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REPORT OF THE AD HOC TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY MONTREAL, CANADA, 4-7 JUNE 2019

INTRODUCTION

A. Background

1. At its fourteenth meeting, the Conference of the Parties to the Convention on Biological Diversity adopted decision 14/19 on synthetic biology, which, among other things, set out a process for further consideration of this matter. The process included:

(a) An invitation to Parties, other Governments, indigenous peoples and local communities, and relevant organizations and stakeholders to submit relevant information to the Executive Secretary (para. 16);

(b) A request to the Executive Secretary to convene moderated online discussions under the Open-ended Online Forum on Synthetic Biology (para. 17(a));

(c) The extension of the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology with renewed membership and a request to the Executive Secretary to convene a meeting of the group in accordance with the terms of reference contained in the annex to decision 14/19.

2. The AHTEG is to submit the outcomes of its work for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice at a meeting to be held prior to the fifteenth meeting of the Conference of the Parties.

3. Pursuant to the above, and with generous financial support from the European Union, a meeting of the AHTEG was held at the offices of the Secretariat of the Convention on Biological Diversity from 4 to 7 June 2019.

B. Attendance

4. By notification 2019-023 of 20 February 2019,[1] Parties, other Governments, indigenous peoples and local communities, relevant organizations and stakeholders were invited to nominate experts to the AHTEG.

5. The Secretariat received a total of 54 nominations from Parties to the Convention and 27 nominations from observers, of which 1 was from a non-Party, 8 were from indigenous peoples and local communities and 18 from relevant organizations. The experts were selected in accordance with the consolidated modus operandi of the Subsidiary Body on Scientific, Technical and Technological Advice (see decision VIII/10, annex III), and through the application of decision 14/33 on the procedure for avoiding or managing conflicts of interest in expert groups. The selection also took into account the expertise and experience of the nominees and the need to ensure equitable geographical distribution and gender balance.

6. Following consultation with the Bureau of the Subsidiary Body on Scientific, Technical and Technological Advice, the composition of the AHTEG was announced in notification 2019-037 of 5 April 2019.[2]

[1] No. SCBD/CPU/KG/MA/MW/87944.

7. Experts nominated by Australia, Austria, Belarus, Benin, Brazil, Bulgaria, Canada, China, Colombia, Cuba, Ecuador, Germany, Madagascar, Malaysia, Namibia, Norway, the Republic of Moldova, Serbia, Slovenia, South Africa, Sudan, the Syrian Arab Republic and Viet Nam attended the meeting. The experts from the Philippines, Mexico and Sudan, who had been selected and invited, were unable to attend the meeting. An expert from the United States of America (a non-Party to the Convention) also attended the meeting.

8. Two experts nominated by the following organizations representing indigenous peoples and local communities participated in the meeting: La Red de Mujeres Indígenas sobre Biodiversidad de América Latina y el Caribe and Ole Siosiomaga Society Inc.

9. Experts nominated by the following organizations also participated in the meeting: ETC Group, EuropaBio, Federation of German Scientists, GenØk, International Union for Conservation of Nature, J. Craig Venter Institute, North Carolina State University, Third World Network and World Health Organization.

ITEM 1. OPENING OF THE MEETING

10. The meeting was opened at 9 a.m. on Tuesday, 4 June 2019, by the Executive Secretary of the Convention. She welcomed the experts and highlighted the importance of the topic of synthetic biology, indicating that it holds much promise but also potential risks. She encouraged the AHTEG members to share their technical expertise and to learn from one another in order to achieve better understanding of the challenges and opportunities presented by synthetic biology. A special mention was made of the many women active in the field of synthetic biology who were ready to contribute to the discussions of the AHTEG.

11. The Executive Secretary underlined that discussions on the development of the post-2020 global biodiversity framework must be mindful of technological changes and how they may impact biodiversity in the future. She emphasized the history of the Convention in bringing together different points of view to achieve common understanding on some of the most challenging issues of our time.

ITEM 2. ORGANIZATIONAL MATTERS

12. The AHTEG elected Ms. Maria de Lourdes Torres and Mr. Casper Linnestad as co-chairs of the meeting.

13. The group adopted the following agenda on the basis of the provisional agenda (CBD/SYNBIO/AHTEG/2019/1/1) prepared by the Secretariat:

1. Opening of the meeting.
2. Organizational matters.
3. Consideration of topics as mandated by the Conference of the Parties:
    - 3.1. New technological developments in synthetic biology;
    - 3.2. Synthetic biology applications that are in early stages of research and development, vis-à-vis the three objectives of the Convention;
    - 3.3. Synthetic biology organisms that may fall outside the definition of living modified organisms as per the Cartagena Protocol;
    - 3.4. The state of knowledge on the potential environmental impacts of applications of synthetic biology, including those applications that involve organisms containing engineered gene drives;
    - 3.5. Options for regular horizon scanning, monitoring and assessing of developments;
    - 3.6. Relationship between synthetic biology and the criteria set out in decision IX/29, paragraph 12.

[2] No. SCBD/CPU/KG/MA/MW/87944.

4. Other matters.

5. Adoption of the report.

6. Closure of the meeting.

14. The group agreed on the organization of its work as outlined in annex I to the annotated provisional agenda (CBD/SYNBIO/AHTEG/2019/1/1/Add.1).

ITEM 3. CONSIDERATION OF TOPICS AS MANDATED BY THE CONFERENCE OF THE PARTIES

15. Under this agenda item, the Secretariat recalled the process and requests set out in decision 14/19 and introduced a note by the Executive Secretary summarizing the activities on synthetic biology (CBD/SYNBIO/AHTEG/2019/1/2) and four background documents: a synthesis of submissions (CBD/SYNBIO/AHTEG/2019/INF/1); a synthesis of discussions of the Online Forum (CBD/SYNBIO/AHTEG/2019/INF/2); a list of references (CBD/SYNBIO/AHTEG/2019/INF/3); and information for deliberations on agenda item 3.4 (CBD/SYNBIO/AHTEG/2019/INF/4).

16. The co-chairs recalled the common understanding from the 2015 meeting of the AHTEG that the term "components" would refer to parts used in a synthetic biology process (for example, a DNA molecule), and the term "products" would refer to the resulting output of a synthetic biology process (for example, a chemical substance), and to consider both "components" and "products" as non-living entities. They also recalled paragraph 4 of decision XIII/17, whereby the Conference of the Parties acknowledged the operational definition of synthetic biology[3] and considered it useful as a starting point for the purpose of facilitating scientific and technical deliberations under the Convention and its Protocols. The co-chairs indicated that the AHTEG would work on the basis of that common understanding and the operational definition.

3.1. New technological developments in synthetic biology

17. Under this item, the experts were invited to take stock of new technological developments in synthetic biology since the last meeting of the AHTEG, in 2017, including the consideration, among other things, of concrete applications of genome editing if they relate to synthetic biology, in order to support a broad and regular horizon scanning process.

3.2. Synthetic biology applications that are in early stages of research and development, vis-à-vis the three objectives of the Convention

18. Under this item, the experts were invited to 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.

3.3. Synthetic biology organisms that may fall outside the definition of living modified organisms as per the Cartagena Protocol

19. Under this item, the experts considered whether any living organism developed thus far through new developments in synthetic biology fell outside the definition of a living modified organism (LMO) as per the Cartagena Protocol on Biosafety.

3.4. The state of knowledge on the potential environmental impacts of applications of synthetic biology, including those applications that involve organisms containing engineered gene drives

20. Under this item, the experts were invited to undertake a review of the current state of knowledge by analysing information, including but not limited to peer-reviewed published literature, on the potential

[3] "Synthetic biology is a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems".

positive and negative environmental 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.

3.5. Options for regular horizon scanning, monitoring and assessing of developments

21. Under this item, the experts considered options for carrying out the regular horizon scanning, monitoring and assessing of developments referred to in paragraph 3 of decision 14/19.

3.6. Relationship between synthetic biology and the criteria set out in decision IX/29, paragraph 12

22. Under this item, the experts were invited to 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 CBD/SBSTTA/22/INF/17.

23. The outcomes of the group's deliberations on each of these agenda sub-items are outlined in annex I below.

ITEM 4. OTHER MATTERS

24. The AHTEG recognized the need for capacity-building for developing countries and indigenous peoples and local communities and other actors to enable them to engage in the assessment of actual and potential impacts of synthetic biology. It also noted the need for the participation of youth and indigenous peoples and local communities in activities related to synthetic biology carried out under the Convention. It considered that appropriate communication and engagement with communities was important for building the necessary understanding for informed consideration. The AHTEG also considered that, although the need for capacity development had been repeatedly noted, more support was needed in that regard. The need for technology transfer was also noted.

25. Some members suggested that there might be a gap in procedures under the Convention for assessment of organisms, components and products of synthetic biology and that any such gap would need to be addressed.

ITEM 5. ADOPTION OF THE REPORT

26. The co-chairs introduced the draft report of the meeting, which was adopted as orally amended.

ITEM 6. CLOSURE OF THE MEETING

27. Following the customary exchange of courtesies, the meeting was closed at 11:30 pm on Friday, 7 June 2019.

Annex I

OUTCOMES OF THE MEETING OF THE AD HOC TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY

1. The AHTEG recognized that the different elements of its mandate were interrelated and that there may be some overlap in the discussions on these elements. It considered that new technological developments (addressed under its agenda item 3.1) was a broad topic while synthetic biology applications in early stages of research and developments (addressed under item 3.2) was more concrete. It also noted that the discussions under a number of items, particularly 3.1, 3.2 and 3.4, could inform consideration of the process for broad and regular horizon scanning, monitoring and assessment [4] addressed under item 3.5.

2. The AHTEG recognized that the submissions of information and the online forum had provided important and useful information for its deliberations. It also recognized, however, that the online forum may have had limitations, for example, for those who come from an oral tradition of communication or whose mother tongue is not English.

3. The AHTEG also expressed its appreciation for the compilation of the bibliographic references (CBD/SYNBIO/AHTEG/2019/1/INF/3), which had served as a useful source of information. It agreed that it would be beneficial if the Secretariat continued to update this document as new research on synthetic biology was published.

I. NEW TECHNOLOGICAL DEVELOPMENTS IN SYNTHETIC BIOLOGY

4. The AHTEG recalled the discussions on recent technological developments in the field of synthetic biology during its 2017 meeting, and noted that the outcomes of that discussion remain relevant.

5. The AHTEG noted that new technological developments could be grouped into trends that could inform a process for horizon scanning, monitoring and assessment. The Group identified a number of trends as follows, recognizing that this list is not exhaustive:

(a) Increased field testing of organisms, components and products derived from new developments in synthetic biology;

(b) Increased development of technologies that genetically modify organisms directly in the field;

(c) A shift to the development of synthetic biology for environmental, conservation, agricultural and health uses (some examples are provided in paragraph 12 below);

(d) Increasing sophistication of methods, including, for example, new genome editing techniques, more complex metabolic engineering, the recoding of genomes, and the use of artificial intelligence/machine learning for the redesign of biological systems;

(e) The use of transient modification of organisms, including, for example, through the use of synthetic double-stranded RNA molecules, nano-particles and genetically modified viruses;

(f) Ability to produce new synthetic biomolecules using non-canonical nucleotides and amino acids;

(g) The use of synthetic biology for non-biological purposes, for example in data storage.

6. It was noted that the technological developments mentioned within the various trends referred to above could be at different stages of progress and may be more advanced in some countries than in others.

[4] In decision 14/19, paragraph 3, the Conference of the Parties agreed "that broad and regular horizon scanning, monitoring and assessing of the most recent technological developments is needed 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". The phrase "horizon scanning, monitoring and assessment" is used in the text that follows to refer to this process.

7. The potential dual use nature of some advances in synthetic biology might raise biosecurity concerns in relation to the three objectives of the Convention.[5]

8. In taking stock of new technological developments in synthetic biology, the AHTEG acknowledged the importance of considering the speed of development, geographic spread and availability and accessibility of tools and expertise. These factors may, among other things, pose challenges to the capacity to conduct risk assessment and the ability to understand the full range of possible impacts.

II. SYNTHETIC BIOLOGY APPLICATIONS THAT ARE IN EARLY STAGES OF RESEARCH AND DEVELOPMENT, VIS-À-VIS THE THREE OBJECTIVES OF THE CONVENTION

9. The AHTEG recognized that synthetic biology applications are at different stages of research and development and that, therefore, their relation to the objectives of the Convention should not be generalized.

10. The AHTEG recalled that, in decision 14/19, paragraph 5, the Conference of the Parties had recognized that synthetic biology applications could pose challenges to the ability of some countries, especially developing countries which might lack the necessary capacity, to assess the potential impacts in relation to the three objectives of the Convention. Such applications could, for example, have cultural and socioeconomic impacts over a large geographic area and in locations far from the place of use.

11. It was noted that indigenous peoples and local communities could have different perspectives, different ways of perceiving potential impacts and be impacted differently by synthetic biology applications in relation to the objectives of the Convention, since, for indigenous peoples and local communities, natural elements are living entities. It was recalled that the free, prior informed consent of potentially affected indigenous peoples and local communities should be sought or obtained.

12. Recognizing the similarities between this topic and the discussion on new technological developments in synthetic biology (see section I above), the AHTEG identified the following as examples of specific synthetic biology applications, chosen primarily from those that are in early stages of research and development (R and D), that may be relevant to the three objectives of the Convention:

(a) Applications intended for use in the environment in managed and wild populations:

(i) Genetically engineered nitrogen-fixing bacteria and other genetically engineered bacteria/viruses for agriculture – some close to or at field trials;

(ii) Genetically engineered bacteria for such environmental applications as bioremediation, biodegradation and biomining – various stages of R and D;

(iii) Engineered gene drive system in mice for conservation purposes, control of vector-borne disease and agricultural pests, medical research – early laboratory R and D stage;

(iv) Engineered gene drives in a few mosquito species for potential control of vector-borne diseases through either population collapse or to interrupt the ability to transmit disease – laboratory R and D stage;

(v) Engineered gene drive for an agricultural pest (spotted wing *Drosophila*) – laboratory R and D stage;

(vi) Genetically engineered sorghum to produce a new synthetic protein to improve digestibility for food and feed – early field trial stage;

(vii) Insect delivery of modified viruses for the modification of crops (horizontal environmental genetic alteration agents (HEGAAs)) for biodefense, agriculture – early laboratory R and D stage;

[5] See also paragraph 19 of the 2017 AHTEG report (CBD/SYNBIO/AHTEG/2017/1/3).

(viii) Improving the resilience of wild animal and plant populations, for example the ability of genetically engineered corals to withstand stress – early laboratory R and D stage;

(ix) Transient modification of agricultural plants through, for example RNAi spray (non-living biopesticide) – laboratory R and D stage;

(x) Cyanobacteria production platforms (i.e. engineered for the photosynthetic production of fuels and fine chemicals) in contained environmental facilities – laboratory R and D stage;

(b) Applications intended for use in the laboratory:

(i) Development of protocells and minimal cells for basic research – early stage laboratory research;

(ii) Applications to produce non-native nucleotides and amino acids inside the cell (novel engineered synthetic pathways) for basic research and production of pharmaceuticals – early stage R and D;

(iii) Development of synthetic virus-like assemblies for drug delivery and vaccine applications (synthetic nucleocapsids) for human health and perhaps animal health – early laboratory R and D stage;

(iv) Re-creation of an extinct infectious horsepox virus from chemically synthesized DNA fragments, for the purpose of creating a smallpox vaccine. This demonstrated proof of concept of *de novo* synthesis of a complex virus (health implications, biosecurity concerns);

(c) Applications with intended use in both the environment and the laboratory:

(i) Genetically engineered bio-containment systems within the cell, primarily for use in the environment but also some laboratory applications – various stages of R and D;

(ii) Biofoundries (i.e., highly automated service laboratories) that engineer microbes for a variety of purposes – biofoundries exist now, products in various stages of R and D and on the market;

(iii) Genetically engineered plants to produce recombinant polyclonal antibodies against snake venom toxins – early laboratory R and D stage.

III. SYNTHETIC BIOLOGY ORGANISMS THAT MAY FALL OUTSIDE THE DEFINITION OF LIVING MODIFIED ORGANISMS AS PER THE CARTAGENA PROTOCOL

13. The AHTEG noted that both legal and technical considerations inform the question of whether a synthetic biology organism falls within or outside the definition of "living modified organism" as per the Cartagena Protocol.

14. The AHTEG recalled the statement from its 2017 report whereby it had noted that "indigenous peoples and local communities regarded all components of Mother Nature as living entities."

15. The AHTEG discussed a number of examples that had been identified through the submissions and the online forum, of synthetic biology organisms that may fall outside the definition of "living modified organism" (see CBD/SYNBIO/AHTEG/2019/1/2, para. 17).

16. From these examples, it was acknowledged that both virus-like macromolecular assemblies and protocells were not living organisms.

17. Views differed on whether organisms whose genomes had been edited without the use of nucleic acids using only protein reagents introduced into the cell, for example by ZFN/TALEN/MN applications, would fall under the definition of "living modified organism".

18. In addition, the AHTEG considered that it was unclear whether some transiently modified organisms fall within or outside the definition of "living modified organism".

19. In this light, the AHTEG recalled the related discussion reflected in its 2017 report in which 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." The AHTEG agreed that this conclusion was still valid.

20. The AHTEG also noted, however, that, given the rapid developments in the field, it may be possible that synthetic biology organisms developed in the future could fall outside the definition of "living modified organism" in the Protocol. Were such a situation to arise, it was recognized that the relevant obligations in the Convention would continue to apply.

21. In discussing the use of terms in Article 3 of the Cartagena Protocol, the AHTEG considered how interpretations of these definitions are now being challenged by new technological developments. It was noted, however, that the Convention contains a definition of "biotechnology" which is broader than the definition of "modern biotechnology" in the Cartagena Protocol, and it was recognized that all Parties to the Convention have obligations with regard to biotechnology and living modified organisms and that the Conference of the Parties has adopted decisions with regard to organisms, components and products of synthetic biology.

22. The AHTEG agreed that it would be important to take a coordinated, complementary and non-duplicative approach on issues related to synthetic biology under the Convention and the Cartagena Protocol.

IV. THE CURRENT STATE OF KNOWLEDGE BY ANALYSING, INCLUDING BUT NOT LIMITED TO PEER REVIEWED PUBLISHED LITERATURE, ON THE POTENTIAL POSITIVE AND NEGATIVE ENVIRONMENTAL IMPACTS OF CURRENT AND NEAR FUTURE APPLICATIONS OF SYNTHETIC BIOLOGY, INCLUDING THOSE APPLICATIONS THAT INVOLVE ORGANISMS CONTAINING ENGINEERED GENE DRIVES, TAKING INTO ACCOUNT HUMAN HEALTH, CULTURAL AND SOCIOECONOMIC IMPACTS, ESPECIALLY WITH REGARD TO THE VALUE OF BIODIVERSITY TO INDIGENOUS PEOPLES AND LOCAL COMMUNITIES

23. The AHTEG highlighted the challenges associated with addressing its mandate under point (c) of its terms of reference, noting that undertaking a review of the current state of knowledge is a complex task.

24. The AHTEG noted that the review of the current state of knowledge may provide valuable contributions towards a broad and regular horizon scanning, monitoring and assessment exercise.

25. It also noted that there were multiple factors highlighted in the terms of reference which may require a structured approach or framework in order to undertake this task in a proper way. A consideration of potential benefits and risks is useful but would not be sufficient; it would also be important to identify knowledge gaps in a broad perspective that would continue to be relevant in the future.

26. It was pointed out that multiple dimensions need to be considered when assessing the current state of knowledge, including environmental, human heath, cultural, socioeconomic and ethical dimensions as well as the implications for indigenous peoples and local communities. Likewise, the need to consider what kind of technology assessment tools should be used was highlighted as an important aspect that could inform a proper assessment of potential impacts.

27. The following current challenges were pointed out concerning the identification of potential gaps with respect to data and information as well as tools and instruments as a basis for compiling and assessing the state of knowledge:

(a) Information on the potential receiving environment and its interaction with some organisms, products and components of synthetic biology intended for release into the environment;

(b) Analytical tools to detect, identify and monitor some organisms, products and components of synthetic biology;

(c) Tools to complement risk assessment methods, e.g. regarding assessment of ethical, cultural and socioeconomic factors, including potential benefits, in addition to environmental and human health factors.

28. The AHTEG recalled its discussion on risk assessment and risk management during its 2017 meeting as reflected in section 3.5 of the report on that meeting and agreed that these considerations were still valid.

29. The AHTEG noted that more information for assessing potential impacts may become available in the future (e.g. during contained use experiments, field trials, at the time of release, by modelling), highlighting that the state of knowledge will be constantly evolving as new information becomes available.

30. The AHTEG also pointed out that experience from the risk assessment of LMOs as well as other fields, such as technology assessment and experience with and management of invasive alien species, could be a useful source of information to anticipate potential impacts. The usefulness of the Biosafety Clearing-House as a source of information was also highlighted.

31. The AHTEG noted that some applications of synthetic biology aimed at biodiversity conservation could raise a number of conceptual and legal issues with regard to the status of protected or threatened species, regulation of trade in wildlife products and the compatibility of these approaches with conservation and the cultural practices of indigenous peoples and local communities. These issues may warrant further consideration in cooperation with the appropriate bodies, e.g. CITES.

32. The AHTEG also noted that synthetic biology could raise more general issues regarding the nature of biological diversity.

33. The AHTEG recognized that the state of knowledge on potential impacts of current and near future applications of synthetic biology should consider that, for indigenous peoples and local communities, those applications that may impact their traditional knowledge, innovation, practices, livelihoods and use of land, resources and water should seek their free, prior and informed consent, and the assessment of those applications is usually undertaken in a participatory manner involving the whole community.

34. The AHTEG noted that the online forum and the submissions on synthetic biology raised a number of general considerations related to potential positive and negative impacts from current and near-future applications of synthetic biology, recognizing that these were similar to the points reflected in the 2015 meeting of the AHTEG. These considerations are summarized in CBD/SYNBIO/AHTEG/2019/INF/4, paragraph 3.

V. OPTIONS FOR REGULAR HORIZON SCANNING, MONITORING AND ASSESSMENT

35. The AHTEG recalled that the Conference of the Parties, in decision 14/19, paragraph 3, agreed that broad and regular horizon scanning, monitoring and assessment of the most recent technological developments was needed 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, and had mandated the AHTEG to recommend options in this regard.

36. The AHTEG considered this agenda item in the light of the other agenda items which provided some relevant experience in reviewing information regarding the potential impacts of synthetic biology vis-à-vis the Convention and the protocols.

37. The AHTEG considered that the process for horizon scanning, monitoring and assessment requires the following steps:

(a) Information gathering;

(b) Compilation, organization and synthesis of information;

(c) Assessment;

(d) Reporting on outcomes.

38. The AHTEG suggested that:

(a) The steps of information gathering and of compiling, organizing and synthesizing of information, should be coordinated by the Secretariat;

(b) The steps of assessing the information and of reporting on outcomes should be undertaken primarily by a multidisciplinary technical expert group, and/or another assessment body. The Subsidiary Body on Scientific, Technical and Technological Advice may have a role in approving the main conclusions of the process;

(c) Other actors could be involved in the steps as further elaborated in paragraph 41 and the table in the appendix.

39. The outcomes of the process would be reviewed by the Subsidiary Body on Scientific, Technical and Technological Advice, and its conclusions and recommendations would be submitted to the Conference of the Parties and, where appropriate, the Parties to the Cartagena Protocol and/or the Parties to the Nagoya Protocol, for consideration. The outcomes of the assessment, related conclusions and recommendations of the Subsidiary Body on Scientific, Technical and Technological Advice, and related decisions of the Conference of the Parties and the Parties to the protocols, may also be used by other bodies under the Convention and the protocols (such as the compliance committees), may be communicated to relevant bodies in the United Nations system, may be used to inform decision-making by individual Parties and others, and may be used to support capacity-building.

40. The process, comprising the four steps, would be a periodic one, with each cycle occurring over an intersessional period (i.e. a biennium). The process would be kept under review by the Subsidiary Body on Scientific, Technical and Technological Advice and the Conference of the Parties with a periodic review of the effectiveness of the process.

41. The AHTEG also noted the following considerations:

(a) Possible mechanisms for the step of information gathering include: submissions of information through notifications, outreach to relevant institutions and intergovernmental organizations, online forums and other existing tools, such as national reports, and the clearing-house mechanism;

(b) Mechanisms for information gathering should seek inputs from a diverse range of actors, facilitate the engagement of indigenous peoples and local communities, among other major groups, and build on the work done by other processes (including relevant horizon scanning or technology assessment processes, such as those under United Nations bodies and processes);

(c) All of the information compiled and synthesized could be made available, including through the clearing-house mechanism;

(d) Some issues identified during one cycle may need to continue to be considered in subsequent cycles with a view to supporting ongoing monitoring of these issues;

(e) Consistency in the way the process is carried out would be important with a view to obtaining results that could be comparable over time;

(f) Expertise from a broad range of disciplines, as well as interdisciplinary and intercultural expertise, would be necessary, especially for the assessment step;

(g) The selection of experts for the multidisciplinary technical expert group, and/or another assessment body will be undertaken in accordance with the consolidated modus operandi of Subsidiary Body on Scientific, Technical and Technological Advice;

(h) The assessment step should employ tools and approaches to enable a participatory assessment process;

(i) The assessment step may be supported by, among other things, commissioning technology assessment exercises and/or collaborative activities with regional and national technology assessment platforms;

(j) Key actors in the horizon scanning, monitoring and assessment process, including consultants and members of any assessment body, should be subject to the procedure for avoiding or managing conflicts of interest set out in decision 14/33;

(k) Online mechanisms could support the various steps of the process, but face-to-face meetings would be necessary for the assessment step;

(l) External review of the draft outcomes of the process would be desirable to ensure their quality;

(m) Efforts would be needed to communicate the outputs effectively to a broad range of potential users, in a culturally appropriate format and in the official languages of the United Nations and, where possible, in local languages;

(n) The capacity, cost implications and effectiveness of the process, including the foregoing considerations, would need to be taken into account;

(o) Collaboration with other bodies in the United Nations system could be explored to support the horizon scanning, monitoring and assessment process;

(p) Efforts should be made to ensure the transparency of the process;

(q) Other bodies under the Convention and the protocols (e.g. the Informal Advisory Committee to the Clearing-House Mechanism, the Informal Advisory Committee on Biosafety Clearing-House) should contribute to various steps of the process and make use of the outcomes, as appropriate.

42. An overview of the options for the process is also presented in the appendix below.

VI. RELATIONSHIP BETWEEN SYNTHETIC BIOLOGY AND THE CRITERIA SET OUT IN DECISION IX/29, PARAGRAPH 12

43. The AHTEG deliberated extensively on how synthetic biology developments could be related to each of the criteria listed below as per decision IX/29.

44. The AHTEG recognized the challenge in bringing the criteria into context, understanding the criteria and the lack of guidance as to how they should be applied. The AHTEG noted the difficulty in applying the criteria to a broad topic, such as synthetic biology. There were questions regarding the suitability and wording of the criteria for identifying new and emerging issues. Recalling its mandate,[6] the AHTEG noted that it would be for the Subsidiary Body on Scientific, Technical and Technological Advice and the Conference of the Parties to take its advice into account in considering whether synthetic biology should be a new and emerging issue.

[6] Decision 14/19, annex, paragraph (a): "The Ad Hoc Technical Expert Group on Synthetic Biology shall 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 CBD/SBSTTA/22/INF/17".

Criterion (a)
Relevance of the issue to the implementation of the objectives of the Convention and its existing programmes of work

45. The AHTEG agreed that organisms, products and components developed through the use of synthetic biology were relevant to the implementation of the Convention and its programmes of work.

Criterion (b)
New evidence of unexpected and significant impacts on biodiversity

46. Experts had a range of perspectives regarding this criterion. There was an extensive discussion on the nature of evidence and what is considered evidence.

Criterion (c)
Urgency of addressing the issue/imminence of the risk caused by the issue to the effective implementation of the Convention as well as the magnitude of actual and potential impact on biodiversity

47. Experts had a range of perspectives regarding this criterion, including with respect to the imminence of possible release of organisms, components and products of synthetic biology. The interconnections between criteria (c), (d) and (e) were noted.

48. It was acknowledged that current regulatory mechanisms, including the Cartagena Protocol, already provide a framework for addressing the potential adverse effects of most organisms resulting from synthetic biology, including organisms that are likely to be produced by synthetic biology in the near future. On the other hand, some experts identified the lack of control strategies for engineered gene drives, including those with a greater potential for transboundary movement, as well as the lack of traceability and detectability methods for certain genome edited organisms and products thereof.

Criterion (d)
Actual geographic coverage and potential spread, including rate of spread, of the identified issue relating to the conservation and sustainable use of biodiversity

49. Views differed on the actual geographical coverage and potential spread, including the rate of spread, of organisms, components and products produced from synthetic biology. It was noted that some of the applications of synthetic biology, such as engineered gene drives, have not been released, and, thus, the actual geographical spread of these cannot be assessed. It was also noted that applications, such as gene drives or horizontal engineered genetic alteration agents, may have the potential for rapid spread over a wide geographical range.

50. It was noted that, for genome-edited organisms, the current lack of tools to detect these organisms could lead to them spreading more widely.

51. The continued expansion of access to the tools of synthetic biology was highlighted with regard to its potential to enable rapid spread and development of synthetic biology and its applications. Likewise, the increased accessibility of these tools could facilitate the release of organisms, components and products of synthetic biology by new actors (e.g. for example, do it yourself (DIY) practitioners and artists), which could pose challenges to the conservation and sustainable use of biodiversity.

Criterion (e)
Evidence of the absence or limited availability of tools to limit or mitigate the negative impacts of the identified issue on the conservation and sustainable use of biodiversity

52. Experts had a range of perspectives regarding this criterion.

53. It was acknowledged that current regulatory mechanisms, including the Cartagena Protocol, provide a framework for addressing the potential adverse effects of most organisms resulting from synthetic biology. However, some experts highlighted the lack of analytical tools for the detection, identification, and monitoring of some products and organisms of synthetic biology, and the lack of control measures as posing challenges for the mitigation of negative impacts. It was noted that the detectability of single nucleotide or small genomic changes could pose further challenges for some

countries. Further, some noted that there is a lack of appropriate tools for performing risk assessment to address the specific challenges from some organisms, products and components of synthetic biology.

Criteria (f) and (g)
Magnitude of actual and potential impacts of the identified issue on human well-being

Magnitude of actual and potential impact of the identified issue on productive sectors and economic well-being as related to the conservation and sustainable use of biodiversity

54. The AHTEG considered criteria (f) and (g) together. Experts had a range of perspectives regarding these criteria.

55. Potential health impacts were noted with respect to the reduction in vector-borne diseases, the reduction of the cost of pharmaceuticals through the utilization of synthetic biology, and the production of new vaccines. Potential impacts were noted regarding the challenges of shifting land use, lack of informed consent for society and lack of free, prior informed consent for indigenous peoples and local communities, and economic losses for small farmers. However, it was noted that the magnitude of impacts of synthetic biology, positive or negative, cannot be predicted in a generalized manner and should be assessed on a case-by-case basis, taking into account a broad range of areas beyond an environmental context.

56. The AHTEG recalled that the issue of digital sequence information on genetic resources and fair and equitable benefit-sharing was initially identified during its 2015 meeting and is now being considered through the process set out in decision 14/20. It noted the relevance of the issue to synthetic biology and human and economic well-being.

Appendix

Overview of possible elements of a process for broad and regular horizon scanning, monitoring and assessment

Process and steps		Coordinating actors	Other actors, considerations and options
Horizon scanning, monitoring and assessment process	(a) **Information gathering**	• Secretariat	• Possible mechanisms include: submissions of information through notifications, outreach to relevant institutions and intergovernmental organizations, online forums and other existing tools, such as national reports, and the clearing-house mechanism. • Seek inputs from a diverse range of actors, facilitate engagement of indigenous peoples and local communities, among others, and build on the work done by other relevant horizon scanning or technology assessment processes. • The work of the Secretariat could be supported through the use of consultants. • Some issues identified during one cycle may need to continue to be considered in subsequent cycles, with consistency in the way the process is carried out with a view to obtaining results that could be comparable over time.
	(b) **Compilation, organization and synthesis of information**	• Secretariat	• All of the information compiled and synthesized could be made available, including through the clearing-house mechanism. • The work of the Secretariat could be supported through the use of consultants.
	(c) **Assessment**	• Multidisciplinary technical expert group and/or another assessment body • Subsidiary Body on Scientific, Technical and Technological Advice (approval of the main conclusions of the process)	• Expertise from a broad range of disciplines, as well as interdisciplinary and intercultural expertise necessary. • Face-to-face meetings with support of online mechanisms. • Employ tools and approaches to enable a participatory assessment process. • Selection of experts for the multidisciplinary technical expert group, and/or another assessment body will be undertaken in accordance with the consolidated modus operandi of Subsidiary Body on Scientific, Technical and Technological Advice. • Key actors in the horizon scanning, monitoring and assessment process, including consultants and members of any assessment body, should be subject to the procedure for avoiding or managing conflicts of interest set out in decision 14/33. • Assessment step may be supported by, among other things,

Process and steps		Coordinating actors	Other actors, considerations and options
			commissioning technology assessment exercises and/or collaborative activities with regional and national technology assessment platforms.
	(d) **Reporting on outcomes**	• Multidisciplinary technical expert group, and/or another assessment body reports to Subsidiary Body on Scientific, Technical and Technological Advice. • Subsidiary Body on Scientific, Technical and Technological Advice reports to Conference of the Parties (and/or Parties to the Cartagena Protocol, Parties to the Nagoya Protocol)	• External review of the draft outcomes. • Communicate the outputs effectively to a broad range of potential users, in a culturally appropriate format and languages.
Use of outcomes in support of decision-making		• Subsidiary Body on Scientific, Technical and Technological Advice (review of outcomes, preparation of conclusions and recommendations) • Conference of the Parties and/or Parties to the Cartagena Protocol, Parties to the Nagoya Protocol (decision-making) • Parties and others, including other United Nations bodies.	
Review of process and its effectiveness		• Conference of the Parties on basis of review by Subsidiary Body on Scientific, Technical and Technological Advice	

Annex II

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