



**Convention on
Biological Diversity**

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SUBSIDIARY BODY ON SCIENTIFIC,
TECHNICAL AND TECHNOLOGICAL ADVICE
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Agenda item 6

**RECOMMENDATION ADOPTED BY THE SUBSIDIARY BODY ON SCIENTIFIC,
TECHNICAL AND TECHNOLOGICAL ADVICE**

XX/8. Synthetic biology

The Subsidiary Body on Scientific, Technical and Technological Advice,

Having considered the information submitted by Parties, other Governments, relevant organizations and stakeholders, the outcomes of the Open-ended Online Forum on Synthetic Biology and the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology, as well as the comments from the peer-review process, *notes* that:

(a) The following is the outcome of the deliberations of the AHTEG on Synthetic Biology from 21 to 25 September 2015 on an operational definition: “synthetic biology is a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems”;

(b) In deliberations regarding synthetic biology, the AHTEG on Synthetic Biology arrived at a common understanding that the term “components” refers to parts used in a synthetic biology process (for example, a DNA molecule), and the term “products” to the resulting output of a synthetic biology process (for example, a chemical substance);

(c) The AHTEG on Synthetic Biology discussed that organisms, components and products of synthetic biology fall within the scope of the Convention and its three objectives, and that the conservation and sustainable use of biodiversity, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources may be affected, both positively and negatively, by living organisms resulting from synthetic biology, as well as by non-living components and products of synthetic biology;

(d) Living organisms developed through current applications of synthetic biology are similar to living modified organisms as defined in the Cartagena Protocol on Biosafety, whereas non-living components (such as a DNA molecule) and products/outputs of synthetic biology (such as a chemical

substance) do not fall under the scope of the Cartagena Protocol but may be regulated under other processes;

(e) The general principles and methodology for risk assessment under the Cartagena Protocol and existing biosafety frameworks provide a good basis for risk assessment regarding living organisms developed through current and near future applications of synthetic biology, but such methodologies may need to be updated and adapted for current and future developments and applications of synthetic biology;

(f) The sharing of experience and information among Parties is crucial and needs to be encouraged, including information on actual risk assessments and gaps in existing national, regional and/or international instruments to regulate the organisms, components or products derived from synthetic biology techniques;

(g) Scientific and technological developments and information in the field of synthetic biology need to be reviewed regularly to ensure that regulatory oversight and risk assessment methodologies remain up to date;

(h) Coordination is needed among current and future processes under the Convention and its Protocols, including with the AHTEG on Risk Assessment and Risk Management and the AHTEG on Socio-economic Considerations under the Cartagena Protocol, as appropriate;

(i) Cooperation and the establishment of synergies are needed with other United Nations and international organizations, whose mandates are relevant to synthetic biology.

Recommendation to the Conference of the Parties

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

The Conference of the Parties

(a) *Reaffirms* decision XII/24, in which it urged Parties and invited other Governments to take a precautionary approach, in accordance with decision XI/11, paragraph 4;

(b) *Commends* the work of the Online Forum and the AHTEG on Synthetic Biology, and *welcomes* the conclusions and recommendations of the AHTEG as a basis for further discussion;

[(c) *Acknowledges* that the outcome of the deliberations of the AHTEG on Synthetic Biology on the operational definition is “synthetic biology is a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems”, and *notes* that additional work is required, in particular on the inclusion and exclusion criteria;]

[(c alt) *Deems it appropriate*, for the purpose of facilitating scientific and technical deliberations under the Convention and its Protocols, to use the operational definition as proposed by the AHTEG on Synthetic Biology that, “synthetic biology is a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems”];]

(d) *Takes note* of the conclusion of the AHTEG on Synthetic Biology that living organisms developed through current applications of synthetic biology, or that are currently in the early stages of research and development, are similar to living modified organisms as defined in the Cartagena Protocol;

(e) *Notes* that the general principles and methodologies for risk assessment under the Cartagena Protocol and existing biosafety frameworks provide a good basis for risk assessment regarding living organisms developed through current applications of synthetic biology, or that are currently in the early stages of research and development, but such methodologies may need to be updated and adapted for current and future developments and applications of synthetic biology;

(f) *Also notes* that it is not clear, given the current stage of knowledge, whether or not some organisms of synthetic biology, which are currently in the early stages of research and development, would fall under the definition of living modified organisms under the Cartagena Protocol, and *further notes* that there are cases in which there may be no consensus on whether the result of a synthetic biology application is “living” or not;

(g) *Invites* Parties, in accordance with their applicable domestic legislation or national circumstances, to take into account, as appropriate, socio-economic, cultural and ethical considerations when identifying the potential benefits and potential adverse effects of organisms, components and products resulting from synthetic biology techniques in the context of the three objectives of the Convention;

(h) *Encourages* Parties and *invites* other Governments and relevant organizations, in the context of the three objectives of the Convention [and taking into account, as appropriate, socio-economic, cultural and ethical considerations]:

- (i) To conduct research on the benefits and adverse effects of organisms, components and products of synthetic biology on biodiversity, with a view to filling knowledge gaps and identifying how those effects relate to the objectives of the Convention and its Protocols;
- (ii) To promote and enable public and multi-stakeholder dialogues and awareness-raising activities on the potential benefits and potential adverse effects of organisms, components and products of synthetic biology on biodiversity, involving all relevant stakeholders and with the full and effective engagement of indigenous peoples and local communities;
- (iii) To cooperate in the development of guidance and capacity-building activities with a view to assessing the potential benefits and potential adverse effects of organisms, components and products of synthetic biology and, if necessary, updating and adapting current methodologies for risk assessment of living modified organisms to organisms resulting from synthetic biology, as appropriate;

(i) *Invites* Parties, other Governments, relevant organizations and indigenous peoples and local communities to submit to the Executive Secretary information and supporting documentation on:

- (i) Research, cooperation and activities noted in paragraph (h) above;
- (ii) Evidence of benefits and adverse effects of synthetic biology vis-à-vis the three objectives of the Convention;
- (iii) Experiences in conducting risk assessments of organisms, components and products of synthetic biology, including any challenges encountered, lessons learned and implications for risk assessment frameworks;
- (iv) Examples of risk management and other measures that have been put in place to avoid or minimize the potential adverse effects of organisms, components and products of synthetic biology, including experiences of safe use and best practices for the safe handling of organisms developed through synthetic biology;

- (v) Regulations, policies and guidelines in place or under development which are directly relevant to synthetic biology;
- (j) *Decides* to extend the mandate of the current AHTEG on Synthetic Biology in accordance with the terms of reference attached hereto and also to contribute to the completion of the assessment as requested in paragraph 2 of decision XII/24;
- (k) *Also decides* to extend the open-ended online forum to support the work of the AHTEG on Synthetic Biology, and invites Parties, other Governments, indigenous peoples and local communities and relevant organizations to continue nominating experts to take part in the open-ended online forum;
- (l) *Requests* the Subsidiary Body on Scientific, Technical and Technological Advice to review the recommendations of the AHTEG on Synthetic Biology and make further recommendation to the Conference of the Parties including on the analysis using the criteria set out in paragraph 12 of decision IX/29;
- (m) *Requests* the Executive Secretary, subject to the availability of resources:
 - (i) Continue to facilitate moderated discussions under the open-ended online forum on synthetic biology through the Biosafety Clearing-House, and to continue to invite Parties, other Governments, indigenous peoples and local communities and relevant organizations to nominate experts to take part in the forum;
 - (ii) To make the information received through paragraph (i) above available online;
 - (iii) To compile and synthesize the results of the work referred to in the paragraphs above and make them available for further discussion through the online forum and the Ad Hoc Technical Expert Group;
 - (iv) To convene moderated online discussions under the open-ended online forum and, subject to the availability of funds, a face-to-face meeting of the AHTEG on Synthetic Biology with the terms of reference annexed to the present decision, and submit the report of the AHTEG to peer review by Parties for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice at a meeting held prior to the fourteenth meeting of the Conference of the Parties;
 - (v) To cooperate and establish synergies with other United Nations and international organizations whose mandates are relevant to synthetic biology;
 - (vi) To promote the full and effective engagement of indigenous peoples and local communities in future activities relating to synthetic biology under the Convention;
- (n) *Welcomes* the recommendation of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, in its decision BS-VII/12, on a coordinated approach on the issue of synthetic biology, including its work on risk assessment and risk management [as well as socio-economic considerations, as appropriate], and *invites* the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety to take into account in its future deliberations relevant information resulting from the processes under the Convention;
- (o) [*Invites* the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol to clarify, if and how, the use of digital sequence information on genetic resources relates to access and benefit-sharing.]

*Annex***TERMS OF REFERENCE FOR THE AD HOC TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY**

1. Building on the previous work of the Online Forum and AHTEG, and drawing upon relevant information submitted by Parties, other Governments, relevant organizations and indigenous peoples and local communities through paragraph (i) above, as well as information made available through the online forum and by the Secretariat, the AHTEG on Synthetic Biology shall, in coordination with other bodies of the Convention and its Protocols:

(a) Review recent technological developments within the field of synthetic biology to assess if the developments could lead to impacts on biodiversity and the three objectives of the Convention, including unexpected and significant impacts;

(b) Identify any living organisms already developed or currently under research and development through techniques of synthetic biology which do not fall under the definition of living modified organisms under the Cartagena Protocol;

(c) Further analyse evidence of benefits and adverse effects of organisms, components and products of synthetic biology vis-à-vis the three objectives of the Convention, and gather information on risk management measures, safe use and best practices for safe handling of organisms, components and products of synthetic biology;

(d) In order to avoid or minimize any potential negative effects on the conservation and sustainable use of biodiversity, evaluate the availability of tools to detect and monitor the organisms, components and products of synthetic biology;

(e) [Propose elements to the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol to facilitate the clarification of, if and how, the use of digital sequence information on genetic resources relates to access and benefit-sharing;]

(f) Provide, for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice at a meeting held prior to the fourteenth meeting of the Conference of the Parties, recommendations on the basis of its deliberations to facilitate future discussions and actions on synthetic biology under the Convention, as well as an analysis against the criteria set out in paragraph 12 of decision IX/29 to contribute to the completion of the assessment requested in paragraph 2 of decision XII/24 by the Subsidiary Body on Scientific, Technical and Technological Advice;

2. Subject to the availability of funds, the AHTEG shall meet at least once face-to-face prior to the fourteenth meeting of the Conference of the Parties and make use of online tools to facilitate its work, as appropriate.
