

CONFERENCE OF THE PARTIES TO THE  
CONVENTION ON BIOLOGICAL DIVERSITY  
Fourteenth meeting  
Sharm El-Sheikh, Egypt, 17-29 November 2018  
Agenda item 27

**SYNTHETIC BIOLOGY**

**Draft decision submitted by the Chair of Working Group II**

*The Conference of the Parties,*

*Recalling* decisions XII/24 and XIII/17,

1. *Welcomes* the outcomes of the meeting of the Ad Hoc Technical Expert Group on Synthetic Biology held in Montreal, Canada, from 5 to 8 December 2017;<sup>1</sup>
2. *Recognizes* that synthetic biology is rapidly developing and a cross-cutting issue, with potential benefits and potential adverse effects vis-à-vis the three objectives of the Convention on Biological Diversity;
3. *Agrees* that broad and regular horizon scanning, monitoring and assessing of the most recent technological developments is needed[,taking into account that this may include genome editing,]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 and Nagoya Protocol;
4. *Recognizes* the need to conduct an analysis of synthetic biology against the criteria in decision IX/29, paragraph 12, in order to complete the analysis requested in decisions XII/24, paragraph 2, and XIII/17, paragraph 13;
5. *Also recognizes* that developments arising from research and development in the field of synthetic biology may pose challenges to the ability of some countries, especially developing countries, in particular those with limited experience or resources, to assess the full range of applications and potential impacts of synthetic biology on the three objectives of the Convention;
6. *Further recognizes* the role of information and resources under the clearing-house mechanism of the Convention and the Biosafety Clearing-House of the Cartagena Protocol and capacity-building initiatives in assisting those countries;
7. *Emphasizes* 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;
8. *Takes note* of the current efforts by Parties, other Governments, relevant organizations and others to inform on development, gaps in knowledge and other matters relevant to the objectives of the Convention in relation to synthetic biology;
9. *Calls* 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, and *also calls* upon Parties and other Governments to only consider introducing organisms containing engineered gene drives into the environment, including for experimental releases and research and development purposes, when:

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<sup>1</sup> CBD/SBSTTA/22/4, annex.

- (a) Scientifically sound case-by-case risk assessments have been carried out;
- (b) Risk management measures are in place to avoid or minimize potential adverse effects, as appropriate;
- (c) Where appropriate, the “prior and informed consent”, the “free, prior and informed consent” or “approval and involvement”<sup>2</sup> of potentially affected indigenous peoples and local communities is sought or obtained, where applicable in accordance with national circumstances and legislation;

10. *Recognizes* that, as there could be potential adverse effects arising from organisms containing engineered gene drives, before these organisms are considered for release into the environment, research and analysis are needed, and specific guidance may be useful,<sup>3</sup> to support case-by-case risk assessment;

11. *Notes* the conclusions of the Ad Hoc Technical Expert Group on Synthetic Biology<sup>4</sup> that, given the current uncertainties regarding engineered gene drives, the free, prior and informed consent of indigenous peoples and local communities might be warranted when considering the possible release of organisms containing engineered gene drives that may impact their traditional knowledge, innovation, practices, livelihood and use of land and water;

12. *Calls upon* Parties, other Governments and relevant organizations to continue to develop or implement, as appropriate, measures to prevent or minimize potential adverse effects arising from exposing the environment to organisms, components and products of synthetic biology in contained use, including measures for detection, identification and monitoring, in accordance with domestic circumstances or internationally agreed guidelines, as appropriate, with special consideration to the centres of origin and genetic diversity;

13. *Also calls upon* Parties, other Governments and relevant organizations to continue to disseminate information and share, especially through the clearing-house mechanisms of the Convention and the Biosafety Clearing-House, their experiences on scientific assessments of the potential benefits and potential adverse impacts of synthetic biology to biological diversity, including, inter alia, that of specific applications of organisms containing engineered gene drives, and from the use of living modified organisms that have been released into the environment;

14. *Decides* to extend the Ad Hoc Technical Expert Group on Synthetic Biology with renewed membership, taking into account, inter alia, the work on risk assessment under the Cartagena Protocol, to work in accordance with the terms of reference annexed hereto;

15. *Also decides* to extend the Open-ended Online Forum on Synthetic Biology, taking into account the work on risk assessment under the Cartagena Protocol, to support the deliberations of the Ad Hoc Technical Expert Group on Synthetic Biology, and *invites* Parties, other Governments, indigenous peoples and local communities and relevant organizations to continue to nominate experts to take part in the Online Forum on Synthetic Biology;

16. *Invites* Parties, other Governments, indigenous peoples and local communities, and relevant organizations to provide the Executive Secretary with relevant information related to paragraphs (a) to (d) of the annex in order to contribute to the work of the Ad Hoc Technical Expert Group;

17. *Requests* the Executive Secretary, subject to the availability of resources:

(a) To convene moderated online discussions under the Open-ended Online Forum on Synthetic Biology;

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<sup>2</sup> Decision XIII/18.

<sup>3</sup> The Subsidiary Body on Scientific, Technical and Technological Advice has recommended that the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (recommendation 22/2) consider the need for specific guidance on risk assessment of living modified organisms containing engineered gene drives at its tenth meeting.

<sup>4</sup> <https://www.cbd.int/meetings/SYNBIOAHTEG-2017-01>.

(b) To facilitate the work of the Ad Hoc Technical Expert Group on Synthetic Biology by, among other things, collecting and synthesizing and arranging for peer review of relevant information, and convening at least one face-to-face meeting;

(c) To update the Technical Series on Synthetic Biology for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice based on the peer review of scientific information and other relevant information;

(d) To further pursue cooperation with other organizations, conventions and initiatives, including academic and research institutions, from all regions, on issues related to synthetic biology, including the exchange of experiences and information;

(e) To explore ways to facilitate, promote and support capacity-building and knowledge-sharing regarding synthetic biology, taking into account the needs of Parties and of indigenous peoples and local communities, including through necessary funding, and the co-design of information and training materials in the official languages of the United Nations and, where possible, in local languages;

(f) To collaborate and convene discussions, including through the Network of Laboratories for the Detection and Identification of Living Modified Organisms,<sup>5</sup> for sharing experiences on the detection, identification and monitoring of organisms, components and products of synthetic biology, and to continue inviting laboratories, including analytical laboratories, to join the Network;

(g) To ensure the full and effective participation of indigenous peoples and local communities in the discussions and decision-making on synthetic biology, in accordance with decision X/40.

18. *Requests* the Subsidiary Body on Scientific, Technical and Technological Advice:

(a) To consider the work of the Open-ended Online Forum and the Ad Hoc Technical Expert Group on Synthetic Biology;

(b) To note the preliminary analysis done by the Executive Secretary<sup>6</sup> and to consider further analyses and advice from the Ad Hoc Technical Expert Group on Synthetic Biology of the relationship between synthetic biology and the criteria set out in decision IX/29, paragraph 12, in order to contribute to the completion of the analysis requested in decision XII/24, paragraph 2;

(c) To submit a recommendation to the Conference of the Parties at its fifteenth meeting.

#### *Annex*

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

The Ad Hoc Technical Expert Group on Synthetic Biology shall:

(a) Provide advice on the relationship between synthetic biology and the criteria set out in decision IX/29, paragraph 12, in order to contribute to the completion of the assessment requested in decision XII/24, paragraph 2, building on the preliminary analysis prepared by the Executive Secretary in document SBSTTA/22/INF/17;

(b) Take stock of new developments in synthetic biology since the Ad Hoc Technical Expert Group's last meeting[, including to consider whether specific organisms developed through genome editing should be included in this exercise][, taking into account that this may include some applications of genome editing] in order to support a regular horizon scanning process;

(c) Undertake a review of the current state of knowledge by analysing information, including but not limited to peer-reviewed published literature, on the potential positive and negative environmental

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<sup>5</sup> [http://bch.cbd.int/onlineconferences/portal\\_detection/lab\\_network.shtml](http://bch.cbd.int/onlineconferences/portal_detection/lab_network.shtml).

<sup>6</sup> SBSTTA/22/INF/17.

impacts, taking into account human health, cultural and socioeconomic impacts, especially with regard to the value of biodiversity to indigenous peoples and local communities, of current and near-future applications of synthetic biology, including those applications that involve organisms containing engineered gene drives, taking into account the traits and species potentially subject to release and the dynamics of their dissemination, as well as the need to avoid duplication with the work on risk assessment under the Cartagena Protocol on Biosafety;

(d) Consider whether any living organism developed thus far through new developments in synthetic biology fall outside the definition of living modified organisms as per the Cartagena Protocol;

(e) Prepare a forward-looking report on synthetic biology applications that are in early stages of research and development, vis-à-vis the three objectives of the Convention, by compiling and analysing information, including but not limited to peer-reviewed published literature;

(f) Recommend options for carrying out the regular horizon scanning, monitoring and assessing of developments referred to in paragraph 3 of decision CP-9/--;

(g) Prepare a report on the outcomes of its work for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice at a meeting to be held before the fifteenth meeting of the Conference of Parties.

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