Synthetic biology

Draft decision submitted by the Chair of Working Group II

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,

Recalling also 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,

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,

Recalling also 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 on genetic resources and ongoing discussions and noting also the need for a coordinated, complementary and non-duplicative approach on issues related to digital sequence information on genetic resources,

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,

1 CBD/SBSTTA/24/4/Rev.1, annex I, sect. VI.
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; 2

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;

3. Notes that this should not be seen as setting a precedent regarding synthetic biology as a permanent item under the Convention, nor on the permanent adoption of procedures established in this decision, such as horizon scanning, nor on future processes to consider any 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 to the present decision and agrees to start its work for 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 and the multidisciplinary Ad Hoc Technical Expert Group will inform the 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:

   (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;

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2 Ibid., annex I.
3 Ibid., annex I, sect. I.
(c) To convene at least one meeting of the multidisciplinary Ad Hoc Technical Expert Group to work according to the terms of reference as set out in section B of the annex;

(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 meeting prior to the sixteenth meeting of the Conference of the Parties;

(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;

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, and to make recommendations for consideration by the Conference of the Parties at its sixteenth meeting and, as appropriate, by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its eleventh meeting and by the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol at its fifth meeting;

11. Also requests the Subsidiary Body on Scientific, Technical and Technological Advice to consider the report on effectiveness of the horizon scanning process established in paragraph 4 above, at its meeting prior to the sixteenth meeting of the Conference of the Parties, 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.

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. The coordinating actors for the steps 1(a) and 1(b) of the process will be the Secretariat with the support of consultants, as appropriate; for 1(c) the multidisciplinary Ad Hoc Technical Expert Group and the Subsidiary Body on Scientific, Technical and Technological Advice; for 1(d) the multidisciplinary Ad Hoc Technical Expert Group, the Subsidiary Body on Scientific, Technical and Technological Advice, Conference of Parties, and the Conference of Parties serving as a meeting of the Parties to the Cartagena Protocol on Biosafety and the Conference of Parties serving as a meeting of the Parties to the Nagoya Protocol. The actors involved in the process will, when possible, make use of digital tools for disseminating and collecting information, including among others, submissions of information; outreach to relevant institutions and organizations; online fora; and collaborative activities, as appropriate.

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.
4. The effectiveness of the process shall be considered by the Conference of the 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) Make use of existing tools and approaches to enable a participatory 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 vis-à-vis the objectives of the Convention, taking into account the 2019 report of the AHTEG on synthetic biology⁴, as appropriate;

   (b) Identify and prioritize trends and issues regarding developments of synthetic biology that need to be considered vis-à-vis the three objectives of the Convention;

   (c) 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;

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

   (e) 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 Conference of Parties serving as a meeting of the Parties to the Cartagena Protocol and Conference of Parties serving as a meeting of the Parties to the Nagoya Protocol.

2. The multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology will be convened to start its work for one intersessional period 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 scientific disciplines, as well as interdisciplinary and intercultural expertise, indigenous peoples and local communities.

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 Ad Hoc 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.