



## Convention on Biological Diversity

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CONFERENCE OF THE PARTIES TO THE  
CONVENTION ON BIOLOGICAL DIVERSITY  
Twelfth meeting  
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Agenda item 24

### NEW AND EMERGING ISSUES: SYNTHETIC BIOLOGY

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

*The Conference of the Parties,*

*Reaffirming* paragraph 4 of decision XI/11, “Recognizing the development of technologies associated with synthetic life, cells or genomes, and the scientific uncertainties of their potential impact on the conservation and sustainable use of biological diversity, urges Parties and invites other Governments to take a precautionary approach, in accordance with the preamble of the Convention and with Article 14, when addressing threats of significant reduction or loss of biological diversity posed by organisms, components and products resulting from synthetic biology, in accordance with domestic legislation and other relevant international obligations”,

*Noting* decision BS-VII/12, of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, recommending a coordinated approach on the issue of synthetic biology taking into account that the provisions of the Cartagena Protocol may also apply to living organisms resulting from synthetic biology,

1. *Takes note* of the conclusions of the Subsidiary Body on Scientific, Technical and Technological Advice at its eighteenth meeting, as contained in paragraph 1 of recommendation XVIII/7, *recognizes* that this issue is of relevance to the Convention and *concludes* that there is currently insufficient information available to finalize an analysis, using the criteria set out in paragraph 12 of decision IX/29, to decide whether or not this is a new and emerging issue related to conservation and sustainable use of biological diversity;

2. *Awaits* the completion of a robust analysis using the criteria in paragraph 12 of decision IX/29;

3. *Urges* Parties and *invites* other Governments, to take a precautionary approach in accordance with paragraph 4 of decision XI/11, and:

(a) To establish, or have in place, effective risk assessment and management procedures and/or regulatory systems to regulate environmental release of any organisms, components or products resulting from synthetic biology techniques, consistent with Article 3 of the Convention on Biological Diversity;

(c) To approve organisms resulting from synthetic biology techniques for field trials only after appropriate risk assessments have been carried out in accordance with national, regional and/or international frameworks, as appropriate;

(d) To carry out scientific assessments concerning organisms, components and products resulting from synthetic biology techniques with regard to potential effects on the conservation and sustainable use of biodiversity, taking into account risks to human health and addressing, as appropriate, and according to national and/or regional legislation, other issues such as food security and socioeconomic considerations with, where appropriate, the full participation of indigenous and local communities;

(e) To encourage the provision of funding for research into synthetic biology risk assessment methodologies and into the positive and negative impacts of synthetic biology on the conservation and sustainable use of biodiversity, and to promote interdisciplinary research that includes related socioeconomic considerations; and

(f) To cooperate in the development and/or strengthening of human resources and institutional capacities, including methodologies for risk assessments in synthetic biology and its potential impacts on biodiversity, in developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, including through existing global, regional and national institutions and organizations and, as appropriate, by facilitating civil society involvement. The needs of developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, for: financial resources; access to and transfer of technology consistent with Article 16 of the Convention; establishing or strengthening regulatory frameworks; and the management of risks related to the release of organisms, components and products resulting from synthetic biology techniques, should be taken fully into account in this regard;

4. *Decides*, subject to the availability of resources, to establish an Ad Hoc Technical Expert Group, with terms of reference as in the annex to the present decision, to be convened after the Executive Secretary has completed the requests in paragraph 7 below;

5. *Invites* Parties, other Governments, relevant organizations and stakeholders to submit information to the Executive Secretary relevant to the work of the Ad Hoc Technical Expert Group, as established in the present decision, as well as on measures undertaken in accordance with paragraph 3 above, including identifying needs for guidance;

6. *Invites* Parties, other Governments, relevant international organizations, indigenous and local communities and relevant stakeholders to continue to provide further information to the Executive Secretary in response to decision XI/11 paragraph 3 (a);

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

(a) Make available the information reported in accordance with paragraphs 5 and 6 above through the clearing-house mechanism of the Convention and other means;

(b) To convene a moderated open-ended<sup>1</sup> online forum to support the work of the Ad Hoc Technical Expert Group established in paragraph 4 (above) in meeting its terms of reference;

(c) To prepare an updated report on the work specified in paragraphs 3(a), 3(b) and 3(c) of decision XI/11, taking into account information submitted in paragraphs 5 and 6 above and a synthesis of the outcomes of the process mentioned in paragraph 7(b) and to submit these for consideration by the Ad Hoc Technical Expert Group;

(d) To submit for consideration by a meeting of the Subsidiary Body on Scientific, Technical and Technological Advice prior to the thirteenth meeting of the Conference of the Parties, the peer reviewed reports of the outcomes of the process mentioned in paragraph 7(b) and 7(c) above;

8. *Invites* relevant organizations, including relevant United Nations organizations and bodies, to consider the possible implications of synthetic biology as it relates to their mandates.

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<sup>1</sup> The open-ended online forum will be open to all interested participants and continue for a finite period of time.

*Annex*

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

The Ad Hoc Technical Expert Group will include balanced representation of Parties from all regions and include representation of indigenous and local communities and all relevant stakeholders, including other Governments, with knowledge of the Convention and its Protocols,<sup>2</sup> and will report on its work to a meeting of the Subsidiary Body on Scientific, Technical and Technological Advice prior to the thirteenth meeting of the Conference of the Parties.

The Ad Hoc Technical Expert Group will:

(a) Take note of the exchange views on how to address the relationship between synthetic biology and biological diversity;

(b) Identify the similarities and differences between living modified organisms (as defined in the Cartagena Protocol) and organisms, components and products of synthetic biology techniques to determine if living modified organisms derived from synthetic biology fall under the scope of the Cartagena Protocol;

(c) Identify if other national, regional and/or international instruments adequately regulate the organisms, components or products derived from synthetic biology techniques in so far as they impact on the objectives of the Convention on Biological Diversity and its Protocols;

(d) Work towards an operational definition of synthetic biology, comprising inclusion and exclusion criteria, using all relevant information, based on scientific and peer reviewed studies;

(e) Identify the potential benefits and risks of organisms, components and products arising from synthetic biology techniques to the conservation and sustainable use of biodiversity and related human health and socioeconomic impacts relevant to the mandate of the Convention and its Protocols;

(f) Building on the work on risk assessment and risk management undertaken by the Cartagena Protocol, compile information on best practices on risk assessment and monitoring regimes currently used by Parties to the Convention on Biological Diversity and other Governments, including transboundary movement, to inform those who do not have national risk assessment or monitoring regimes, or are in the process of reviewing their current risk assessment or monitoring regimes, to help those Parties and other Governments regulate organisms, components and products from synthetic biology techniques appropriately;

(g) Identify if the existing arrangements constitute a comprehensive framework in order to address impacts of organisms, components and products resulting from synthetic biology relevant to the objectives of the Convention on Biological Diversity and its Protocols, in particular threats of significant reduction or loss of biological diversity.

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<sup>2</sup> The Ad Hoc Technical Expert Group will be convened in accordance with the *modus operandi* of the Subsidiary Body on Scientific, Technical and Technological Advice, except that there will be 5 to 8 experts nominated by each of the five regions.