



## Convention on Biological Diversity

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### REPORT OF THE AD HOC TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY

MONTREAL, CANADA, 5-8 DECEMBER 2017

#### INTRODUCTION

1. In [decision XIII/17](#), the Conference of the Parties to the Convention on Biological Diversity commended the work of the online forum and the Ad Hoc Technical Expert Group on Synthetic Biology (AHTEG) and welcomed the conclusions and recommendations of the report of the AHTEG as a basis for further discussion. The Conference of the Parties also considered the operational definition useful as a starting point for the purpose of facilitating scientific and technical deliberations under the Convention and its Protocols and took note of the conclusion of the AHTEG that living organisms developed through synthetic biology are similar to living modified organisms (LMOs) as defined in the Cartagena Protocol. The Conference of the Parties noted that the general principles and methodologies for risk assessment under the Cartagena Protocol and existing biosafety frameworks provide a good basis for risk assessment of living organisms developed through synthetic biology, but such methodologies might need to be updated and adapted.

2. In the same decision, the Conference of the Parties (a) extended the mandate of the current AHTEG in accordance with the terms of reference contained in the annex to the decision; (b) extended the open-ended online forum to support the work of the AHTEG; (c) invited Parties, other Governments, relevant organizations and indigenous peoples and local communities and other relevant stakeholders to submit information and supporting documentation on topics relevant to the work of the AHTEG, as outlined in paragraph 10 of the decision; and (d) requested the Executive Secretary, among other things, to continue to facilitate moderated discussions under the open-ended online forum on synthetic biology through the Biosafety Clearing House.

3. In response to this decision, with a view to supporting the work of the AHTEG, the Secretariat has taken the following actions:

(a) It issued a notification<sup>1</sup> inviting the submission of information and documentation, as outlined in paragraph 10 of the decision. A total of 29 submissions were received, of which 15 were from Parties, 1 from a non-Party and 13 from organizations;<sup>2</sup>

(b) It convened a series of moderated online discussions of the open-ended online forum on synthetic biology from July to October 2017;<sup>3</sup>

<sup>1</sup> Notification SCBD/SPS/DC/DA/MW/86375, available at <https://www.cbd.int/doc/notifications/2017/ntf-2017-025-bs-en.pdf>.

<sup>2</sup> Submissions are available through the Biosafety-Clearing House at <http://bch.cbd.int/synbio/submissions/2017-2018.shtml>.

<sup>3</sup> The discussions under the Open-ended Online Forum on Synthetic Biology are available at <https://bch.cbd.int/synbio/open-ended/discussion/>.

(c) It compiled and synthesized the outputs of the activities referred to in subparagraphs (a) and (b) above in [CBD/SYNBIO/AHTEG/2017/1/2](#) to facilitate the deliberations of the AHTEG.

4. In working towards fulfilling its mandate as per decision XIII/17, the AHTEG held its face-to-face meeting in Montreal, Canada, from 5 to 8 December 2017. The list of participants is contained in the annex.

## **ITEM 1. OPENING OF THE MEETING**

5. The meeting was opened at 9:50 a.m. on Tuesday, 5 December 2017, by Mr. David Cooper, Deputy Executive Secretary on behalf of Ms. Cristiana Pasça-Palmer, Executive Secretary of the Convention on Biological Diversity.

6. The Deputy Executive Secretary welcomed the members of the AHTEG and thanked them for bringing their expertise to the meeting and to the online discussions that had preceded the meeting. He emphasized the importance of the work of the AHTEG, emphasizing the scientific and technical nature of its work, and elaborated on the need to achieve the outcomes outlined in the terms of reference. He noted that the outcomes of the meeting would be considered by the Subsidiary Body on Scientific, Technical and Technological Advice at its twenty-second meeting, to be held in Montreal, Canada, from 2 to 7 July 2018. Mr. Cooper also thanked the European Union and Switzerland for generously providing funds to support the participation of experts from developing country Parties and representatives of indigenous peoples and local communities.

7. Following his opening remarks, the Deputy Executive Secretary invited the members of the AHTEG to briefly introduce themselves.

## **ITEM 2. ORGANIZATIONAL MATTERS**

### **2.1. Election of officers**

8. The AHTEG elected Mr. Nikolay Tzvetkov (Bulgaria) and Ms. Maria de Lourdes Torres (Ecuador) as co-chairs and Mr. Peter Kwapong (Ghana) as the meeting Rapporteur.

9. The co-chairs made introductory statements in which they highlighted the importance of the task at hand and the challenges before the Group.

### **2.2. Adoption of the agenda**

10. The co-chairs invited the AHTEG to consider and adopt the provisional agenda ([CBD/SYNBIO/AHTEG/2017/1/1](#)).

11. Following a proposal from one of its members, the AHTEG agreed to consider paragraph 1(e) of its terms of reference under agenda item 5 on “Other matters”.

### **2.3. Organization of work**

12. The AHTEG decided to proceed on the basis of the organization of work contained in annex I to the annotations to the agenda ([CBD/SYNBIO/AHTEG/2017/1/1/Add.1](#)).

## **ITEM 3. SUBSTANTIVE ISSUES**

13. Ms. Dina Abdelhakim of the Secretariat of the Convention on Biological Diversity provided an overview of the outcomes of the work of the Open-ended Online Forum on Synthetic Biology and

introduced the background document ([CBD/SYNBIO/AHTEG/2017/1/2](#)) to assist the AHTEG in its deliberations on each of the substantive items.

### **3.1. Recent technological developments in the field of synthetic biology**

14. In its deliberations under this agenda item, the AHTEG acknowledged that technological developments within the field of synthetic biology were advancing at an accelerated rate, resulting in an increasing number of organisms that had been engineered using various tools and techniques.

15. In reviewing the recent technological developments of synthetic biology, the AHTEG noted, inter alia, the following:

(a) Some recent synthetic biology techniques expand the range of organisms that can be modified;

(b) Synthesis of whole genomes and chromosomes is now possible and can have significant implications on the way modification of organisms is done;

(c) The development of various gene editing tools enables the simultaneous targeting of multiple sites, or multiplexing, within a genome in one step;

(d) Engineered gene drives are being developed in a range of sexually reproducing organisms, such as some insects and rodents;

(e) Biotechnology tools have become increasingly available in some countries to the “do-it-yourself” (DIY) community and the public at large outside of formal laboratory facilities;

(f) Some recent developments in synthetic biology have advanced to the point at which organisms might be considered for introduction into the environment at an accelerated rate;

(g) Approaches such as machine learning, artificial intelligence, robotics and those related to “big data” are being applied with a view to constructing and engineering genomes and genetic circuits, and are expected to enable rapid prototyping and testing of highly novel organisms;

(h) Combining new biotechnology tools and automation allows the more rapid production of modified organisms;

(i) Modified algae, being used for the production of chemical substances, might require relatively “open” production ponds/facilities due to the need for sunlight;

(j) The development of whole-cell and cell-free sensors is being pursued with a potential for use inside and outside laboratories;

(k) External genome regulation methods are being developed, such as RNA interference vectors or reagents being applied in the form of sprays.

16. The ever increasing speed of development within the field of synthetic biology might pose a challenge to the capacity to conduct risk assessments in some countries.

17. The recent developments in synthetic biology and the continued pace of development might pose challenges to the ability to understand the possible impacts on biodiversity and human health. There might be a need to consider more thoroughly the potential benefits and potential adverse effects at the ecosystem level, particularly for some developments, such as engineered gene drives.

18. The development and implementation of well-designed strategies, including physical containment and built-in systems to effectively limit the survival or spread, might be needed to prevent or minimize the exposure of the environment to organisms, components and products of synthetic biology

under contained use.<sup>4</sup> These strategies should be commensurate to the risk posed by the organisms, components and products.

19. The potential dual use nature of some advances in synthetic biology might raise biosecurity concerns in relation to the three objectives of the Convention.

20. The AHTEG noted that regular horizon scanning, monitoring and assessing of developments in the field of synthetic biology could be useful for reviewing new information regarding the positive and negative impacts of synthetic biology vis-à-vis the three objectives of the Convention and its Protocols.

21. The AHTEG also noted that most synthetic biology research and development took place in developed countries and in a limited number of developing countries, and that many developing countries as well as indigenous peoples and local communities might need capacity development to stay abreast of developments in that field. The AHTEG highlighted the need to explore ways to facilitate, promote and support capacity-building and knowledge sharing regarding synthetic biology, risk analysis and related matters, to meet the needs of developing countries and of indigenous peoples and local communities, including through necessary funding, and the co-design of programmes, with training provided in the official languages of the United Nations and, where possible, in local languages.

### **3.2. Evidence of benefits and adverse effects of organisms, components and products of synthetic biology vis-à-vis the three objectives of the Convention**

22. Under this agenda item, the AHTEG recalled the conclusion reached at its previous meeting that the organisms, components and products of synthetic biology were expected to have similar types of positive and negative impacts on biological diversity as classical genetic engineering. However, it considered that the potential positive and negative impacts of synthetic biology might be broader and more wide-ranging due to the potential for synthetic biology to produce organisms and biological systems with ranging levels of complexity for use in a range of applications.

23. The AHTEG noted that, beyond the experience gained from LMOs already released into the environment, to date, there was limited direct empirical evidence of the benefits and adverse effects on biodiversity resulting from the organisms, components and products of synthetic biology.

24. However, the AHTEG also noted the availability of other types of information and knowledge that were of scientific value in informing an assessment of the potential benefits or adverse effects of organisms, components and products that had been developed through synthetic biology techniques. That could include information based on modelling and scenarios, data from experiments performed under contained use, such as in laboratories, and experience gained through the management of pests and invasive alien species, including biological control, as well as from the use of LMOs that had been released into the environment. Information gathered from traditional animal and crop breeding, forestry, aquaculture and other human interventions in the environment, including knowledge, innovations and practices of indigenous peoples and local communities, could also be useful in exploring possible positive and negative impacts of organisms resulting from synthetic biology.

25. The AHTEG noted that consideration of the potential benefits and adverse effects of organisms produced through synthetic biology could be particularly relevant and urgent for those organisms that had been developed to contain engineered gene drives, in the light of the impacts that such organisms might have on the conservation and sustainable use of biological diversity, as well as the knowledge, innovations and practices of indigenous peoples and local communities, particularly if they were released into the environment. Uncertainties related to the efficacy and safety of engineered gene drive systems, as

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<sup>4</sup> Insofar as they are consistent with Conference of the Parties [decision V/5](#), para. 23.

well as the relative risks that could be posed by the different applications of engineered gene drive systems (for example, for population replacement or suppression) were noted. Furthermore, while there could be potential benefits to the development of such organisms, it was noted that additional research and guidance were needed before any organism containing engineered gene drives could be considered for release into the environment, including into lands and territories of indigenous peoples and local communities. The AHTEG also noted the potential for the unintended transboundary movements and geographic spread of organisms released into the environment. Given the current uncertainties regarding engineered gene drives, a precautionary approach and cooperation with all countries and stakeholders that could be affected, taking into account the need for the free, prior and informed consent of indigenous peoples and local communities, might be warranted in the development and release of organisms containing engineered gene drives, including experimental releases, in order to avoid potential significant and irreversible adverse effects to biodiversity.

26. The discussion under this agenda item also considered the possible impacts of synthetic biology on the traditional knowledge, innovation, and practices of indigenous peoples and local communities, as well as how synthetic biology would impact the relationship of indigenous peoples and local communities with Mother Nature. The development of such technologies should be accompanied by the full and effective participation of indigenous peoples and local communities with a view to creating a vision that would further guide advances and understanding in the field of synthetic biology and to integrating the concerns and needs of indigenous peoples and local communities in decision-making.

### **3.3. Living organisms developed through synthetic biology that may not be regarded as living modified organisms as per the Cartagena Protocol on Biosafety**

27. The AHTEG discussed this item on the basis of the contributions of the online forum and further analysed whether and how organisms developed through synthetic biology fulfilled the criteria of the definition of LMOs as per Article 3 of the Cartagena Protocol.

28. As a result of its deliberations, the AHTEG concluded that most living organisms already developed or currently under research and development through techniques of synthetic biology, including organisms containing engineered gene drives, fell under the definition of LMOs as per the Cartagena Protocol.

29. Techniques involving cell-free systems did not result in the development of living organisms. Likewise, to date, protocells that were capable of replicating genetic material did not exist and, as such, were not living organisms. In the future, however, protocells that were capable of transferring or replicating genetic material might be developed and those might be regarded as LMOs.

30. Furthermore, there were different interpretations as to whether or not organisms modified through epigenetic engineering contained novel combinations of genetic material and, therefore, those organisms might or might not be regarded as LMOs.

31. The AHTEG also noted that indigenous peoples and local communities regarded all components of Mother Nature as living entities.

### **3.4. Tools to detect and monitor the organisms, components and products of synthetic biology**

32. The AHTEG noted that most tools that were currently in use for the detection, identification and monitoring of LMOs could also be used for organisms developed through synthetic biology, but those tools might need to be updated and adapted.

33. The AHTEG also noted that challenges might arise in the case of organisms that might not have a suitable target marker(s) and when the resulting LMO was indistinguishable from a naturally occurring or conventionally bred counterpart. In such cases, the development of additional detection, identification and monitoring tools might be needed.

34. With regard to detecting and monitoring products of synthetic biology, it was noted that analytical techniques could be used to distinguish between products of synthetic biology and naturally occurring or chemically synthesized counterparts. However, further development in that area might be needed.

35. The AHTEG further noted that relying on traceability and documentation for identity preservation were also useful and cost-effective tools for identification and monitoring. In addition, regulatory tools, reporting and auditing mechanisms, as well as the use of online databases, such as the Biosafety Clearing-House and the Food Safety platform of the Food and Agriculture Organization of the United Nations, were useful for sharing information on the detection and monitoring of organisms, components and products of synthetic biology.

36. It was suggested that the Network of Laboratories for the Detection and Identification of LMOs,<sup>5</sup> among others, might be able to contribute to the assessment of the availability of tools for the detection of organisms developed through synthetic biology techniques and the identification of best practices as well as any gaps and challenges in existing methodologies that might need to be addressed. It was also suggested that the Network could be expanded to bring together experts in the field of analytical chemistry in order to facilitate the assessment of the availability of tools for the detection and monitoring of components and products of synthetic biology.

37. It was noted that, while tools for the detection, identification and monitoring of organisms, components and products of synthetic biology might be available, some countries might not have access to such tools due to insufficient technical infrastructure and technical capacity, and legal barriers. Capacity-building and legal and technological cooperation were therefore needed.

38. It was also suggested that developers of organisms resulting from synthetic biology that were intended for introduction into the environment or for placing on the market could be made responsible for providing validated tools, relevant sequence data and reference materials, in an accessible manner, that would facilitate the detection, identification and monitoring of such organisms and products thereof, as was already the case for LMOs under some frameworks.

### **3.5. Risk management measures, safe use and best practices for safe handling of organisms, components and products of synthetic biology**

39. The AHTEG took the view that it would be important to consider risk assessment as well as risk management in the discussion on this agenda item.

#### *Risk assessment*

40. The AHTEG reiterated that the general principles and methodologies for risk assessment under the Cartagena Protocol and existing national biosafety frameworks, as well as voluntary guidance, could provide a good basis for risk assessment of organisms developed through synthetic biology. These methodologies might need to be periodically updated and adapted.

41. Updates and adaptations might be needed to account for:

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

- (a) The lack of suitable comparators in cases whereby organisms developed through techniques of synthetic biology contain features that are significantly different from existing organisms;
- (b) Knowledge gaps in assessing unintended effects that might result from complex changes and novel traits;
- (c) Knowledge gaps in assessing interactions of combinatorial and cumulative effects of multiple organisms developed through synthetic biology being released in the same environment;
- (d) Lack of experience with the introduction of organisms containing engineered gene drives into natural populations.

42. The AHTEG also noted the existence of voluntary guidance documents that could be taken into account in the risk assessment of organisms developed through synthetic biology.<sup>6</sup>

43. In addition, the AHTEG noted the need to develop and conduct assessments of the potential positive and negative impacts of synthetic biology on the three objectives of the Convention, taking into account the continuing loss of biodiversity, including species extinctions and degradation of ecosystems, the relationship between indigenous peoples and local communities and Mother Nature, and the rights recognized by the United Nations Declaration on the Rights of Indigenous Peoples.

44. The AHTEG further noted that existing risk assessment considerations and methodologies might not be sufficient or adequate to assess and evaluate the risks that might arise from organisms containing engineered gene drives due to limited experience and the complexity of the potential impacts on the environment. The development or further development of guidelines on risk assessment of organisms containing engineered gene drives by the Convention, other international organizations, national governments and professional bodies would be useful in that regard.

45. Some experts noted that a stepwise approach might be appropriate in order to gather information that is needed to fill knowledge gaps and avoid adverse effects or minimise the likelihood of them occurring. However, the step of release into the environment might be irreversible and, therefore, a precautionary approach might be warranted.

46. The AHTEG noted the need to promote and support capacity-building and knowledge-sharing on synthetic biology, risk analysis and related matters in order to meet the needs of developing countries and of indigenous peoples and local communities, taking into account traditional knowledge, innovation, culture, free, prior and informed consent, customary practices and community protocols in the context of articles 8(j) and 10(c) of the Convention and the Akwé: Kon guidelines.

#### *Risk management*

47. The AHTEG noted that risk management measures should be imposed to the extent necessary to prevent adverse effects, taking into account uncertainties and lack of knowledge, and in accordance with national legislation and the customary law of indigenous peoples and local communities.

48. Current strategies for risk management and monitoring of LMOs might provide a good basis for managing the risks and monitoring potential impacts of organisms developed through synthetic biology. These strategies might need to be adapted and complemented in order to address specific characteristics of organisms developed through synthetic biology.

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<sup>6</sup> Such as the Guidance on Risk Assessment developed by the AHTEG on Risk Assessment and Risk Management and other relevant guidance documents as per decision [CP VIII/12](#).

49. Cooperation with international organizations and other relevant stakeholders could assist in identifying best practices within other frameworks that were relevant for risk management and monitoring of organisms, components and products of synthetic biology, and that were consistent with the objectives of the Convention.

50. The AHTEG discussed the appropriateness of current containment measures and noted the existence of guidelines for various levels of containment, ranging from laboratory settings to outdoor facilities. The AHTEG also noted that the requirements for the implementation of these containment measures varied among countries.

51. Regarding the containment of organisms containing engineered gene drives, the following points were raised:

(a) Best practices for effective containment of LMOs should be adapted and applied for organisms containing engineered gene drives;

(b) Islands are not ecologically fully contained environments and should not be regarded as fulfilling the conditions in the definition of contained use as per Article 3 of the Cartagena Protocol unless it is so demonstrated;

(c) Internationally agreed standards for effective containment of organisms containing engineered gene drives might be useful in order to avoid accidental releases from laboratory facilities.

52. The AHTEG noted that horizon scanning of synthetic biology under the Convention could also keep track of progress in the adaptation of risk assessment and risk management of organisms developed through synthetic biology.

53. The AHTEG highlighted the need to take into account the socio-economic impacts, perspectives, rights and lands of indigenous peoples and local communities when considering the possible release of organisms developed through synthetic biology into the lands and territories of indigenous peoples and local communities.

#### **ITEM 4. CONCLUSIONS AND WAYS FORWARD**

54. The outcomes of the deliberations of the AHTEG in response to paragraphs 1(a) to (d) of its terms of reference in decision XIII/17 are set out in paragraphs 14 to 53 above.

55. The AHTEG recommended that the Subsidiary Body on Scientific, Technical and Technological Advice at its twenty-second meeting consider the outcomes of this meeting to facilitate future discussions and actions on synthetic biology under the Convention.

#### **ITEM 5. OTHER MATTERS**

56. The AHTEG noted that the Subsidiary Body on Scientific, Technical and Technological Advice at its twenty-first meeting, to be held in Montreal, Canada, from 11 to 14 December 2017, would consider how to apply the criteria, as set out in paragraph 12 of [decision IX/29](#), for the selection of new and emerging issues relating to the conservation and sustainable use of biological diversity. The AHTEG decided to defer the analysis requested in paragraph 1(e) of its terms of reference until further guidance was provided.

57. The importance of addressing the potential socio-economic impacts of the commercialization of products of synthetic biology that replaced naturally occurring products was noted.



58. The participation of representatives of indigenous peoples and local communities at the meeting was acknowledged. The Secretariat was encouraged to continue facilitating their full and effective participation in all meetings that were relevant to the three objectives of the Convention.

**ITEM 6. ADOPTION OF THE REPORT**

59. The draft report was introduced to the AHTEG by the Rapporteur. The co-Chairs invited the AHTEG to consider the report. The report was adopted as orally amended.

**ITEM 7. CLOSURE OF THE MEETING**

60. The meeting closed on Saturday, 9 December 2017, at 3:05 a.m.

## Annex

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