



Convention on Biological Diversity

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SUBSIDIARY BODY ON SCIENTIFIC, TECHNICAL AND TECHNOLOGICAL ADVICE

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Item 5 of the provisional agenda*

SYNTHESIS OF VIEWS PROVIDED THROUGH THE PEER-REVIEW OF THE REPORT OF THE AD HOC TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY

Note by the Executive Secretary

1. In decision XIII/17, the Conference of the Parties extended the mandate of the Ad Hoc Technical Expert Group on Synthetic Biology (AHTEG), and requested the Subsidiary Body on Scientific, Technical and Technological Advice to review the recommendations of the AHTEG 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.
2. The decision also requested the Executive Secretary, among other things, 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, and to submit the report of the AHTEG to peer review by Parties for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice.
3. Accordingly, the Executive Secretary established a process comprising: (a) the submission of information on synthetic biology; (b) an open-ended online forum with discussions on specific topics of synthetic biology; (c) one face-to-face meeting of the AHTEG on Synthetic Biology; and (d) peer review of the report of the AHTEG on Synthetic Biology.
4. The present document presents a synthesis of the comments provided through the peer-review of the report of the AHTEG meeting held in Montreal, Canada, from 5 to 8 December 2017.¹

SYNTHESIS OF VIEWS

5. The Secretariat issued a notification² inviting Parties, other Governments, relevant organizations and indigenous peoples and local communities to peer review the report of the AHTEG. A total of 21 submissions were received by the Secretariat. Among the submissions, eight were from Parties, one was from a non-Party, eleven were from organizations, and two were from indigenous peoples and local communities.³

* CBD/SBSTTA/22/1.

¹ The AHTEG report is available at <https://www.cbd.int/meetings/SYNBIOAHTEG-2017-01>.

² Notification SCBD/SPS/DC/MPM/MW/87112.

³ *Parties*: Argentina, Australia, Brazil, Canada, Colombia, Netherlands, Switzerland, and United Kingdom of Great Britain and Northern Ireland; *Non-Party*: United States of America. *Organizations*: European Plant Science Organisation, International Seed Federation, Central Committee on Biological Safety, Global Industry Coalition, Third World Network, University of Edinburgh (Science, Technology and Innovation Studies), German Life Sciences Association, German Association for Synthetic Biology GASB e.V., European Association for Bioindustries (EuropaBio), Public Research & Regulation Initiative, and Royal Society. *Indigenous Peoples and Local Communities*: Indigenous Women Network on Biodiversity from Latin America and the Caribbean.

6. The following paragraphs attempt to synthesize the views submitted through the peer-review of the report of the AHTEG. Due to the extensive nature of comments, it is noted that some views may not have been adequately reflected. Furthermore, some submissions proposed specific changes to the text, including eliminating some paragraphs entirely, replacing some words, clarifying concepts, among others. The full list of comments and proposed changes is available through the original submissions.⁴

General comments

7. Some reviewers noted that synthetic biology is relevant to several areas of the Convention and its Protocols, and a holistic view is needed when addressing synthetic biology. As such, Parties need to use and maintain an oversight on processes to conduct stock-taking, and adopt cross-cutting decisions.

8. With regard to general comments on the AHTEG report, it was further noted that it is unclear whether or not some statements in the report represent consensus among all of its members. Furthermore, it was noted that considering the divergence of views amongst AHTEG members, the report often resorts to inconclusive language, such as “might need” and “might be needed”. It was recommended that references or links to relevant journal/research articles could be provided to parts of the report, such as paragraph 15.

9. One of the submissions made through the peer-review process was of the view that the AHTEG had discussed a variety of new developments in modern biotechnology without having first assessed these ‘new developments’ against the operational definition of synthetic biology. It was also mentioned that the report contributes to the misperception that the use of new breeding techniques and the development of gene drives per se, constitute synthetic biology, while noting that synthetic biology is not any particular technique but rather an overall approach based on design.

10. It was pointed out in some of the comments that the operational definition of synthetic biology, as established by the AHTEG at its first meeting, is too broad and does not allow for discriminating between living modified organisms, as defined in the Cartagena Protocol on Biosafety, and living organisms developed through synthetic biology that may need further consideration vis-à-vis the three objectives of the Convention. Further in relation to the operational definition, a reviewer was of the view that the AHTEG had discussed a variety of new developments in modern biotechnology without first assessing these ‘new developments’ against the definition of synthetic biology. The reviewer further noted that synthetic biology should not be confused with the application of new breeding techniques.

11. The importance of having representatives of indigenous peoples and local communities participating in the AHTEG was emphasized in some of the submissions.

12. Beyond the issues mentioned above, many editorial changes were proposed along the lines of eliminating some paragraphs entirely, replacing some terms and clarifying some concepts, among others.

Synthetic biology and the Convention on Biological Diversity

13. It was indicated in a submission that since the issue of synthetic biology is relevant to several areas of the Convention and its Protocols, it must also be ensured that how synthetic biology is addressed is not just divided into constituent pieces at the expense of an oversight of the whole; arguing that Parties therefore need to use and maintain this oversight process to conduct stock-taking and adopt cross-cutting decisions.

14. One reviewer noted that the report is unbalanced in that it fails to adequately explain the potential benefits of synthetic biology for the conservation and sustainable use of biodiversity.

15. In relation to traditional knowledge, one submission highlighted that in order to be able to fully consider the possible impacts of synthetic biology on the traditional knowledge, innovation, and practices of indigenous peoples and local communities, this issue should be placed on the agenda of the Working Group on Article 8j.

16. In relation to references to “accelerated rate” or “speed of development” in the report of the AHTEG, it was noted in a submission that the rate of development does not necessarily imply the

⁴ <http://bch.cbd.int/synbio/peer-review/>.

existence of gaps in the existing regulation and guidance materials nor should it be construed as a justification for enacting additional regulations. Moreover, it was pointed out that the identified gaps are not specific to synthetic biology, but they rather relate to our limited understanding about complex ecosystem dynamics.

Relationship with the Cartagena Protocol on Biosafety

17. It was noted one submission that the AHTEG has not identified any living organism developed through synthetic biology that cannot be regarded as a living modified organism as per the Cartagena Protocol on Biosafety. One reviewer suggested that further deliberations on organisms developed through synthetic biology should be considered under the Cartagena Protocol. Another reviewer noted the need to continue monitoring activities in the field of synthetic biology to identify and focus on those organisms that do not fall within the scope of the Cartagena Protocol and might need further consideration with regard to the three objectives of the Convention on Biological Diversity.

18. It was noted in another submission that for an organism to be regarded as living modified organism (LMO), it needs to fulfil the requirement of a novel combination of genetic material overcoming natural physiological reproductive or recombination barriers, and that the reference to an LMO that is indistinguishable from a non-modified organism should be removed from the AHTEG report.

19. It was further mentioned that several established tools of modern biotechnology are assigned incorrectly to the field of synthetic biology, including gene editing tools, organisms containing engineered gene drives, modified algae used for the production of chemical substances, and RNA interference, and should be removed from the AHTEG report. It was also mentioned that epigenetics is not considered as a technique of modern biotechnology as these do not result in a novel combination of genetic material.

Risk assessment of organisms developed through synthetic biology

20. A reviewer noted that the AHTEG report does not provide examples of specific cases where a risk assessment of an organism developed through synthetic biology could not be performed under existing risk assessment frameworks and methodologies for LMOs. In the same vein, the reviewer suggested that the AHTEG report should note the existence of the various risk assessment approaches that are available through the Biosafety Clearing-House.

21. Further in relation to risk assessment, it was noted that the update and adaptation of risk assessment methodologies must only be done following a scientific review that establishes that the existing methodologies are no longer adequate for performing risk assessment of organisms developed through synthetic biology. On the other hand, it was noted that the update and adaptation of existing risk assessment methodologies, in particular for organisms containing engineered gene drives, and including for assessing risks stemming from organisms under contained use, is already warranted on the basis that the new developments and applications of synthetic biology will likely have increased impacts on biodiversity.

Detection of organisms developed through synthetic biology

22. It was noted in a submission that Article 7 of the Convention calls for identification and monitoring, which may require detection methods, to support conservation and sustainable use of biodiversity.

23. It was also noted in one of the submissions that the Network of Laboratories for the Detection and Identification of LMOs has not yet been able to produce a handbook for detection of LMOs.⁵ Therefore, the submitter questioned whether it is realistic to expect that the Network would be in a position to address the more technically challenging issue of synthetic biology.

⁵ A revised version of the draft manual on detection and identification of LMOs, prepared in collaboration with the Network of Laboratories, will be presented for consideration of the Conference of the Parties serving as the meeting of the Parties to the Cartagena protocol on Biosafety, at its ninth meeting, in accordance with [decision CP VIII/16](#).