

Convention on Biological Diversity Distr. GENERAL

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**ENGLISH ONLY** 

AD HOC TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY Montreal, Canada, 5-8 December 2017

## ANNOTATED PROVISIONAL AGENDA

#### INTRODUCTION

- 1. In <u>decision XIII/17</u> the Conference of the Parties to the Convention on Biological Diversity (COP), commended the work of the online forum and the Ad Hoc Technical Expert Group on Synthetic Biology (AHTEG), and welcomed the conclusions and recommendations of the report of the AHTEG as a basis for further discussion. The Conference of the Parties also acknowledged that the operational definition is a useful starting point for the purpose of facilitating scientific and technical deliberations under the Convention and its Protocols and took note that living organisms developed through synthetic biology are similar to living modified organisms as defined in the Cartagena Protocol. The Conference of the Parties further noted that the general principles and methodologies for risk assessment under the Cartagena Protocol and existing biosafety frameworks provide a good basis for risk assessment of living organisms developed through synthetic biology, but such methodologies may need to be updated and adapted.
- 2. In the same decision, the Conference of the Parties (a) extended the mandate of the current Ad Hoc Technical Expert Group on Synthetic Biology (AHTEG) in accordance with the terms of reference contained in the annex to the decision; (b) extended the open-ended online forum to support the work of the AHTEG; (c) invited Parties, other Governments, relevant international organizations, indigenous and local communities and other relevant stakeholders to submit information and supporting documentation on topics relevant to the work of the AHTEG, as outlined in paragraph 10 of the decision; and (d) requested the Executive Secretary, among other things, to continue to facilitate moderated discussions under the open-ended online forum on synthetic biology through the Biosafety Clearing-House.
- 3. In response to this decision, with a view to supporting the work of the AHTEG, the Secretariat:
- (a) Issued a notification<sup>1</sup> inviting the submission of information and documentation, as outlined in paragraph 10 of the decision. A total of 29 submissions were received, of which 15 were from Parties, 1 from a non-Party and 13 from organizations;<sup>2</sup>
- (b) Convened a series of moderated online discussions of the open-ended online forum on synthetic biology in July and September 2017;<sup>3</sup>

 $<sup>^{1} \</sup> Notification \ SCBD/SPS/DC/DA/MW/86375, available \ at \ \underline{https://www.cbd.int/doc/notifications/2017/ntf-2017-025-bs-en.pdf.}$ 

<sup>&</sup>lt;sup>2</sup> Submissions are available through the Biosafety-Clearing House at <a href="http://bch.cbd.int/synbio/submissions/2017-2018.shtml">http://bch.cbd.int/synbio/submissions/2017-2018.shtml</a>.

<sup>&</sup>lt;sup>3</sup> The discussions under the Open-ended Online Forum on Synthetic Biology are available at <a href="http://bch.cbd.int/synbio/open-ended/discussion.shtml">http://bch.cbd.int/synbio/open-ended/discussion.shtml</a>.

- (c) Compiled and synthesized the outputs of the activities referred to in subparagraphs (a) and (b) above in CBD/SYNBIO/AHTEG/2017/1/2 to facilitate the deliberations of the AHTEG.
- 4. The AHTEG on Synthetic Biology is scheduled to meet in Montreal, Canada, from 5 to 8 December 2017 to fulfil its mandate as per decision XIII/17. The report of the AHTEG will be submitted for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice at its twenty-second meeting, scheduled to be held in Montreal, Canada, from 2 to 7 July 2018. The report will also be made available through the CBD website and Biosafety Clearing-House for peer review.

#### ITEM 1. OPENING OF THE MEETING

5. A representative of the Secretariat of the Convention on Biological Diversity will open the meeting of the AHTEG on Synthetic Biology at 9:30 a.m. on Tuesday, 5 December 2017. This will be followed by self-introductions by the members of the AHTEG.

#### ITEM 2. ORGANIZATIONAL MATTERS

### 2.1. Election of officers

6. The members of the AHTEG will be invited to elect a Chairperson, or Chairpersons, and a Rapporteur for the meeting.

## 2.2. Adoption of the agenda

7. The AHTEG will be invited to consider and adopt its agenda on the basis of the provisional agenda prepared by the Executive Secretary (CBD/SYNBIO/AHTEG/2017/1/1).

## 2.3. Organization of work

- 8. The AHTEG will be invited to consider and adopt the proposed organization of its work as contained in annex I to the present document. The work will be conducted in plenary, with the establishment of working groups, as appropriate.
- 9. The working document and information documents prepared for the meeting are listed in annex II below.

## ITEM 3. SUBSTANTIVE ISSUES

- 10. The AHTEG will consider the issues set out in its terms of reference, building on its work at its first meeting and on that of the Online Forum carried out during the last intersessional period, as well as drawing upon relevant information submitted by Parties, other Governments, relevant organizations and indigenous peoples and local communities as per paragraph 2 above, and information made available through the online forum.
- 11. To facilitate its deliberations on substantive items, the AHTEG will have before it a background document (CBD/SYNBIO/AHTEG/2017/1/2) prepared by the Secretariat containing a synthesis of the submissions and a summary of the interventions from the online discussions. AHTEG members are also strongly encouraged to review the original submissions and online discussions.<sup>4</sup>
- 12. Furthermore, the AHTEG will be invited to deliberate on the basis of the common understanding that the term "components" (e.g. a naked DNA molecule) refers to parts used in a synthetic process, and

<sup>&</sup>lt;sup>4</sup> See footnotes 3 and 4.

that the term "products" (e.g. a chemical fragrance) refers to the resulting output of a synthetic biology process, and to consider "components" and "products" as non-living entities.<sup>5</sup>

## 3.1. Recent technological developments in the field of synthetic biology

- 13. In accordance with paragraph (a) of its terms of reference, the AHTEG will review recent technological developments within the field of synthetic biology to assess if the developments could lead to impacts, including unexpected and significant impacts, on biodiversity and the three objectives of the Convention, namely, the conservation of biological diversity, the sustainable use of the components of biological diversity and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.
- 14. In its deliberations, the AHTEG may take into account the submissions and discussions of the Open-ended Online Forum on this topic,<sup>6</sup> as well as ongoing research and cooperation activities on the possible benefits and potential adverse effects of organisms, components and products of synthetic biology on biodiversity to identify how positive and negative impacts of synthetic biology relate to the objectives of the Convention and its Protocols.

# 3.2. Evidence of benefits and adverse effects of organisms, components and products of synthetic biology vis-à-vis the three objectives of the Convention

- 15. In accordance with its terms of reference, the AHTEG will analyse whether concrete evidence of benefits and/or adverse effects vis-à-vis the three objectives of the Convention can be drawn from experiences with organisms, components and products that have already been developed through synthetic biology.
- 16. In its deliberations, the AHTEG will be invited to consider the evidence provided through the submissions of information and the discussions of the Open-ended Online Forum on this topic<sup>7</sup> to identify any known benefits and/or adverse effects of the organisms, components and products of synthetic biology.

# 3.3. Living organisms developed through synthetic biology that may not be regarded as living modified organisms as per the Cartagena Protocol on Biosafety

17. As per paragraph (b) of its terms of reference, the AHTEG will be invited to identify if any living organisms which have already been developed or which are currently under research and development through techniques of synthetic biology fall outside of the definition of living modified organisms as per the Cartagena Protocol on Biosafety, where:

"Living modified organisms are any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology"; and

"Modern biotechnology means the application of:

- (a) In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
  - (b) Fusion of cells beyond the taxonomic family,

<sup>&</sup>lt;sup>5</sup> Terminology agreed upon following the deliberations of the Online Forum and the AHTEG at its first meeting.

<sup>&</sup>lt;sup>6</sup> http://bch.cbd.int/synbio/open-ended/discussion/#topic1

<sup>&</sup>lt;sup>7</sup> http://bch.cbd.int/synbio/open-ended/discussion/#topic2

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection."

# 3.4. Tools to detect and monitor the organisms, components and products of synthetic biology

- 18. As per paragraph (c) of its terms of reference, the AHTEG was mandated to evaluate the availability of tools to detect and monitor the organisms, components and products of synthetic biology.
- 19. Taking into account the views expressed in the submissions and discussions of the online forum on this topic, the AHTEG will be invited to deliberate on the extent to which tools are available to detect and monitor organisms, components and products of synthetic biology are necessary and/or adequate.

# 3.5. Risk management measures, safe use and best practices for safe handling of organisms, components and products of synthetic biology

- 20. Further to paragraph (c) of its terms of reference, the AHTEG will review the information gathered on risk management measures, safe use and best practices for safe handling of organisms, components and products of synthetic biology.
- 21. The AHTEG will be invited to consider the information gathered through the submissions and the online forum on this topic<sup>9</sup> with a view to taking stock of current risk management methodologies and assessing whether or not such methodologies need to be updated and adapted for current and future developments and applications of synthetic biology.

## ITEM 4. CONCLUSIONS AND WAYS FORWARD

22. In the light of the discussions under agenda item 3 above, AHTEG members will be invited to consider the conclusions of its work and to identify possible ways forward to facilitate future discussions and actions on synthetic biology under the Convention.

#### ITEM 5. OTHER MATTERS

23. Under this item, participants may raise other matters relevant to the subject matter of the meeting.

#### ITEM 6. ADOPTION OF THE REPORT

24. AHTEG members will be invited to consider and adopt the report of the meeting on the basis of a draft to be prepared by the Rapporteur with the support of the Secretariat.

## ITEM 7. CLOSURE OF THE MEETING

25. The meeting is expected to close at 5 p.m. on Friday, 8 December 2017.

<sup>&</sup>lt;sup>8</sup> http://bch.cbd.int/synbio/open-ended/discussion/#topic3.

<sup>&</sup>lt;sup>9</sup> http://bch.cbd.int/synbio/open-ended/discussion/#topic4.

#### Annex I

#### PROVISIONAL PROGRAMME OF WORK

## Tuesday, 5 December 2017

9.30 a.m. Opening of the meeting (agenda item 1)Morning Organizational matters (agenda item 2)

Substantive issues (agenda item 3)

Recent technological developments in the field of synthetic biology (agenda item 3.1)

Afternoon Evidence of benefits and adverse effects of organisms, components and products of

synthetic biology vis-à-vis the three objectives of the Convention (agenda item 3.2)

Living organisms developed through synthetic biology that may not be regarded as living modified organisms as per the Cartagena Protocol on Biosafety (agenda

item 3.3)

## Wednesday, 6 December 2017

Morning Tools to detect and monitor the organisms, components and products of synthetic

biology (agenda item 3.4)

Risk management measures, safe use and best practices for safe handling of

organisms, components and products of synthetic biology (agenda item 3.5)

Afternoon Outstanding items

## Thursday, 7 December 2017

Morning Outstanding items

Afternoon Conclusions and ways forward (agenda item 4)

## Friday, 8 December 2017

Morning Conclusions and ways forward (agenda item 4) (continued)

Afternoon Adoption of the report (agenda item 5)

Other matters (agenda item 6)

5 p.m. Closure of the meeting (agenda item 7)

#### Annex II

## LIST OF DOCUMENTS FOR THE MEETING OF THE AD HOC TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY

## **Working documents**

CBD/SYNBIO/AHTEG/2017/1/1 Provisional agenda

CBD/SYNBIO/AHTEG/2017/1/1/Add.1 Annotations to the provisional agenda

CBD/SYNBIO/AHTEG/2017/1/2 Overview of the work done in response to

decision XIII/17

Information and other background documents

bch.cbd.int/synbio/submissions/2017-2018.shtml Submissions of views on synthetic biology by

Parties, other Governments and organizations

<u>bch.cbd.int/synbio/open-ended/discussion/</u>
Discussions under the Open-ended Online Forum

on Synthetic Biology