



EUROPEAN COMMISSION

Brussels, 24 May 2021

FORMAL SESSION IN OF THE 24TH MEETING OF THE SUBSIDIARY BODY ON SCIENTIFIC, TECHNICAL AND TECHNOLOGICAL ADVICE

STATEMENT ON BEHALF OF THE EUROPEAN UNION

AGENDA ITEM 4 – SYNTHETIC BIOLOGY

Thank you, Chair for giving me the floor to speak on behalf of the European Union.

Distinguished Delegates

Dear colleagues

The European Union wishes to confirm the statement delivered at the informal session of SBSTTA, last February. In addition, we would like to raise the following points.

Regarding the format of the group established to support the horizon scanning, monitoring and assessment, the European Union's initial option would be a multidisciplinary AHTEG. We propose to refer to a "multidisciplinary Ad Hoc Technical Expert Group" as this already clarifies its modus operandi. However, we are ready to evaluate any other format, provided it guarantees the necessary expertise and efficient operation.

Regarding the process of horizon scanning, monitoring and assessment, we believe it is important to ensure its effectiveness and envisage the possibility for improvements, if needed, for the next intersessional period. Therefore, the European Union proposes an interim report on the effectiveness of the process provided by the Executive Secretary to the SBSTTA at its 26th meeting. This would allow for a timely adaptation of the process, if recommended by the SBSTTA and decided by the sixteen Conference of the Parties.

In view of clarifying the aim and the meaning of technology assessments the European Union proposes to specify that they consist of studies on potential positive and negative environmental impacts taking into account human, animal and plant health as well as cultural and socioeconomic impacts.

Finally, with respect to evaluating synthetic biology against the criteria of new and emerging issues as listed in paragraph 12 of decision IX/29, the European Union takes note of the analysis of AHTEG and recognises the various challenges identified. The European Union does not see the necessity to go beyond the work performed so far by AHTEG and SBSTTA-22.

Together with the statement, the European Union will submit amendments to the draft recommendation.

Thank you very much, Chair.

Proposed amendments to the draft recommendations

39. The Subsidiary Body on Scientific, Technical and Technological Advice may wish to recommend that the Conference of the Parties at its fifteenth meeting adopt a decision along the following lines:

The Conference of the Parties,

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,

Further 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,

Further recalling paragraphs 9 to 11 of decision 14/19, and recalling upon Parties and other Governments, to take into account the current uncertainties regarding engineered gene drives, including when used for biodiversity conservation purposes, to apply a precautionary approach in accordance with the objectives of the Convention,

Noting the analysis on needs and priorities for further guidance made by the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management,

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 2019,¹

0. Recognizes the work of the Ad Hoc Technical Expert Group on Synthetic Biology in analyzing and describing relevant trends of synthetic biology;

0bis. Takes note of the analysis on the relationship between synthetic biology and the criteria for new and emerging issues of the Ad Hoc Technical Expert Group on Synthetic Biology, and also recognizes the various challenges experienced by the Ad Hoc Technical Expert Group on Synthetic Biology in performing this analysis;

0ter. Takes note of the conclusion of the Ad Hoc Technical Expert Group on Synthetic Biology that most living organisms already developed or currently under research and development through techniques of synthetic biology, including organisms containing engineered gene drives, fall under the definition of living modified organisms as per the Cartagena Protocol;

1. *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 annex II, section A;

1 bis. Decides that this process should be periodic as synthetic biology is rapidly evolving, starting with the first two cycles in the intersessional periods between the next two successive Conferences of the Parties;

2. *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 annex II, section B;

3. *Decides* that the trends in new technological developments in synthetic biology identified by the Ad Hoc Technical Expert Group on Synthetic Biology² will inform the horizon scanning, monitoring and assessment for the ~~next biennium~~ **intersessional period preceding the sixteenth meeting of the Conference of the Parties; and decides that trends in new technological developments in synthetic biology identified by the Multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology will inform the horizon scanning, monitoring and assessment for the intersessional period preceding the seventeenth meeting of the Conference of the Parties;**

4. *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**

¹ See Annex 1

² See paragraph 5 of annex I of CBD/SYNBIO/AHTEG/2019/1/3

paragraph 3 to inform the horizon scanning, monitoring and assessment;

5. *Requests* the Executive Secretary, [subject to the availability of resources]:

(a) To commission ~~technology assessments~~ **studies on the potential positive and negative environmental impacts, taking into account human, animal and plant health, and cultural and socioeconomic impacts** on the trends identified **referred to in paragraph 3 above** by the ~~Ad Hoc Technical Expert Group on Synthetic Biology~~, **vis-à-vis the three objectives of the Convention and its Protocols;**

(b) To convene online discussions **of the Open-ended Online Forum on Synthetic Biology** to support the ~~work of the Multidisciplinary Technical Expert Group as needed~~ **overall process outlined in paragraph 1 above;**

(c) To synthesize the information submitted in response to paragraph 4 above as well as the information provided through the online discussions **of the Open-ended Online Forum on Synthetic Biology;**

(d) To convene at least one meeting of the Multidisciplinary **Ad Hoc** Technical Expert Group **prior to the twenty-sixth and one meeting prior to the twenty- eighth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice** to consider the ~~technology assessments~~ **studies** and the synthesis of information referred to in subparagraphs (a) ~~and to~~ (c) above, and to review the components, products and organisms being developed through the trends referred to in paragraph 3 above and consider their possible impacts on the objectives of the Convention;

5bis. Requests the Executive Secretary to give an interim report to the Subsidiary Body on Scientific, Technical and Technological Advice at its twenty-sixth meeting and a concluding report at its twenty-eighth meeting on the effectiveness of the process for broad and regular horizon scanning, monitoring and assessment of technological developments in synthetic biology;

6. *Requests* the Subsidiary Body on Scientific, Technical and Technological Advice to consider the outcomes of the work **outlined in paragraph 1 above** ~~of the Multidisciplinary Technical Expert Group~~ and make recommendations for the consideration of the Conference of the Parties at its sixteenth **and seventeenth** meeting and, as appropriate, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its eleventh **and twelfth** meeting and the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol at its fifth **and sixth** meeting;

7. *Also requests* the Executive Secretary to continue pursuing cooperation with other organizations, conventions and initiatives, including academic and research institutions, on issues related to synthetic biology.

40. The Subsidiary Body on Scientific, Technical and Technological Advice may also wish to recommend 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.

Annex II

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 consists of the following steps:

- (a) **Gathering of** information ~~gathering~~ **relevant to Annex II.B.1:**
- (b) Compilation, organization and synthesis of information;
- (c) Assessment;
- (d) Reporting on outcomes.

These steps will be repeated for the intersessional periods before the sixteenth and seventeenth meeting of the Conference of the Parties.

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 horizon scanning, monitoring and assessment and prepare conclusions and recommendations on technological developments in synthetic biology and their potential positive and negative impacts for the objectives of the Convention.

4. The **Subsidiary Body on Scientific, Technical and Technological Advice shall review, based on the report by the Executive Secretary, the effectiveness of the process for broad and regular horizon scanning, monitoring and assessment of technological developments in synthetic biology shall be reviewed four years following its adoption and submit conclusions and recommendations on the periodicity of the horizon scanning, monitoring and assessment process and its procedures to the Conference of the Parties at its seventeenth meeting.**

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 shall:

(a new) Assess, vis-à-vis the three objectives of the Convention and its Protocols, based on the results of steps a) and b) of the process outlined in Annex II, chapter A, and building on the previous relevant work under the Convention and its Protocols:

- (i) New technological developments in synthetic biology and synthetic biology applications that are in early stages of research and development,**
- (ii) the state of knowledge on the potential impacts on biodiversity and the environment of current and future synthetic biology applications, taking into account human, animal and plant health, and cultural and socioeconomic impacts,**
- (iii) whether any living organism developed through new developments in synthetic biology fall outside the definition of living modified organisms as per the Cartagena Protocol;**

- (a) ~~Employing~~ **Make use of** tools and approaches to enable a participatory assessment process; ~~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 implications for the objectives of the Convention;~~
- (b) Identify **trends and** issues identified during one cycle that may need to continue to be considered in subsequent cycles, as well as additional **trends and** issues that may be considered priorities for the next intersessional period;
- (c) Prepare a report on the outcomes of its assessment to be presented to the Subsidiary Body on Scientific, Technical and Technological Advice;
- (d) 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.

2. The Multidisciplinary **Ad Hoc** Technical Expert Group on Synthetic Biology will be constituted **for the following two intersessional periods and** according to section H of the consolidated modus operandi of 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.
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 **of the Open-ended Online Forum on Synthetic Biology.**

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

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"> • <u>Take into account the trends referred to in paragraph 3 of the recommendation.</u> • Possible mechanisms include submissions of information through notifications; outreach to relevant institutions and intergovernmental organizations; online forums; commissioning <u>technology assessment exercises studies</u> and/or collaborative activities with regional and national technology assessment platforms; and other existing tools, such as national reports, and the clearing-house mechanism. • Seek inputs from a diverse range of actors, 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. • 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.
	(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"> • The information compiled and synthesized will be made available, including through the clearing-house mechanism • <u>Use digital tools for dissemination of information and feedback inter alia by webinars, directed to Parties, but also other stakeholders.</u>

Process and steps	Coordinating actors	Other actors and considerations
(c) Assessment	<ul style="list-style-type: none"> • Multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology • Subsidiary Body on Scientific, Technical and Technological Advice 	<ul style="list-style-type: none"> • Expertise from a broad range of disciplines, as well as necessary interdisciplinary and intercultural expertise necessary. • Face-to-face meetings with support of online mechanisms. • Employ Make use of tools and approaches to enable a participatory assessment process. • Selection of experts for the Multidisciplinary Technical Expert Group will be undertaken in accordance with the consolidated modus operandi of the Subsidiary Body on Scientific, Technical and Technological Advice. • Key actors in the horizon scanning, monitoring and assessment process, including consultants and members of the Multidisciplinary Technical Expert Group, will be subject to the procedure for avoiding or managing conflicts of interest set out in decision 14/33.
(d) Reporting on outcomes	<ul style="list-style-type: none"> • Multidisciplinary Ad hoc Technical Expert Group reports to Subsidiary Body on Scientific, Technical and Technological Advice • 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) 	<ul style="list-style-type: none"> • External review of the draft outcomes. • Communicate the outputs effectively to a broad range of potential users. in a culturally appropriate format and languages.

Process and steps	Coordinating actors	Other actors and considerations
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 conclusions and 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 	
Review of process and its effectiveness	<ul style="list-style-type: none"> • Conference of the Parties on basis of periodic review by Subsidiary Body on Scientific, Technical and Technological Advice 	<ul style="list-style-type: none"> • <u>The Subsidiary Body on Scientific, Technical and Technological Advice reviews the different procedures, steps and actors in the process based on the (interim) report by the Executive Secretary.</u> • <u>The first review period ends with the seventeenth meeting of the Conference of the Parties, any follow-up depends on a decision of the Conference of the Parties.</u>