



## Convention on Biological Diversity

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SUBSIDIARY BODY ON SCIENTIFIC,  
TECHNICAL AND TECHNOLOGICAL ADVICE

Twenty-fourth meeting

Online, 3 May – 9 June 2021

Agenda item 4

### SYNTHETIC BIOLOGY

#### Draft recommendation submitted by the Chair

1. The Subsidiary Body on Scientific, Technical and Technological Advice *recommends* that the Conference of the Parties at its fifteenth meeting adopt a decision along the following lines:

*The Conference of the Parties,*

*Recalling* decisions XII/24, XIII/17 and 14/19 of the Conference of the Parties which provided guidance and mandated work on synthetic biology in relation to the three objectives of the Convention,

*Also recalling* Subsidiary Body on Scientific, Technical and Technological Advice recommendation 23/7, paragraph 2, by which the Subsidiary Body deferred consideration of the submission that synthetic biology should be classified as a new and emerging issue to its twenty-fourth meeting,

*Noting* the analysis on the relationship between synthetic biology and the criteria for new and emerging issues established in decision IX/29 performed by the Ad Hoc Technical Expert Group on Synthetic Biology,<sup>1</sup>

*Recalling* decision 14/19, in which it agreed that broad and regular horizon scanning, monitoring and assessing of the most recent technological developments is 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 and those of the Cartagena Protocol on Biosafety and the Nagoya Protocol on Access and Benefit-sharing,

*Also recalling* paragraph 7 of decision 14/19, emphasizing the need for a coordinated, complementary and non-duplicative approach on issues related to synthetic biology under the Convention and its protocols, as well as among other conventions and relevant organizations and initiatives,

[*Noting* the relevance of digital sequence information for synthetic biology, recalling decision 14/20 on digital sequence information and ongoing discussions and noting also the need for a coordinated, complementary and non-duplicative approach on issues related to digital sequence information],

<sup>1</sup> CBD/SBSTTA/24/4/Rev.1, annex I, sect. VI.

*[Recalling paragraphs 9 to 11 of decision 14/19, and calling upon Parties and other Governments, taking into account the current uncertainties regarding engineered gene drives, to apply a precautionary approach, in accordance with the objectives of the Convention],*

*Recognizing* the importance of capacity-building, knowledge sharing, technology transfer and financial resources for addressing issues related to synthetic biology,

*Welcoming* the outcomes of the meeting of the Ad Hoc Technical Expert Group on Synthetic Biology held in Montreal, Canada, from 4 to 7 June 2019,<sup>2</sup>

**A. Considerations for new and emerging issues and associated criteria**

1. *Recognizes* the various challenges experienced by the Ad Hoc Technical Expert Group on Synthetic Biology in performing analysis on the relationship between synthetic biology and the criteria for new and emerging issues;

2. *Also recognizes* that decisions X/13, XI/11, XII/24, XIII/17 and 14/19 mandated work on synthetic biology under the Convention, and that the results of the application of the criteria as set out in decision IX/29 to the issue of synthetic biology have been inconclusive in determining whether synthetic biology is a new and emerging issue or not [and decides not to require further analysis on whether synthetic biology is a new and emerging issue] [while keeping the Convention's work on synthetic biology under review][recognizing that synthetic biology has not been determined to be [or not to be] a new and emerging issue];

3. *Notes* that this should not be seen as setting a precedent for future processes for treating proposed new and emerging issues;

**B. Process for broad and regular horizon scanning monitoring and assessment**

4. *Establishes* a process for broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology as set out in section A of the annex; [and for an [initial] [period of] [two cycles during two consecutive intersessional periods;] [one intersessional period;]]

5. *[Establishes* a multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology to support the process for broad and regular horizon scanning, monitoring and assessment in accordance with the terms of reference contained in section B of the annex;]

6. *Decides* that the trends in new technological developments in synthetic biology identified by the Ad Hoc Technical Expert Group on Synthetic Biology<sup>3</sup> [and the multidisciplinary Ad Hoc Technical Expert Group] will inform the [initial] horizon scanning, monitoring and assessment [of the following intersessional period;]

7. *Invites* Parties, other Governments, indigenous peoples and local communities, and relevant organizations to submit to the Executive Secretary information relevant to the trends referred to in paragraph 6 above to inform the horizon scanning, monitoring and assessment;

8. *Calls upon* Parties and other stakeholders to facilitate broad international cooperation, technology transfer, knowledge sharing, including through the Biosafety Clearing-House, for products of synthetic biology that are considered to be living modified organisms, and capacity-building on synthetic biology, taking into account the needs of Parties and of indigenous peoples and local communities;

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

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<sup>2</sup> Ibid., annex I.

<sup>3</sup> Ibid., annex I, sect. I.

(a) To convene online discussions of the Open-ended Online Forum on Synthetic Biology [to support the work of the multidisciplinary Ad Hoc Technical Expert Group] as well as the overall process outlined in paragraph 4 above;

(b) To synthesize the information submitted in response to paragraph 7 above as well as the information provided through the online discussions of the Open-ended Online Forum on Synthetic Biology to inform the deliberations of [the multidisciplinary Ad Hoc Technical Expert Group][ the Subsidiary Body on Scientific, Technical and Technological Advice];

(c) [To convene at least one meeting of the multidisciplinary Ad Hoc Technical Expert Group to work according to the annex, section B;]

(d) To prepare reports on the outcomes and operation of the horizon scanning process referred to in paragraph 4 above and to submit those reports for peer review to support the review of the effectiveness of the process by the Subsidiary Body on Scientific, Technical and Technological Advice at its meetings [prior to the sixteenth [and seventeenth] meetings of the Conference of the Parties respectively;]

(e) To facilitate international cooperation, promote and support capacity-building, technology transfer and knowledge-sharing, regarding synthetic biology, taking into account the needs of Parties and of indigenous peoples and local communities;

(f) To continue to ensure the full and effective participation of indigenous peoples and local communities in the discussions and in the work on synthetic biology under the Convention, in accordance with decision X/40 [and with a human rights approach;]

10. *Requests* the Subsidiary Body on Scientific, Technical and Technological Advice to consider the outcomes of the horizon scanning process [contained in the report of the multidisciplinary Ad Hoc Technical Expert Group],<sup>4</sup> and make recommendations for the consideration of the Conference of the Parties at its [sixteenth [and seventeenth] meetings] and, as appropriate, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its [eleventh [and twelfth] meetings] and the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol at its [fifth [and sixth] meetings];

11. *Also requests* the Subsidiary Body on Scientific, Technical and Technological Advice to consider the interim and final reports on effectiveness of the horizon scanning process established in paragraph 4 above, at its meetings prior to the [sixteenth [and seventeenth]] meetings of the Conference of the Parties, respectively, and to make a recommendation [on the need to extend that process];

12. *Requests* the Executive Secretary to continue pursuing cooperation with other regional and international organizations, conventions and initiatives, including academic and research institutions, on issues related to synthetic biology.

2. The Subsidiary Body on Scientific, Technical and Technological Advice *recommends* that the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol and the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol each take note of the decision of the Conference of the Parties on this matter.

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<sup>4</sup> Ibid., sect. V.

*Annex*

**BROAD AND REGULAR HORIZON SCANNING, MONITORING AND ASSESSMENT OF THE MOST RECENT TECHNOLOGICAL DEVELOPMENTS IN SYNTHETIC BIOLOGY**

**A. Process for the horizon scanning, monitoring and assessment**

1. The process for broad and regular horizon scanning, monitoring and assessment (hereinafter “the process”) consists of the following steps:
  - (a) Information gathering;
  - (b) Compilation, organization and synthesis of information;
  - (c) Assessment;
  - (d) Reporting on outcomes.
2. [For each step, the coordinating actors, other actors and main considerations for the process are as set out in table 1.]
3. The Subsidiary Body on Scientific, Technical and Technological Advice shall review the outcomes of the process and make recommendations on technological developments in synthetic biology and their potential positive and negative impacts for the objectives of the Convention. [including social, economic and cultural impacts as well as related ethical issues].
4. The effectiveness of the process shall be reviewed [regularly] [~~every four years~~] [in accordance with] decision by Conference of Parties.

**B. [Terms of reference for the multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology to support the process for broad and regular horizon scanning, monitoring and assessment]**

1. The multidisciplinary Ad Hoc Technical Expert Group, building on the previous relevant work under the Convention and its Protocols, including the work of the previous Ad Hoc Technical Expert Groups on Synthetic Biology, shall:
  - [(a) Assess, vis-à-vis the three objectives of the Convention and its Protocols [and making use of tools and approaches to enable a participatory assessment process], based on the results of steps in A1(a) and A1(b) above; (i) new technological developments and applications of synthetic biology, and (ii) state of knowledge on potential impacts on biodiversity and the environment of current and future synthetic biology applications, taking into account impacts on human, animal and plant health, and cultural and socioeconomic issues;]
  - (b) [Make use of tools and approaches to enable a participatory assessment process] to review and assess the information gathered through the process for broad and regular horizon scanning, monitoring and assessment and, on this basis, consider technological developments in synthetic biology and their potential positive and negative impacts [and their implications] for the objectives of the Convention;
  - [(c) Identify a methodology for the assessment of the compiled information, based on [scientific evidence] [best scientific knowledge and other knowledge system], considering the availability and accessibility of tools and expertise;]
  - (d) [Identify trends and issues, [including categories of synthetic biology that may need to be [prioritized][identified] or] that may need to continue to be considered in [subsequent cycles,] as well as additional issues that may be regarded as priorities [vis-à-vis the three objectives of the Convention] [for the next intersessional period;]]
  - [(e) Identify capacity-building, technology transfer and knowledge sharing needs based on priorities determined by Parties on issues related to synthetic biology and in the light of the outcomes of the horizon scanning process;]

[(f) Evaluate the availability of tools to detect, identify and monitor the [organisms, components and products] [potential positive and negative impacts] of synthetic biology;]

(g) Prepare a report on the outcomes of its assessment to be submitted to the Subsidiary Body on Scientific, Technical and Technological Advice;

(h) Make recommendations to the Subsidiary Body on Scientific, Technical and Technological Advice on specific issues that may require further consideration by the Conference of the Parties and/or the Parties to the Cartagena Protocol and the Parties to the Nagoya Protocol.

1 *alt.* [The Subsidiary Body on Scientific, Technical and Technological Advice shall:

(a) Review and assess the information gathered through the process and, on this basis, consider technological developments in synthetic biology and the potential negative and positive impacts vis-à-vis the objectives of the Convention;

(b) Identify issues that may need to continue to be considered, as well as additional issues that may be considered priorities in the next intersessional period;

(c) Prepare conclusions and recommendations on technological development in synthetic biology and their potential positive and negative impacts for the objectives of the convention].

2. The multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology will be constituted for an initial duration of two intersessional periods and according to section H of the consolidated modus operandi of the Subsidiary Body on Scientific, Technical and Technological Advice, including, whenever possible, expertise from a broad range of disciplines, as well as interdisciplinary and intercultural expertise, indigenous peoples and local communities. The continuing need for the Group will be assessed in the light of the overall assessment of the effectiveness of the horizon scanning process.

3. The procedure for avoiding or managing conflicts of interest in expert groups set out in the annex to decision 14/33 shall apply to the Multidisciplinary Technical Expert Group.

4. The multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology will work through a combination of face-to-face meetings, held physically and/or online, supported, as needed by online discussions.]

**[Table 1. Process for broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology**

Process and steps		Coordinating actors	Other actors and considerations
<b>Horizon scanning, monitoring and assessment process</b>	<b>(a) Information gathering</b>	<ul style="list-style-type: none"> <li>Secretariat, with the support of consultants as necessary</li> </ul>	<ul style="list-style-type: none"> <li>Possible mechanisms include submissions of information through notifications; outreach to relevant institutions and intergovernmental organizations; online forums; collaborative activities with regional and national assessment platforms; and other existing tools, such as national reports, and the clearing-house mechanism.</li> <li>Seek inputs from a diverse range of actors, including other organizations working on synthetic biology, facilitate engagement of indigenous peoples and local communities, among others, and build on the work done by other</li> </ul>

Process and steps	Coordinating actors	Other actors and considerations
		<p>relevant horizon scanning or technology assessment processes.</p> <ul style="list-style-type: none"> <li>Some issues identified during one cycle may need to continue to be considered in subsequent cycles, with consistency in the way the process is carried out with a view to obtaining results that could be comparable over time.</li> </ul>
<b>(b) Compilation, organization and synthesis of information</b>	<ul style="list-style-type: none"> <li>Secretariat, with the support of consultants as necessary</li> </ul>	<ul style="list-style-type: none"> <li>Use digital tools for dissemination of information and feedback, inter alia, by webinars, directed to Parties, and other stakeholders.</li> <li>The information compiled and synthesized will be made available, including through the clearing-house mechanism.</li> </ul>
<b>(c) Assessment</b>	<ul style="list-style-type: none"> <li>Multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology</li> <li>Subsidiary Body on Scientific, Technical and Technological Advice (approval of the main conclusions of the process)</li> </ul>	<ul style="list-style-type: none"> <li>Expertise from a broad range of disciplines, as well as interdisciplinary and intercultural expertise necessary.</li> <li>Face-to-face meetings with support of online mechanisms.</li> <li>Make use of tools and approaches to enable a participatory assessment process.</li> <li>Selection of experts for the multidisciplinary Ad Hoc Technical Expert Group will be undertaken in accordance with the consolidated modus operandi of the Subsidiary Body on Scientific, Technical and Technological Advice.</li> <li>Key actors in the horizon scanning, monitoring and assessment process, including consultants and members of the multidisciplinary Ad Hoc Technical Expert Group, will be subject to the procedure for avoiding or managing conflicts of interest set out in decision 14/33.</li> <li>Assessment step may be supported by, among other things, commissioning technology assessment studies.</li> </ul>
<b>(d) Reporting on outcomes</b>	<ul style="list-style-type: none"> <li>Multidisciplinary Ad Hoc Technical Expert Group reports to Subsidiary Body on</li> </ul>	<ul style="list-style-type: none"> <li>External review of the draft outcomes.</li> <li>Communicate the outputs effectively to a broad range of potential users, in a</li> </ul>

<b>Process and steps</b>		<b>Coordinating actors</b>	<b>Other actors and considerations</b>
		<p>Scientific, Technical and Technological Advice.</p> <ul style="list-style-type: none"> <li>• Subsidiary Body on Scientific, Technical and Technological Advice reports to Conference of the Parties (and/or the meeting of the Parties to the Cartagena Protocol, the meeting of the Parties to the Nagoya Protocol) on the outcome of step (a), (b) and (c).</li> </ul>	<p>culturally appropriate format and languages.</p>
<b>Use of outcomes in support of decision-making</b>		<ul style="list-style-type: none"> <li>• Subsidiary Body on Scientific, Technical and Technological Advice (review of outcomes, preparation of conclusions and recommendations)</li> <li>• Conference of the Parties and/or the meeting of the Parties to the Cartagena Protocol, the meeting of the Parties to the Nagoya Protocol (decision-making)</li> <li>• Parties and others, including other United Nations bodies</li> </ul>	
<b>Review of process and its effectiveness</b>		<ul style="list-style-type: none"> <li>• Conference of the Parties on basis of periodic review by Subsidiary Body on Scientific, Technical and Technological Advice</li> </ul>	