

CONVENTION ON BIOLOGICAL DIVERSITY (Convention)
15th Meeting of the Parties (COP15)
7-19 December 2022, Montreal, Canada
Synthetic Biology

The Global Industry Coalition (GIC)¹ continues to have significant concerns regarding the ongoing negotiations on synthetic biology under the Convention and its Protocols. Parties will consider a draft decision on synthetic biology at COP15 in Montreal Canada, 7-19 December 2022. The draft decision proposes to continue and expand the synthetic biology work program through a proposed horizon scanning process. The GIC is of the view that this horizon scanning process should be limited to one intersessional period only, and should focus solely on information gathering, compilation, organization and synthesis of this information for SBSTTA to consider at its 25th meeting. Any assessment or recommendations resulting from this horizon scanning work should be completed at a meeting of the SBSTTA with its recommendations to be considered by the 16th Conference of the Parties.

A. Background

During 24th meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA-24), SBSTTA members agreed to draft recommendations on synthetic biology which, *inter alia*, propose a process for extensive horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology, and establish a role for yet another Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology to support this process. The recommendations also provide extensive terms of reference for the AHTEG. Parties will consider these recommendations in a draft decision at COP15. What follows are the GIC's views on the proposed draft decision.

B. GIC Views on the Draft Decision on Synthetic Biology for COP15

The GIC supports the collection and sharing of objective, scientifically-sound information among Parties in a transparent and inclusive manner. However, the GIC does not support proposals to establish yet another AHTEG for this work, or its formalization through a poorly defined "horizon scanning, monitoring and assessment process". While it was agreed by the Parties in decision 14/19 that a process for "broad and regular horizon scanning, monitoring and assessing" was needed, there remains no agreement on how the process should be performed or by whom.

We also point out that both Decision 14/19 and the COP15 draft decision recognize that an analysis of synthetic biology against the "new and emerging" (NEI) issue criteria (set out in Decision IX/29) remains incomplete. We emphasize that the content of any ongoing work on synthetic biology, including the proposed horizon scanning process, should be focused on informing such an analysis. Our continued insistence on this point is simply due to the NEI criteria providing a framework for identifying actual issues related to the conservation and sustainable use of biological diversity posed by synthetic biology applications that justify the time and resources of the Parties. The Convention's work on this topic must be kept under review at each COP and we do not support draft text stating that further NEI analysis is not required.

Open exchange of information has been in place for synthetic biology under the Convention since 2010, with numerous requests for information submissions and online discussions on a range of (often duplicative) topics that have already led to a significant body of information being readily available. This effort can continue without being formalized in an official horizon scanning, monitoring and assessment process. Further, conducting this work through an AHTEG risks a limited, and less transparent result. The proposed draft decision already allows for a sufficient number of mechanisms to supplement the existing body of information in this area, including submissions relevant to the trends in synthetic biology invited from all stakeholders (paragraph B(7) of the draft decision), information-exchange through the Biosafety Clearing-house (paragraph B(8)), continuation of the

¹ The Global Industry Coalition (GIC) for the Cartagena Protocol on Biosafety receives input and direction from trade associations representing thousands of companies from all over the world. Participants include associations representing and companies engaged in a variety of industrial sectors such as plant science, seeds, agricultural biotechnology, food production, animal agriculture, human and animal health care, and the environment.

Open-ended Online Forum on Synthetic Biology (paragraph B(9)(a)), and additional work by the Convention Secretariat (paragraphs B(9)(b), (d), (e) and (f)). There is no demonstrated need to establish another AHTEG to conduct this horizon scanning work.

Lastly, the draft decision already allows for SBSTTA to consider the results of the horizon scanning process to make recommendations for consideration by the Parties at their next meeting, and Parties should support a decision that emphasizes the primary role of SBSTTA on this issue – rather than an AHTEG with limited representation and participation - as this clearly lies within its scope of work. Similarly, SBSTTA should review this work after one intersessional cycle, and make recommendations to COP16 if a subsequent cycle is warranted. A recommendation for two cycles – effectively a minimum of four years – without review risks wasted resources and attention that could focus on more important priorities, like implementation of the ambitious targets of the Post-2020 Global Biodiversity Framework.

For these reasons, the GIC is of the view that the Parties should agree to recommendations for COP-15 that:

- (a) **Propose the horizon scanning, monitoring and assessment process be undertaken for a period of one intersessional cycle, with the need for a second intersessional cycle to be decided by the sixteenth meeting of the Conference of the Parties (COP-16); and**
- (b) **Recommend that SBSTTA is the body that will review, assess and make recommendations on the reports of the outcomes and operation of the horizon scanning, monitoring and assessment process that are prepared by the Secretariat; or**
- (c) **As an alternative to (b) above, recommend that an AHTEG could only be convened for one intersessional period, and with the limited horizon scanning roles of information gathering, and compilation, organization and synthesis of this information, with SBSTTA having the responsibility for undertaking an assessment of this work and developing recommendations for the Parties to consider at COP-16.**
- (d) **Recommend that the Convention's work on synthetic biology is reviewed at each meeting of the Conference of Parties**

C. COP15 Draft Decision Revised

Please see the Annex attached for a full red-lined edit of the COP15 draft decision on synthetic biology.

ITEM 27. SYNTHETIC BIOLOGY

The following is taken from recommendation 24/4 of the Subsidiary Body on Scientific, Technical and Technological Advice

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 consideration of the relationship between synthetic biology and the criteria for new and emerging issues established in decision IX/29 undertaken by the Ad Hoc Technical Expert Group on Synthetic Biology,²

Recalling paragraph 3 of 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 on genetic resources for synthetic biology, and recalling decision 14/20 and ongoing discussions],

[*Recalling* paragraph 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 2019,³

A. Considerations for new and emerging issues and associated criteria

1. *Recognizes* that the Ad Hoc Technical Expert Group on Synthetic Biology had a range of views on the relationship between synthetic biology and the criteria set out in decision IX/29, paragraph 12, 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 previous application of the criteria as set out in decision IX/29 by the Subsidiary Body on Scientific, Technical and Technological Advice was inconclusive in determining whether synthetic biology is a new and emerging issue or not;

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

³ Ibid., annex I.

3. *Decides* that the Convention’s work on synthetic biology is reviewed at each meeting of the Conference of Parties, and *notes* that the Convention’s ongoing work on synthetic biology 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

5. *Decides* that the horizon scanning, monitoring and assessment process will be undertaken for a period of one intersessional cycle, with the need for a second intersessional cycle to be decided by the sixteenth meeting of the Conference of the Parties;

6. *Decides* that the trends in new technological developments in synthetic biology identified by the Ad Hoc Technical Expert Group on Synthetic Biology⁴ will inform the initial horizon scanning, monitoring and assessment process;

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 process;

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 horizon scanning, monitoring and assessment 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 Subsidiary Body on Scientific, Technical and Technological Advice;

(d) To prepare reports on the outcomes and operation of the horizon scanning, monitoring and assessment 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 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;

⁴ Ibid., annex I, sect. I.

(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 effectiveness of the horizon scanning, monitoring and assessment process established in paragraph 4 above, and make a recommendation on the need to extend it for a second intersessional cycle for the consideration of the sixteenth meeting of the Conference of the Parties;

11. *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

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. .

4.

A.

- (b) ;
- (g) .

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, and on this basis:

(i) Identify issues that require assessment as a new and emerging issue according to the separate process established in dec IX/29.

(ii) Identify issues that may need further consideration through the process in a second intersessional period;

(c) Prepare recommendations for consideration by the Conference of the Parties .

1. .

2. .

3.

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
Horizon scanning, monitoring and assessment process	(a) Information gathering	<ul style="list-style-type: none"> • Secretariat, with the support of consultants as necessary 	<ul style="list-style-type: none"> • 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. • Seek inputs from a diverse range of actors, including other organizations working on synthetic biology and the scientific community, facilitate engagement of indigenous peoples and local communities, among others, and build on the work done by other relevant horizon scanning or technology assessment processes. •
	(b) Compilation, organization and synthesis of information	<ul style="list-style-type: none"> • Secretariat, with the support of consultants as necessary 	<ul style="list-style-type: none"> • Use digital tools for dissemination of information and feedback, inter alia, by webinars, directed to Parties, and other stakeholders. • The information compiled and synthesized will be made available, including through the clearing-house mechanism. • Any work commissioned (e.g. consultants) to support the process will need to be peer-reviewed.
	(c) Assessment	<ul style="list-style-type: none"> • Subsidiary Body on Scientific, Technical and Technological Advice 	<ul style="list-style-type: none"> • The assessment step is detailed in paragraph 3 above. • . • . • • •
	(d) Reporting on outcomes	<ul style="list-style-type: none"> • • Subsidiary Body on Scientific, Technical and Technological 	<ul style="list-style-type: none"> • •



Process and steps		Coordinating actors	Other actors and considerations
		Advice reports to Conference of the Parties on the outcomes of steps (a), (b) and (c).	
Use of outcomes in support of decision-making		<ul style="list-style-type: none"> • Subsidiary Body on Scientific, Technical and Technological Advice (review of outcomes, preparation of recommendations) • 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) • Parties and others, including other United Nations bodies (where applicable) 	
Review of process and its effectiveness		<ul style="list-style-type: none"> • Conference of the Parties at their sixteenth meeting, on basis of review by Subsidiary Body on Scientific, Technical and Technological Advice 	

