



**Convention on
Biological Diversity**

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CONFERENCE OF THE PARTIES TO THE CONVENTION
ON BIOLOGICAL DIVERSITY SERVING AS THE
MEETING OF THE PARTIES TO THE CARTAGENA
PROTOCOL ON BIOSAFETY

Seventh meeting

Pyeongchang, Republic of Korea, 29 September-3 October 2014

Item 12 of the provisional agenda*

**RECOMMENDATION OF THE SUBSIDIARY BODY ON SCIENTIFIC, TECHNICAL AND
TECHNOLOGICAL ADVICE REGARDING SYNTHETIC BIOLOGY**

Note by the Executive Secretary

1. At its eighth meeting, the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), in paragraph 3 of its recommendation XVIII/7 on “New and emerging issues: synthetic biology”, requested the Executive Secretary, inter alia, to bring that recommendation to the attention of the seventh meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety and its Bureau.¹
2. Accordingly, recommendation XVIII/7 is annexed to the present note for the attention of the Parties to the Cartagena Protocol on Biosafety at their seventh meeting.
3. Furthermore, in their deliberations, Parties may also wish to consider the information contained in document UNEP/CBD/COP/12/20.²

* UNEP/CBD/BS/COP-MOP/7/1.

¹ See UNEP/CBD/COP/12/3, annex.

² Available at <http://www.cbd.int/doc/?meeting=COP-12>.

Annex

**RECOMMENDATION XVIII/7 OF THE SUBSIDIARY BODY ON SCIENTIFIC, TECHNICAL
AND TECHNOLOGICAL ADVICE (SBSTTA) AT ITS EIGHTH MEETING**

The Subsidiary Body on Scientific, Technical and Technological Advice

1. *Recalling* decision XI/11, paragraphs 3 and 4, *notes* that:

(a) Synthetic biology may be understood to involve various techniques, organisms and components that result in a range of products, living and non-living, and of differing characteristics; however, there is lack of common understanding of the differences between synthetic biology and conventional genetic engineering;

(b) Some of these techniques, organisms and components have resulted in commercial products and industrial processes, others are expected to in the near-term, while yet others may do so in the longer-term or are speculative;

(c) There are intended benefits from research and from current and near-term commercial, industrial applications and products of synthetic biology but these are currently poorly understood;

(d) There are also risks to biological diversity and human livelihoods associated with the components, organisms and products resulting from synthetic biology techniques but these are currently poorly understood;

(e) Existing regulations that may be relevant to synthetic biology techniques and the components, organisms and products resulting from them do not form a coherent and comprehensive international framework; nevertheless, the Cartagena Protocol on Biosafety may provide a regulatory platform for some aspects;

(f) There are some existing national and international regulatory regimes which provide useful models to regulate the components, organisms and products resulting from synthetic biology but there is no comprehensive international regulatory regime;

2. *Requests* the Executive Secretary to provide additional opportunities for peer-review of the information documents on synthetic biology and its potential impacts on biodiversity and on the possible gaps and overlaps with the Convention, its Protocols and other relevant agreements and then to present the updated documents prior to the twelfth meeting of the Conference of the Parties;³

3. *Also requests* the Executive Secretary to bring this recommendation to the attention of the seventh meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety and its Bureau.

Recommendation to the Conference of the Parties

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

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”,

³ UNEP/CBD/SBSTTA/18/INF/3 and INF/4.

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 [high] 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 [which could include] [in accordance with paragraph 4 of decision XI/11]:

[(a) To establish, or have in place and use, as appropriate, effective risk assessment and management procedures and regulatory processes, including definition of terms and guidance, that regulate and/or guide [any consideration [prior to][of]] environmental release of any organisms[, components or products] resulting from synthetic biology techniques;

(b) [[Not] To [approve][authorize][ensure] field testing of organisms[, components and products] resulting from synthetic biology techniques [provided a rigorous, science-based risk assessment has been carried out][[only with][following] [unless] appropriate scientific risk assessment justifying such testing [following][in accordance with] guidance, procedures and regulatory processes developed in 2 (a)];

(c) [To carry out scientific assessment concerning organisms, components and products resulting from synthetic biology technique for commercial use with regard to adverse effects for conservation and sustainable use of biological diversity, taking into account risks to human health as well as their potential socioeconomic impacts including food security, as appropriate][To approve organisms, components and products resulting from synthetic biology techniques for commercial use only after appropriate, authorized and strictly controlled scientific assessments with regard to their potential ecological and socioeconomic impacts and any adverse effects for biological diversity, food security and human health, including, if possible, potential cumulative and synergistic impacts, have been carried out in a transparent manner and the conditions for the safe and beneficial use of these organisms, components and products have been validated];]

[(a, b, c *alt*) To ensure that field testing, environmental release or commercial release of organisms and products resulting from synthetic biology are not approved until a global, international, transparent, legal regulatory framework, and ensure that all guidance and assessments for organisms and products resulting from synthetic biology to comply with all obligations under the Convention and its Protocols, including environmental, socio-economic and cultural impacts;] [(d)To ensure that funding for synthetic biology research includes appropriate resources for research into risk assessment methodologies as well as the positive and negative impacts of synthetic biology on the conservation and sustainable use of biodiversity, and to promote interdisciplinary research;

(e) To cooperate in the development and/or strengthening of human resources and institutional capacities in synthetic biology and its potential impacts in developing country Parties, in particular the least developed and small island developing States, and Parties with economies in transition including through existing global, regional, subregional and national institutions and organizations and, as appropriate, by facilitating private sector involvement. The needs of developing country Parties, in particular the least developed and small island developing States, and Parties with economies in transition, for: financial resources; access to and transfer of technology and know-how; establishing or strengthening regulatory frameworks; and the management of risks related to the release of organisms, components and products resulting from synthetic biology techniques, shall be taken fully into account in this regard;]

4. *Invites* Parties and other Governments to submit information to the Executive Secretary on measures undertaken in accordance with paragraph 2 above and to identify needs for guidance;]

5. *Invites* Parties, other Governments, relevant international organizations, indigenous and local communities and relevant stakeholders to provide further information on potential and actual positive and

negative impacts of organisms, components and products resulting from synthetic biology techniques on the conservation and sustainable use of biological diversity taking into account the risks to human health as well as their potential socioeconomic impacts, including food security, as appropriate as well as on existing national and regional regulatory frameworks and supporting guidance and gaps before a meeting of the Subsidiary Body on Scientific, Technical and Technological Advice to be held prior to the thirteenth meeting of the Conference of the Parties;]

[6. *Requests* the Executive Secretary to make available the information reported in accordance with paragraphs x and y above through the clearing-house mechanism of the Convention and other means;]

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

(a) To prepare, provide for peer-review, and submit for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice at a meeting to be held prior to the thirteenth meeting of the Conference of the Parties an updated report on the potential impacts of components, organisms and products resulting from synthetic biology techniques on the conservation and sustainable use of biological diversity and associated socioeconomic considerations;

(b) To convene an open-ended⁴ online forum followed by an open workshop of experts, including representatives of indigenous and local communities and relevant organizations, with knowledge of the Convention and its Protocols with terms of reference that include:

(i) Exchanging views on how to address the relationship between synthetic biology and biological diversity;

(ii) Considering the differences between genetic engineering and synthetic biology;

(iii) Working towards an operational definition of synthetic biology comprising inclusion and exclusion criteria, using all relevant information;

(c) To report the outcomes of the workshop to the Subsidiary Body on Scientific, Technical and Technological Advice at a meeting to be held prior to the thirteenth meeting of the Conference of the Parties;

8. *Invites* relevant organizations, including the Food and Agriculture Organization of the United Nations, [the Committee on World Food Security] and the United Nations Permanent Forum on Indigenous Issues to consider the possible implications of synthetic biology as it relates to their mandates.

⁴ An open-ended online forum will be open to all interested participants and continue for a finite period of time.