Synthetic biology

Annex I

Thematic action plan to support capacity-building and development, access to and transfer of technology and knowledge-sharing in the context of synthetic biology for the implementation of the Convention on Biological Diversity and the Kunming-Montreal Global Biodiversity Framework

I. Introduction

1. The thematic action plan to support capacity-building and development, access to and transfer of technology and knowledge-sharing in the context of synthetic biology is designed to support the needs and priorities of Parties, especially developing country Parties, in particular the least developed countries and small island developing States, and Parties with economies in transition, for the implementation of the three objectives of the Convention on Biological Diversity and the Kunming-Montreal Global Biodiversity Framework in the context of synthetic biology.[1]

2. In accordance with decision 16/21, the thematic action plan has been developed taking the following aspects into account:

(a) The specific needs of Parties and indigenous peoples and local communities that are complementary to the capacity-building action plan for the Cartagena Protocol on Biosafety;[2]

(b) The identification of areas where capacity-building and development, access to and transfer of technology and knowledge-sharing are needed for research and development and for assessment in the field of synthetic biology;

(c) Strategies to facilitate the equitable participation of developing country Parties, indigenous peoples and local communities, women, youth, academia, the business sector and relevant institutions in research and development in the field of synthetic biology;

(d) Strategies to promote the fair and equitable sharing of benefits arising from synthetic biology, in line with Articles 16 and 19 of the Convention and with the Framework;

(e) Mechanisms for technology transfer, knowledge-sharing and international technical and scientific cooperation to foster innovation, in line with Articles 16 and 18 of the Convention and with the Framework.

II. Structure

3. The enclosure contains the outcome areas and indicative strategic actions of the thematic action plan. The three outcome areas are:

(a) Strengthened capacity for research and development in and the assessment of synthetic biology;

(b) Improved access to and transfer of technology relevant to synthetic biology;

(c) Enhanced knowledge-sharing on synthetic biology, including its development, assessment, governance and regulation.

[1] Synthetic biology is operationally defined in decision XIII/17 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.
[2] As identified through notification Nos. 2025-065 and 2025-088.

4. Strategies to facilitate equitable participation in the field of synthetic biology; strategies to promote the fair and equitable sharing of benefits arising from synthetic biology, in line with Articles 16 and 19 of the Convention; and mechanisms for technology transfer, knowledge-sharing and international technical and scientific cooperation to foster innovation, in line with Articles 16 and 18 of the Convention, have been integrated into the three outcome areas.

5. Where relevant, and to avoid duplication, the thematic action plan includes references to the other action plans developed under the Convention and its Protocols, in addition to relevant documents and resources developed by other intergovernmental organizations.

III. Linkage to the Convention on Biological Diversity, the Kunming-Montreal Global Biodiversity Framework and existing plans

6. The thematic action plan is developed to support Parties and other stakeholders in achieving, in the context of synthetic biology, the three objectives of the Convention, namely, the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. The plan could therefore help to minimize the potential adverse impacts on biological diversity (Articles 7 (c), 8 (g) and 14 of the Convention), while also facilitating access to and transfer of technology, scientific and technical cooperation and the distribution of benefits arising from biotechnology based upon genetic resources (Articles 16, 18 and 19). The plan can also contribute to the implementation of the goals and targets of the Framework, specifically Targets 2, 4, 6, 7, 8, 9, 10, 11, 13, 16, 17, 19, 20, 21, 22 and 23, where applicable and as a complement to other actions that may contribute to their achievement.

7. In addition, the thematic action plan is complementary to the capacity-building action plan for the Cartagena Protocol and the capacity-building and development action plan for the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization. The Implementation Plan for the Cartagena Protocol can also support and guide Parties in addressing elements related to biosafety.

IV. Use of the thematic action plan

8. The thematic action plan can be used by any actors, such as national Governments, indigenous peoples and local communities, women, youth, the Secretariat and the bodies established under the Convention,, the Global Environment Facility and other international, regional and national funding organizations, and other relevant stakeholders and organizations. The suggested actions are voluntary and will vary according to national circumstances, priorities and needs, as well as the role of the actors involved. Actions should be taken in line with the guiding principles listed in section V below.

9. To ensure effective implementation, a phased approach is recommended, starting with the identification of needs and priorities related to research and development, access to and transfer of technology, regulation, assessment, monitoring and knowledge-sharing in the context of synthetic biology that are relevant to the implementation of the Convention and the Framework. According to national and organizational circumstances, activities can then be prioritized to address the identified needs (see outcome area 1, output 1.1).

10. The implementation of any relevant elements of the thematic action plan should be considered in the light of existing capacity-building and development activities, access to and transfer of technology initiatives and knowledge-sharing endeavours related to biosafety, access and benefit-sharing and Kunming-Montreal Global Biodiversity Framework implementation mechanisms with the goal to avoid duplication.

11. The suggested actions can be further prioritized or updated to address gaps in capacity in the light of future developments in the field of synthetic biology, as needed. Future developments can be identified through coordinated broad and regular horizon scanning and foresight activities, as well as engagement with experts, as necessary.

V. Guiding principles

12. The thematic action plan is aimed at contributing to the achievement of the three objectives of the Convention and the goals and targets of the Framework. Thus, all indicated actions should be taken in the context of the Convention, its Protocols and the Framework.

13. In line with decision 16/21, the general principles and strategies for enhancing capacity-building and development, access to and transfer of technology on mutually agreed terms, and knowledge-sharing of the long-term strategic framework for capacity-building and development should apply to the thematic action plan and be taken into consideration when planning activities.[3]

14. When using the thematic action plan, actors should:

(a) Take a precautionary approach, as provided in Principle 15 of the Rio Declaration on Environment and Development;

(b) Adopt a science-based, evidence-based and case-by-case approach;

(c) Take a needs-based approach in line with national priorities and circumstances;

(d) Consider on the basis of multidisciplinary expertise the potential positive and potential negative impacts of synthetic biology applications on the three objectives of the Convention and the goals and targets of the Kunming-Montreal Global Biodiversity Framework;

(e) Consider the potential risks in relation to the intended use and the likely potential receiving environment (e.g. unmanaged or wild settings; semi-managed, managed or urban settings; and contained settings);[4]

(f) Take a multidisciplinary, transdisciplinary or interdisciplinary approach to research and development in and the assessment of synthetic biology;

(g) Recognize the diverse values of nature and its benefits, including biodiversity and ecosystem services, in particular the intrinsic value of biological diversity and the ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic values of biological diversity and its components;[5]

(h) Recognize and respect diverse knowledge systems, including those of indigenous peoples and local communities, and gender-specific elements;

(i) Foster a whole-of-society approach that ensures the full, effective and meaningful participation of all actors;

(j) Ensure the free, prior and informed consent[6] of indigenous peoples and local communities;

[3] See decision 15/8, annex I, paras. 8 and 9.
[4] See CBD Technical Series No. 100.
[5] See *The Methodological Assessment Report on the Diverse Values and Valuation of Nature* of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services.
[6] "Free, prior and informed consent" refers to the tripartite terminology of "prior and informed consent", "free, prior and informed consent" and "approval and involvement".

(k) Ensure the fair and equitable sharing of benefits arising from the commercial and other utilization of genetic resources, including applications of synthetic biology;

(l) Support international and regional scientific and technical cooperation to strengthen activities related to research and development in and the assessment of synthetic biology in the context of the Convention and its Protocols and the Framework;

(m) Take a coordinated, non-duplicative and complementary approach with respect to synthetic biology and other related fields.[7]

15. As appropriate, other principles, frameworks and guidelines containing complementary actions can be taken into account when planning activities and considering the use of synthetic biology relevant to the Convention and the Framework, such as:

(a) Implementation Plan for the Cartagena Protocol on Biosafety[8]

(b) The Gender Plan of Action (2023–2030);[9]

(c) The Akwé: Kon Voluntary Guidelines;[10]

(d) The Mo'otz Kuxtal Voluntary Guidelines;[11]

(e) The plan of action on customary sustainable use of biological diversity;[12]

(f) The knowledge management strategy to support the implementation of the Framework;[13]

(g) The United Nations Declaration on the Rights of Indigenous People;

(h) The United Nations Educational, Scientific and Cultural Organization recommendation on Open Science;[14]

(i) The World Health Organization global guidance framework for the responsible use of life sciences;

(j) The Food and Agriculture Organization of the United Nations Science and Innovation Strategy and its corresponding action plan;

(k) The International Union for Conservation of Nature policy on synthetic biology in relation to nature conservation (8.086);

(l) The Organisation for Economic Co-operation and Development (OECD) framework for anticipatory governance of emerging technologies;

(m) The OECD agile mechanisms for responsible technology development.

VI. Means of implementation

16. Making adequate and predictable resources available in a timely manner is crucial for the effective implementation of the three objectives of the Convention and the Framework in the context of synthetic biology. Thus, there is a need to mobilize resources from all sources, in accordance with Article 20 of the Convention, and to identify and select the financial resources that will support the thematic action plan. Such resource mobilization should be needs-based and accessible, in line with national circumstances and priorities and aimed at

[7] Including by building upon the work conducted under the Protocols to the Convention and the Organisation for Economic Co-operation and Development, as appropriate.
[8] Decision CP-10/3.
[9] Decision 15/11, annex.
[10] Decision VII/16 F, annex.
[11] Decision XIII/18, annex.
[12] Decision XII/12 B, annex.
[13] Decision 16/9 B, annex.
[14] Available at www.unesco.org/en/legal-affairs/recommendation-open-science.

supporting the implementation of the Convention and the Framework. Particular consideration should be given to the least developed countries, small island developing States, and Parties with economies in transition.

17. The thematic action plan can be used as a reference for guiding the development of programmatic directions of the financial mechanism for the Convention and its Protocols (the Global Environmental Facility and its Global Biodiversity Framework Fund), as well as the Biodiversity Finance Initiative of the United Nations Development Programme, regional initiatives, in addition to other funds and donors.

18. National Governments are also encouraged to incorporate dedicated funding in their national finance plans or other similar planning instruments in the context of national biodiversity strategies and action plans, in accordance with national priorities and capacities (see also output 1.1).

VII. Role of the Secretariat and of the scientific and technical support centres

19. While the thematic action plan is directed to national Governments and relevant stakeholders, the Secretariat of the Convention on Biological Diversity will support Parties in their efforts in implementing the plan, in accordance with Article 24 of the Convention. This can include undertaking activities in response to requests from the Conference of the Parties, including sharing information through the clearing-house mechanisms and facilitating capacity-building activities.

20. The regional and subregional support centres forming part of the Technical and Scientific Cooperation Mechanism established in decision 15/8 and operationalized in decision 16/3 can support Parties, upon request, with identifying gaps in scientific capacity, supporting technology transfer and innovation, facilitating scientific and technical cooperation and assisting with knowledge-sharing activities when implementing the thematic action plan.

21. To monitor the implementation of the thematic action plan, the Secretariat may request the voluntary submission of information to complement relevant information from other possible sources, including national reports requested under the Convention and its Protocols, as necessary.

VIII. Monitoring and reporting on progress in the implementation of the thematic action plan

22. The monitoring and reporting of progress in the implementation of the thematic action plan will be conducted in conjunction with the monitoring and reporting of progress in the implementation of the long-term strategic framework for capacity-building and development and the Technical and Scientific Cooperation Mechanism.

23. The thematic action plan can be reviewed, as necessary, upon request of the Conference of the Parties in the light of experiences utilizing the plan and of new developments in the field of synthetic biology.

Enclosure

Outcome areas and indicative strategic actions to support capacity-building and development, access to and transfer of technology and knowledge-sharing in the context of synthetic biology for the implementation of the Convention on Biological Diversity and the Kunming-Montreal Global Biodiversity Framework

Outcome area 1: strengthened capacity for research and development in and the assessment of synthetic biology

Objective: actors[15] have improved capacity and infrastructure for undertaking research and development, responsible innovation, assessment and oversight of synthetic biology applications that are relevant to the implementation of the three objectives of the Convention on Biological Diversity and the Kunming-Montreal Global Biodiversity Framework	
Output	*Indicative strategic actions*
1.1 Identification of needs and priorities	(a) Assess capacities and identify needs related to research and development, access and transfer of technology, regulation, assessment, monitoring and knowledge-sharing in the context of synthetic biology; (b) Prioritize activities for short-, medium- and long-term action on the basis of identified needs and national circumstances; (c) Integrate synthetic biology research and development and assessment needs into various sectoral budget plans, and identify capacity-building and development needs.
1.2 Strengthened physical infrastructure	(a) Establish, strengthen or provide access to technical laboratory infrastructure;[16] (b) Develop governance mechanisms, technical support and sustainability models to ensure long-term functionality and equitable use of laboratory infrastructure; (c) Develop in silico infrastructure; (d) Establish or strengthen public laboratories, university laboratories, reference laboratories, mobile laboratories and biofoundries at the national, subregional or regional level; (e) Promote continued and sustainable financing for the maintenance of infrastructure and the procurement of reagents and materials; (f) Integrate physical, digital and cyberbiosecurity protocols into the design, operation, and maintenance of laboratory and in silico infrastructure.
1.3 Support for personnel capacity	(a) Institutionalize capacity-building and development processes and ensure continued capacity-building through global, regional and national institutions; (b) Provide scholarships, internships and mentorships at the undergraduate and postgraduate levels for areas related to research and development in and the assessment of synthetic biology, in particular for students and women from developing countries and indigenous peoples and local communities; (c) Support the development or use of existing exchange programmes as mechanisms to build capacity, transfer knowledge and promote sustained communication and collaboration across relevant stakeholders; (d) Develop interdisciplinary training programmes for research and development in and the assessment of synthetic biology in national or regional universities and on e-learning platforms, including specialized courses for regulators and decision makers, on advanced science and intellectual property; (e) Foster the training of members of indigenous peoples and local communities in research and development in and the assessment of synthetic biology in locally relevant languages and in line with their self-determined needs and priorities
1.4 Development of capacity for local research and development	(a) Develop national or regional road maps for research and development in synthetic biology, including through convening national or regional workshops; (b) Support the international standardization within the field of synthetic biology;[17] (c) Establish regional and international centres of excellence, networks of laboratories or research consortiums, in particular in developing countries, for activities conducted in the field of synthetic biology; (d) Strengthen research on local genetic resources including through the provision of grants for local research; (e) Develop guidance on licensing arrangements for appropriate local innovation and on other forms of non-monetary benefit-sharing consistent with the objectives of the Convention

[15] National Governments, indigenous peoples and local communities, women, youth, and other relevant stakeholders and organizations.

[16] Where needed to complement infrastructure supported under the capacity-building action plan for the Cartagena Protocol on Biosafety and the capacity-building and development action plan for the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization, for Parties to those respective instruments.

[17] Such as carried out by the International Gene Synthesis Consortium, Synthetic Biology Open Language, the International Biosecurity and Biosafety Initiative for Science, the Synthetic Biology Standards Consortium, the iGEM Registry of Biological Parts and the Engineering Biology Research Consortium.

1.5 Enhanced assessment capacity	(a) For Parties to the Cartagena Protocol on Biosafety, use associated actions under Goals A.5 and A.9 of the capacity-building action plan for the Protocol[18] for synthetic biology applications considered to be living modified organisms; (b) Introduce, utilize or strengthen existing national and international procedures, where appropriate, for the environmental impact assessment of components, organisms and products of synthetic biology that are likely to have significant adverse effects on biological diversity, in line with Article 14 of the Convention and avoiding the creation of duplicative regulatory processes; (c) Ensure meaningful public participation and engagement with a diverse range of experts, including from indigenous peoples and local communities, women, youth, and other relevant stakeholders, in the assessment of synthetic biology applications aligned with international standards; (d) Fund and strengthen research programmes to improve assessment and monitoring capacity for the potential positive and potential negative impacts of synthetic biology; (e) Undertake broad and regular horizon scanning, assessment and monitoring to identify recent developments in synthetic biology with potential positive and potential negative impacts on the objectives of the Convention; (f) Develop tools and methodologies to assess the potential positive and potential negative impacts of synthetic biology on the objectives of the Convention and the Framework. (g) Develop science-based national and international standards to assess the reliability of biocontainment systems
Outcome area 2: improved access to and transfer of technology relevant to synthetic biology **Objective**: access to and the transfer of technology are essential for the attainment of the three objectives of the Convention and the Framework. Thus, the objective of outcome area 2 is to ensure access to synthetic biology technology that is relevant to the conservation and sustainable use of biological diversity and does not result in significant damage to the environment, and to create enabling environments that facilitate the transfer of such technology, in line with Articles 16 and 19 of the Convention	
Output	*Indicative strategic actions*
2.1. Increased access to and transfer of technology	(a) Establish public-private, public-private-academic and academic-private partnerships on technology relevant to research and development in and the assessment of synthetic biology; (b) Develop and maintain an accessible database of tools and methodologies for detection and assessment; (c) Encourage the development and use of open-source tools, low-cost technology platforms and distributed manufacturing models; (d) Invest in and strengthen supply chains, including through cold-chain facilities, regional manufacturing and diversified suppliers; (e) Promote and facilitate the sharing of facilities, including by identifying standardization frameworks, procedures and conditions for the use of the facilities in line with national needs and priorities; (f) Organize matchmaking events or technology fairs to support the establishment of links among technology providers, regulators, assessors and potential users, including at the regional level; (g) Develop tools and guidance for access to and the transfer of synthetic biology technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources, do not result in significant damage to the environment, and are adapted to local contexts; (h) Encourage voluntary licensing arrangements on mutually agreed terms for indigenous peoples and local communities; (i) Encourage voluntary reduced licensing rates and transfer of technical knowledge for use in local innovation and non-commercial research in developing countries.

[18] Goal A.5: Parties carry out scientifically sound risk assessments of living modified organisms and manage and control identified risks to prevent adverse effects of living modified organisms on the conservation and sustainable use of biological diversity taking also into account risks to human health; Goal A.9: Parties that choose to do so take into account socioeconomic considerations when making decisions on the import of living modified organisms and cooperate on research and information exchange in accordance with Article 26 of the Cartagena Protocol (decision CP-10/4, annex).

2.2. Establishment of robust regulatory environments aligned with existing regulation	(a) Establish, maintain and further develop functional biosafety frameworks, which for Parties to the Cartagena Protocol should be in accordance with Goal A.1 of the capacity-building action plan for the Protocol;[19] (b) Review biosafety regulatory frameworks to identify any potential gaps related to synthetic biology and update biosafety systems to address such gaps, as necessary; (c) Establish national coordination mechanisms for activities related to synthetic biology; (d) Promote the use of guidelines to strengthen the governance of synthetic biology aligned with national needs, priorities and existing regulation; (e) Encourage North-South, South-South and triangular cooperation, including through the exchange of scientific knowledge, technical expertise, regulatory experience and best practices related to synthetic biology, while respecting national legislation, national circumstances and the sovereign right of Parties to establish and implement their own regulatory frameworks (f) Promote measures to respect, preserve and maintain the traditional knowledge, innovations and practices of indigenous peoples and local communities relevant to synthetic biology to ensure that their access and use are obtained only with their free, prior and informed consent[20] and that benefits arising from their utilization are shared in a fair and equitable manner, in accordance with relevant intellectual property frameworks.
2.3. Strengthened access and benefit-sharing from synthetic biology technology	(a) For Parties to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization, use the capacity-building and development action plan for the Protocol to strengthen access and benefit-sharing systems; (b) Mobilize financial resources from beneficiaries of synthetic biology technology to enable developing countries to participate in research and development in and the assessment of synthetic biology; (c) Encourage equitable and inclusive non-monetary benefit-sharing, in particular for developing countries and indigenous peoples and local communities; (d) Include reciprocity and co-benefit clauses in public-private, public-academic and other partnership or licensing agreements; (e) Develop appropriate tools and mechanisms to promote the fair and equitable sharing of benefits arising from research and development in and the application of synthetic biology technology.
Outcome area 3: enhanced knowledge-sharing on synthetic biology, including its development, assessment, governance and regulation **Objective**: knowledge relevant to synthetic biology research, development, assessment, governance and regulation is shared widely, in line with Article 17 of the Convention, and made available for use by all actors for research and development in and the assessment, governance and regulation of synthetic biology	
Output	*Indicative strategic actions*
3.1. Improved access to scientific knowledge	(a) Promote the publication of open access scientific articles in the field of synthetic biology and in areas related to its assessment, governance and regulation; (b) Promote the publication of relevant information in public databases in line with the principles of findability, accessibility, interoperability and reusability (FAIR principles) and of collective benefit, authority to control, responsibility and ethics (CARE principles); (c) Encourage capacity-building on data stewardship, data curation and long-term data management, including or improving transparency, metadata standards and the handling of confidential information; (d) Promote the sharing of scientific and technical knowledge related to synthetic biology and its assessment, including through the clearing-house mechanisms of the Convention and its Protocols; (e) Support facilitated access to scientific journals and technical databases for researchers and students from developing countries; (f) Establish synthetic biology information hubs to improve access to relevant information.
3.2. Establishment	(a) Convene national, regional and international knowledge-sharing events on synthetic biology and related areas, including regulatory aspects, assessment and oversight, and

[19] Goal A.1: Parties have in place functional national biosafety frameworks (decision CP-10/4, annex).

[20] "Free, prior and informed consent" refers to the tripartite terminology of "prior and informed consent", "free, prior and informed consent" and "approval and involvement".

of knowledge-sharing initiatives and mechanisms	promote participation in relevant regional and international gatherings, in particular for developing countries; (b) Support the participation of researchers and students in dedicated competitions; (c) Establish knowledge-sharing and cooperation agreements among institutions and promote participation in international or regional research networks; (d) Provide international scholarships and internships for knowledge-sharing initiatives on synthetic biology, in particular for developing countries, women and youth; (e) Facilitate the participation of researchers from developing countries and representatives of indigenous peoples and local communities in international knowledge-sharing events; (f) Encourage regulatory exchanges among countries with developed regulatory systems and those with developing regulatory systems; (g) Promote knowledge-sharing activities that are inclusive of all relevant rights holders and stakeholders; (h) Promote regional, North-South, South-South and triangular cooperation on synthetic biology and ecological research.
3.3. Expanded communication and outreach	(a) Encourage the publication of technical materials and scientific publications in local languages; (b) Support the development of risk communication, biosecurity, ethics and access and benefit-sharing modules in local languages, co-developed with stakeholders; (c) Facilitate public awareness through the use of a variety of media and of local languages; (d) Conduct dialogues and awareness campaigns that are accessible, multilingual and adapted to diverse audiences, including the general public, indigenous peoples and local communities, women and youth; (e) Hold dedicated forums and public consultations with the participation of indigenous peoples and local communities, civil society organizations, women, youth, regulators and the scientific community; (f) Promote the organization of public research discovery days in universities to facilitate the dissemination of knowledge related to synthetic biology and its potential impacts; (g) Establish a community of practice for dialogues between regulators and scientists in synthetic biology to identify emerging issues for regulatory oversight.
3.4. Promotion of inclusive knowledge-sharing	(a) Prioritize intercultural dialogues in knowledge construction through mechanisms that respect and integrate diverse knowledge systems, languages and transmission modes, while ensuring effective participation based on free, prior and informed consent, culturally appropriate engagement and respect for traditional knowledge and gender perspectives; (b) Foster two-way learning between scientific institutions and indigenous peoples and local communities.