on Biological Diversity Decision XIII/17
- Convention on Biological Diversity Decision XIV/19
- Convention on Biological Diversity Decision XV/31
- Convention on Biological Diversity Subsidiary Body on Scientific, Technical and Technological Advice- SBSTTA, Recommendation 26/4

- IUCN Resolution 123 (2020) Towards development of an IUCN policy on synthetic biology in relation to nature conservation

Section B. Audience No instruments referenced in this section.

Section C. Goal No instruments referenced in this section.

Section D. Scope

Operational definition of Synthetic Biology: Convention on Biological Diversity (CBD) - as above

Section E. Principles

General principles:

- IUCN Resolution 123 (2020) Towards development of an IUCN policy on synthetic biology in relation to nature conservation
- * IUCN World Declaration on the Environmental Rule of Law,

2016 Free Prior and Informed Consent (FPIC)

- FPIC, United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP), Article 19:

  "States shall consult and cooperate in good faith with the indigenous peoples concerned through their own representative institutions in order to obtain their free, prior and informed consent before adopting and implementing legislative or administrative measures that may affect them."

Values and Valuation of Nature

- * Convention on Biological Diversity - Preamble: "Conscious of the intrinsic value of biological diversity and of the ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic values of biological diversity and its components…"
- * Methodological assessment regarding the diverse conceptualization of multiple values

of nature and its benefits, including biodiversity and ecosystem functions and services (IPBES 2022)

Conflict of interest and bias

- * Convention on Biological Diversity: Differentiation between "conflict of interest" and "bias": Decision 14/33 (see paragraphs 1.3 and 1.4, Annex – page 2).

Case-by-case approach

- * Convention on Biological Diversity Cartagena Protocol on Biosafety: Article 15/ Annex III. General Principles- Risk assessment: "6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case,depending on the living modified organism concerned, its intended use and the likely potential receiving environment."

Precautionary Principle/Approach

- Rio Declaration 1992, Principle 15: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."
- * United Nations Educational, Scientific and Cultural Organization (UNESCO) World Commission on the Ethics of Scientific Knowledge and Technology working definition (2005): "When human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm. Morally unacceptable harm refers to harm to humans or the environment that
    - is threatening to human life or health, or
    - serious and effectively irreversible, or
    - inequitable to present or future generations, or
    - imposed without adequate consideration of the human rights of those affected.

The judgment of plausibility should be grounded in scientific analysis. Analysis should be ongoing so that chosen actions are subject to review. Uncertainty may apply to, but need not be limited to, causality or the bounds of the possible harm. Actions are interventions that areundertaken before harm occurs that seek to avoid or diminish the harm. Actions should be chosen that are proportional to the seriousness of the potential harm, with consideration of their positive and negative consequences, and with an assessment of the moral implications of both action and inaction. The choice of action should be the result of a participatory process."

- In Dubio Pro Natura as defined in the IUCN World Declaration on the Environmental Rule of Law : "In cases of doubt, all matters before courts, administrative agencies, and other decision-makers shall be resolved in a way most likely to favour the protection and conservation of the environment, with preference to be given to alternatives that are least harmful to the environment. Actions shall not be undertaken when their potential adverse impacts on the environment are disproportionate or excessive in relation to the benefits derived there from."

Section F. General Considerations

I. General considerations for decision-making

See E. Principles

- Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)
- The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety

II. General considerations for risk assessment and benefit assessment for decision-making

See E. Principles

Participatory approaches

- * OECD 2020 Innovative Citizen Participation and New Democratic Institutions: Catching the Deliberative Wave

III. General considerations for participation and Free, Prior and Informed Consent

See E. Principles

Free, Prior and Informed Consent

- FPIC, United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) - Article 19
- Convention on Biological Diversity Article 8(j) - Traditional Knowledge, Innovations and Practices, and subsequent decisions and bodies of work. “Subject to national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge innovations and practices.”
- United Nations Declaration on the Rights of Peasants and Other People Working in Rural Areas (UNDROP)

IV. General considerations for fair and equitable sharing of benefits

- Convention on Biological Diversity - Article 15 - Access to genetic resources
- Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity

- International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

V. General considerations for communication, education, public awareness

- UNESCO Recommendation on Open Science 2021