



Convention on Biological Diversity

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**Subsidiary Body on Scientific,
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Twenty-sixth meeting
Nairobi, 13–18 May 2024
Agenda item 5
Synthetic biology

Synthetic biology

Draft recommendation submitted by the Chair

The Subsidiary Body on Scientific, Technical and Technological Advice,

Recalling decision 15/31 of 19 December 2022 on synthetic biology,

Having conducted a review of the outcomes and operation of the process in accordance with decision 15/31 and taking annex III to document CBD/SBSTTA/26/4 and document CBD/SBSTTA/26/INF/6 into account,

1. *Acknowledges* the work of the multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology, and takes note of the outcomes contained in annexes I to V of document CBD/SBSTTA/26/4;
2. *Welcomes* the peer review process, and takes note of the results contained in document CBD/SBSTTA/26/INF/6;
3. *Emphasizes* that capacity-building and development, access to and transfer of technology and knowledge-sharing need to be strengthened in the context of synthetic biology, considering the inequity of participation by developing countries;
4. *Recommends* that, at its sixteenth meeting, the Conference of the Parties adopt a decision along the following lines:

The Conference of the Parties,

Recalling the call made by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety¹ in its decision BS-VII/12 of 3 October 2014 for a coordinated approach on the issue of synthetic biology, taking into account the fact that the provisions of the Protocol may also apply to living organisms resulting from synthetic biology,

[*Recalling also* decisions XII/24 of 17 October 2014, XIII/17 of 17 December 2016, 14/19 of 29 November 2018 and 15/8 and 15/31 of 19 December 2022,]

[*Recalling further* that, in its decision XIII/17, the Conference of the Parties took note of the conclusion of the Ad Hoc Technical Expert Group on Synthetic Biology that living

¹ United Nations, *Treaty Series*, vol. 2226, No. 30619.

organisms developed through current applications of synthetic biology, or that were currently in the early stages of research and development, were similar to living modified organisms as defined in the Cartagena Protocol,] [and noted that it was not clear, given the current state of knowledge, whether or not some organisms of synthetic biology, which were currently in the early stages of research and development, would fall under the definition of living modified organisms under the Protocol,]

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Recalling that, in its decision 14/19, the Conference of the Parties agreed that broad and regular horizon scanning, monitoring and assessing of the most recent technological developments was needed for reviewing new information regarding the potential positive and potential negative impacts of synthetic biology vis-à-vis the three objectives of the Convention on Biological Diversity² and those of the Cartagena Protocol and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization,³

[*Recalling also* that, in its decision 15/31, the Conference of the Parties recognized that the results of the application of the criteria as set out in decision IX/29 of 30 May 2008 to the issue of synthetic biology had been inconclusive in determining whether synthetic biology was a new and emerging issue or not and decided not to require further analysis on whether synthetic biology was a new and emerging issue, and established a process for broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology,

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Noting the potential positive contributions and negative impacts of synthetic biology applications in relation to the objectives of the Convention and the goals and targets of the Kunming-Montreal Global Biodiversity Framework,⁴

Noting also the potential interlinkages of several issues identified during the horizon scanning, monitoring and assessment process with those under consideration in the context of work on biodiversity and health, in particular the draft global action plan for biodiversity and health,

Acknowledging that a multidisciplinary and Party-driven approach is essential for assessing the potential impacts of synthetic biology on the objectives of the Convention and its Protocols,

Recognizing the inequity in the participation of developing countries in the research, development, assessment and regulation of synthetic biology and the importance of addressing impacts,

Noting with appreciation the outcomes of the work of the multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology, including those contained in annex II to document CBD/SBSTTA/26/4,

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A. Capacity-building and development, access to and transfer of technology and knowledge-sharing in the context of synthetic biology

² United Nations, *Treaty Series*, vol. 2226, No. 30619.

³ United Nations, *Treaty Series*, vol. 3008, No. 30619.

⁴ Decision 15/4, annex.

1. *Emphasizes* the urgent need for capacity-building and development, access to and transfer of technology and knowledge-sharing for synthetic biology;
 2. *Urges* Parties, and invites relevant organizations, to provide financial and technical support for capacity-building and development and technology transfer initiatives in developing countries, including for research, development and assessment in the field of synthetic biology;
 3. *Calls upon* Parties and other stakeholders to facilitate broad international cooperation, technology transfer, knowledge-sharing and capacity-building and development related to synthetic biology, taking the needs of Parties and of indigenous peoples and local communities, women and youth into account;
 4. *Reaffirms* decision 15/8 on capacity-building and development and technical and scientific cooperation and the guiding principles contained in annex II to that decision;
 5. *Decides* to develop a thematic action plan to support capacity-building and development, access to and transfer of technology and knowledge-sharing in the context of [biotechnology including] synthetic biology, as well as the long-term strategic framework for capacity-building and development;
 6. *Invites* Parties, other Governments and relevant organizations to submit information on their capacity-building and development, technology transfer and knowledge-sharing needs and experiences related to synthetic biology to inform the preparation of the action plan for synthetic biology;
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7. *Requests* the Executive Secretary, [subject to the availability of resources and] avoiding duplication with existing plans and strategies, to prepare a thematic action plan to support capacity-building and development, access to and transfer of technology and knowledge-sharing in the context of synthetic biology, taking the following into account:
 - (a) The identification of areas where capacity-building is needed for research, development, assessment and regulation of synthetic biology;
 - (b) Strategies to ensure equitable participation of developing countries and indigenous peoples and local communities, women and youth in research, development, assessment and regulation of synthetic biology;
 - (c) Proposals to promote the fair and equitable sharing of benefits arising from synthetic biology, in line with Articles 16 and 19 of the Convention on Biological Diversity and the objectives of the Kunming-Montreal Global Biodiversity Framework;
 - (d) Mechanisms for technology transfer, knowledge-sharing and international cooperation;
 - (e) The specific needs of Parties as identified in their submissions of information made further to the request in paragraph 6 above and the outcomes of the multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology;⁵
 - (f) A gap analysis, taking other process and initiatives related to the fields of synthetic biology into account;
 8. *Also requests* the Executive Secretary to create a dedicated webpage on the Biosafety Clearing-House to promote the action plan and facilitate knowledge-sharing in the context of synthetic biology;

⁵ CBD/SBSTTA/26/4, annex II.

9. *Requests* the Subsidiary Body on Scientific, Technical and Technological Advice to consider the action plan at a meeting held before the seventeenth meeting of the Conference of the Parties and make recommendations to the Conference of the Parties at its seventeenth meeting;

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B. Broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology

10. [Welcomes][Acknowledges][Takes note of] outcomes of the broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology;

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[11. *Decides* [to extend] [not to continue] the process for broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology [for an additional intersessional period]];

[12. [Adopts][Takes note of] the refined methodology contained in annex IV to document CBD/SBSTTA/26/4, and decides to keep the methodology under review by the Conference of the Parties;

13. *Decides* that the broad and regular horizon scanning, monitoring and assessment process should be a Party-led process;

14. [Establishes][Extends the tenure of the][Re-establishes] the [multidisciplinary] Ad Hoc Technical Expert Group on Synthetic Biology with [additional members][renewed membership] for one additional intersessional period in accordance with the terms of reference contained in the annex to the present decision;

[15. *Decides* to review existing relevant technical information regarding synthetic biology analysed under relevant processes and by relevant organizations and revise the terms of reference on the basis of the findings without duplicating other processes;]

16. *Invites* Parties, other Governments, relevant organizations, indigenous peoples and local communities and women and youth to submit nominations to the [multidisciplinary] Ad Hoc Technical Expert Group on Synthetic Biology;

17. *Also invites* Parties, other Governments, relevant organizations, indigenous peoples and local communities, women and youth to strengthen the multidisciplinary approach when considering nominations for the [multidisciplinary] Ad Hoc Technical Expert Group;]

18. *Requests* the Executive Secretary, subject to the availability of resources:

(a) To update the literature review in order to inform the work of the [multidisciplinary] Ad Hoc Technical Expert Group, taking ecological, socioeconomic, ethical and cultural considerations into account;

(b) To convene online discussions of the Open-ended Online Forum on Synthetic Biology in order to support the work of the [multidisciplinary] Ad Hoc Technical Expert Group;

(c) To convene at least one in-person meeting of the [multidisciplinary] Ad Hoc Technical Expert Group;

(d) To support the full and effective participation of indigenous peoples and local communities in the work relevant to synthetic biology undertaken under the Convention, in accordance with decision X/40 of 29 October 2010;

(e) To support the participation of the research community, women and youth in the work relevant to synthetic biology undertaken under the Convention;

19. *Requests* the Subsidiary Body on Scientific, Technical and Technological Advice to consider the outcomes of the [multidisciplinary] Ad Hoc Technical Expert Group on Synthetic Biology and make recommendations to the Conference of the Parties to the Convention at its seventeenth meeting and, as appropriate, to the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety at its twelfth meeting and the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization at its sixth meeting.

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5. *Recommends* that the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol, at its eleventh meeting, adopt a decision along the following lines:

The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety

Decides that any trends or issues identified through the process of broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology that are considered to be living modified organisms and may require further guidance on risk assessment will need to follow the process outlined in annex I to decision CP-9/13 of 28 November 2018.

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Annex

Terms of reference for the [multidisciplinary] Ad Hoc Technical Expert Group on Synthetic Biology

1. The [multidisciplinary] Ad Hoc Technical Expert Group on Synthetic Biology will be convened in compliance with section H of the consolidated modus operandi of the Subsidiary Body on Scientific, Technical and Technological Advice,⁶ including with regard to expertise [on the impacts that the specific trends might have on the objectives of the Convention on Biological Diversity⁷][on the specific trends prioritized by the Group and,] whenever possible, [expertise from a broad range of scientific disciplines,] as well as interdisciplinary and intercultural expertise, indigenous peoples and local communities, women and youth.

2. The procedure for avoiding or managing conflicts of interest in expert groups set out in the annex to decision 14/33 of 29 November 2018 shall apply to the [multidisciplinary] Ad Hoc Technical Expert Group on Synthetic Biology.

3. The [multidisciplinary] Ad Hoc Technical Expert Group on Synthetic Biology, building on previous relevant work undertaken under the Convention and its Protocols, including the work of previous Ad Hoc Technical Expert Groups and the outcomes of the peer review included in CBD/SBSTTA/26/INF/6, shall:

(a) [Assist the Secretariat in conducting] [Consider] the literature review of the latest developments in synthetic biology[, including scientific and conceptual socioeconomic, cultural, and ethical aspects] [and other relevant materials made available by Parties,] the discussions of the Open-ended Online Forum on Synthetic biology, with a view to integrating the outcomes into the assessment step of the horizon scanning, monitoring and assessment process;

[(a bis) Consider important and outstanding issues, including:

⁶ Decision VIII/10, annex III.

⁷ United Nations, *Treaty Series*, vol. 2226, No. 30619.

(i) The operational definition of synthetic biology as it relates to the mandate and objectives of the Convention;

[(ii) A final assessment of synthetic biology against the criteria for identifying new and emerging issues related to the conservation and sustainable use of biodiversity adopted by the Conference of the Parties in its decision IX/29;]

(iii) An assessment of whether the applications below should be covered by the Cartagena Protocol on Biosafety;⁸]

(iv) The methodology to carry out impact assessments, including, economic, social and health impact assessments;

[(b) Continue the in-depth assessment, including on [their] potential [positive and negative] impacts [in the light of][on] the objectives of the Convention[:] [, ecological, socioeconomic, [including potential threats to livelihoods, the sustainable use of biodiversity,] and ethical and cultural considerations, and taking into special consideration indigenous peoples and local communities, women and youth, on]:

[(i) The potential impacts of the integration of artificial intelligence and machine learning into synthetic biology;]

[(ii) The potential impacts of self-spreading vaccines for wildlife [and health in general and human health;]

[(iii) The potential impacts of engineered gene drives to control vector-borne diseases and invasive species, while avoiding duplication of work performed by the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management;]

[(b bis) Identify benefits of synthetic biology for the implementation of the three objectives of the Convention and the Kunming-Montreal Global Biodiversity Framework;⁹]

[(b ter) Provide advice on capacity-building and development needs of Parties for research, development and assessment of synthetic biology that could be included in the thematic plan of action;]

(c) Provide advice in potential modalities for improving the monitoring of the most recent technological development in synthetic biology;

[(c bis) Review existing relevant technical information regarding synthetic biology analysed under relevant processes and by relevant organizations and revise the terms of reference on the basis of the findings, without duplication of work undertaken under other processes;]

(d) Prepare a [summary] report of the outcome of its work [and make recommendations] to the Subsidiary Body on Scientific, Technical and Technological Advice.

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⁸ United Nations, *Treaty Series*, vol. 2226, No. 30619.

⁹ Decision 15/4, annex.