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Item 4 of the provisional agenda*

SYNTHETIC BIOLOGY

Note by the Executive Secretary

I. BACKGROUND

1. At its fourteenth meeting, in 2018, the Conference of the Parties adopted decision 14/19 on synthetic biology, in which it recognized that synthetic biology is rapidly developing and a cross-cutting issue, with potential benefits and potential adverse effects vis-à-vis the three objectives of the Convention on Biological Diversity. It 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 on Biosafety and the Nagoya Protocol on Access and Benefit-sharing.

2. In addition, the Conference of the Parties called upon Parties and other Governments, taking into account the current uncertainties regarding engineered gene drives, to apply a precautionary approach,[1] in accordance with the objectives of the Convention, and to only consider introducing organisms containing engineered gene drives into the environment, including for experimental releases and research and development purposes, when:

(a) Scientifically sound case-by-case risk assessments have been carried out;

(b) Risk management measures are in place to avoid or minimize potential adverse effects, as appropriate;

(c) Where appropriate, the "prior and informed consent", the "free, prior and informed consent" or "approval and involvement"[2] of potentially affected indigenous peoples and local communities is sought or obtained, where applicable in accordance with national circumstances and legislation.

3. The Conference of the Parties recognized the need to conduct an analysis of synthetic biology against the criteria for identifying new and emerging issues in decision IX/29, paragraph 12, in order to complete the analysis requested in decisions XII/24, paragraph 2, and XIII/17, paragraph 13. It decided to extend the Open-ended Online Forum on Synthetic Biology and the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology with renewed membership and with terms of reference as per the annex to the decision. It also invited Parties, other Governments, indigenous peoples and local communities, and relevant organizations to provide the Executive Secretary with relevant information to contribute to the work of the AHTEG.

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* CBD/SBSTTA/24/1.

[1] See decision XIII/17.

[2] Decision XIII/18.

4. Furthermore, the Conference of the Parties requested the Subsidiary Body on Scientific, Technical and Technological Advice to consider the work of the Open-ended Online Forum and the AHTEG; to note the preliminary analysis done by the Executive Secretary[3] and to consider further analyses and advice from the AHTEG of the relationship between synthetic biology and the criteria set out in decision IX/29; and to submit a recommendation to the Conference of the Parties at its fifteenth meeting.

5. In decision 14/19, the Executive Secretary was also requested, subject to the availability of resources, to undertake a number of activities related to cooperation, capacity-building, updating the Technical Series on synthetic biology, and sharing of experiences on detection, identification and monitoring of organisms, components and products of synthetic biology.

6. In addition to these elements from decision 14/19, the Subsidiary Body, at its twenty-third meeting, held in November 2019, considered proposals for new and emerging issues, two of which related to synthetic biology.

7. Section II of this document provides an overview of the process of submissions, discussions in the Online Forum, and meeting of the AHTEG on synthetic biology during the current intersessional period, while section III summarizes the activities undertaken in response to other requests to the Executive Secretary in decision 14/19. Section IV addresses the issue of the review against the criteria for new and emerging issues, and section V provides a draft recommendation for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice.

II. OVERVIEW OF PROCESS OF SUBMISSIONS, ONLINE FORUM AND MEETING OF THE AHTEG ON SYNTHETIC BIOLOGY

8. Further to the elements of decision 14/19 as summarized in paragraphs 3 and 4 above, the Executive Secretary (a) invited the submission of information on synthetic biology; (b) convened moderated online discussions on specific topics of synthetic biology through the Open-ended Online Forum; and (c) convened a face-to-face meeting of the AHTEG. Further details on each of these steps is provided in the subsections below.

A. Submission of information on synthetic biology

9. In paragraph 16 of decision 14/19, the Conference of the Parties invited Parties, other Governments, indigenous peoples and local communities, and relevant organizations to submit to the Executive Secretary relevant information related to paragraphs (a) to (d) of the terms of reference of the AHTEG as contained in the annex to the decision. In response to the above, the Executive Secretary issued notification 2018-103, dated 14 December 2018.

10. The notification invited the submission of information on four topics:

(a) 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 SBSTTA/22/INF/17;

(b) New technological developments in synthetic biology since the last meeting of the AHTEG in December 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;

(c) The current state of knowledge by analysing information, including but not limited to peer-reviewed published literature, on the potential 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;

[3] SBSTTA/22/INF/17.

(d) Living organisms developed thus far through new developments in synthetic biology that may fall outside the definition of living modified organisms as per the Cartagena Protocol.

11. A total of 28 submissions were received by the Secretariat. Among the submissions, 17 were from Parties, 1 from a non-Party, and 10 from organizations. The original submissions are available online at https://bch.cbd.int/synbio/submissions/.

12. An information document[4] containing a synthesis of the submissions was produced to support the deliberations of the AHTEG and the Subsidiary Body.

B. Open-ended Online Forum on Synthetic Biology

13. As described above, the Conference of the Parties decided to extend the Open-ended Online Forum on Synthetic Biology to support the work of the AHTEG.

14. By notification 2018-103 of 14 December 2018, the Executive Secretary invited Parties, other Governments, indigenous peoples and local communities and relevant organizations to nominate experts to participate in the Open-ended Online Forum on Synthetic Biology. In response, a total of 400 participants registered for the Forum: 236 from Parties, 3 from other Governments, 150 from organizations and 11 from indigenous peoples and local communities.

15. Discussions in the Open-ended Online Forum were convened from 4 to 31 March 2019. The discussions were moderated by Ms. Maria de Lourdes Torres (Ecuador) and Mr. Casper Linnestad (Norway).

16. Seven topics were identified for discussion under the Forum, as follows:

(a) Topic 1: New technological developments in synthetic biology since the last meeting of the Ad Hoc Technical Expert Group;

(b) Topic 2: Recommendations for options for carrying out the regular horizon scanning, monitoring and assessing of developments referred to in paragraph 3 of decision 14/19;

(c) Topic 3: Review of the current state of knowledge 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;

(d) Topic 4: Possible impacts of synthetic biology applications that are in early stages of research and development on the three objectives of the Convention;

(e) Topic 5: Consideration of whether any living organisms developed thus far through new developments in synthetic biology fall outside the definition of living modified organisms as per the Cartagena Protocol;

(f) Topic 6: Sharing of experiences on detection, identification and monitoring of organisms, components and products of synthetic biology;

(g) Topic 7: Relationship between synthetic biology and the criteria set out in decision IX/29.

17. A total of 109 participants were active in the discussions, and 338 interventions were made. Out of this total, 188 interventions were made by Parties, 5 by non-Parties, 141 by organizations and 4 by representatives of indigenous peoples and local communities.

18. A summary of the views shared through the discussions in the Online Forum was prepared to support the deliberations of the AHTEG and the Subsidiary Body.[5] For a full account of all views, it is recommended to refer to the original online interventions (https://bch.cbd.int/synbio/open-ended/discussion/).

[4] CBD/SYNBIO/AHTEG/2019/1/INF/1.

[5] CBD/SYNBIO/AHTEG/2019/1/INF/2.

C. Meeting of the Ad Hoc Technical Expert Group on Synthetic Biology

19. As described above, the Conference of the Parties decided to extend the Ad Hoc Technical Expert Group on Synthetic Biology with renewed membership, taking into account, inter alia, the work on risk assessment under the Cartagena Protocol. Based on this, by notification 2019-023 of 20 February 2019, the Executive Secretary invited Parties, other Governments, indigenous peoples and local communities and relevant organizations to nominate experts to the AHTEG. The experts were selected in accordance with the consolidated modus operandi of the Subsidiary Body (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 as well as bearing in mind the need for balance between new experts and experts from the 2017 AHTEG.

20. Following a consultation with the Bureau of the Subsidiary Body, the composition of the AHTEG was announced in notification 2019-037 of 5 April 2019.

21. Thanks to financial support from the European Union, a meeting of the AHTEG was held at the offices of the Secretariat in Montreal from 4 to 7 June 2019.

22. As set out in the annex to decision 14/19, the terms of reference of the AHTEG were to:

(a) 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;

(b) Take stock of new technological developments in synthetic biology since the last meeting[6] of the Ad Hoc Technical Expert Group, 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;

(c) Undertake a review of the current state of knowledge by analysing information, including but not limited to peer-reviewed published literature, on the potential 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;

(d) Consider whether any living organisms developed thus far through new developments in synthetic biology fall outside the definition of living modified organisms as per the Cartagena Protocol;

(e) 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;

(f) Recommend options for carrying out the regular horizon scanning, monitoring and assessing of developments referred to in paragraph 3 of decision 14/19;

(g) Prepare a report on the outcomes of its work for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice at a meeting to be held before the fifteenth meeting of the Conference of the Parties.

23. The AHTEG worked on the basis of information from the submissions and the discussions in the Online Forum. In addition, an information document containing a compilation of bibliographic references

[6] This refers to the AHTEG meeting held in December 2017.

was prepared by the Secretariat to support the deliberations of the AHTEG. An updated version of that document has been issued for this meeting.[7]

24. The AHTEG also worked on the basis of the common understanding from its 2015 meeting 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. In addition, the AHTEG also worked on the basis of the operational definition of synthetic biology[8] which the Conference of the Parties had acknowledged in decision XIII/17, paragraph 4, and considered useful as a starting point for the purpose of facilitating scientific and technical deliberations under the Convention and its Protocols.

25. The outcomes of the deliberations of the AHTEG in response to its terms of reference are presented in annex I to the present document. The full report of the AHTEG is available for information (CBD/SYNBIO/AHTEG/2019/1/3).

26. The Subsidiary Body may wish to welcome the outcomes of the AHTEG and, in line with these outcomes, recommend the establishment of a broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology. A draft recommendation to this effect is provide in section V.

III. OTHER REQUESTS TO THE EXECUTIVE SECRETARY IN DECISION 14/19

27. As outlined in paragraph 5 above, decision 14/19 contained a number of other requests to the Executive Secretary. A summary of actions related to these requests is presented here below.

28. The Executive Secretary was requested to update the Technical Series on Synthetic Biology[9] for consideration by the Subsidiary Body based on the peer review of scientific information and other relevant information. With financial support from the Governments of Austria and the Netherlands, the Secretariat started the process of updating the Technical Series in November 2020 in collaboration with the International Centre for Genetic Engineering and Biotechnology (ICGEB). The first draft of the Technical Series will be made available for peer review before the twenty-fourth meeting of the Subsidiary Body. An information document containing information on the update of the Technical Series on Synthetic Biology will be produced.

29. The Secretariat has undertaken cooperative activities on issues related to synthetic biology, following the request to further pursue cooperation with other organizations, conventions and initiatives, including academic and research institutions, from all regions, on issues related to synthetic biology. This has included the exchange of experiences and information, including providing input to and reviewing a publication by the United Nations Environment Programme, "Frontiers 2018/19 Emerging Issues of Environmental Concern",[10] and the International Union for Conservation of Nature (IUCN) assessment on synthetic biology and biodiversity conservation.[11] It has also included sharing information as a member of the United Nations Inter-Agency Committee on Bioethics[12] coordinated by the United Nations Educational, Scientific and Cultural Organization (UNESCO).

30. Paragraph 17 (e) of decision 14/19 requested the Executive Secretary to explore ways to facilitate, promote and support capacity-building and knowledge-sharing regarding synthetic biology, taking into

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[7] List of references on synthetic biology, CBD/SBSTTA/24/INF/6.

[8] "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".

[9] https://www.cbd.int/doc/publications/cbd-ts-82-en.pdf.

[10] https://wedocs.unep.org/bitstream/handle/20.500.11822/27544/Frontiers1819_ch1.pdf?sequence=1&isAllowed=y.

[11] "Genetic frontiers for conservation", https://portals.iucn.org/library/node/48408.

[12] See https://en.unesco.org/themes/ethics-science-and-technology/UNIACB.

account the needs of Parties and of indigenous peoples and local communities, including through necessary funding, and the co-design of information and training materials in the official languages of the United Nations and, where possible, in local languages. In line with this request, and considering the need for a coordinated, complementary and non-duplicative approach on issues related to synthetic biology under the Convention and its Protocols as stated in decision 14/19, paragraph 7, the Secretariat included topics related to organisms containing engineered gene drives in a capacity-building activity on risk assessment[13] that was carried out during the current intersessional period.

31. The Executive Secretary was requested to collaborate and convene discussions, including through the Network of Laboratories for the Detection and Identification of Living Modified Organisms, for sharing experiences on the detection, identification and monitoring of organisms, components and products of synthetic biology, and to continue inviting laboratories, including analytical laboratories, to join the Network. Through notification 2019-069 of 7 August 2019, the Secretariat invited the nomination of experts to the Network of Laboratories. Furthermore, through the Biosafety Clearing-House, the Secretariat hosted online discussions of the Network of Laboratories[14] from 28 October to 11 November 2019, which included the topic "Sharing of experiences on the detection, identification, and monitoring of organisms, components and products of synthetic biology". This topic was aimed at allowing participants to exchange information on (a) which tools are currently available for detecting, identifying and monitoring organisms, components and products of synthetic biology; (b) detection, identification and monitoring tools that may be needed due to the novelty that some organisms, components and products of synthetic biology might present; and (c) whether the current analytical techniques could be used to distinguish between products of synthetic biology and their naturally occurring or chemically synthesized counterparts. A summary of the online discussions will be presented as part of the document on detection and identification that the Secretariat will prepare for the tenth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol.

32. The Subsidiary Body may wish to recommend that the Executive Secretary continue pursuing cooperation on issues related to synthetic biology.

IV. CONSIDERATIONS FOR NEW AND EMERGING ISSUES AND ASSOCIATED CRITERIA

33. In accordance with the procedure in decision IX/29, the Executive Secretary, in notification 2019-041 of 9 April 2019, invited submissions of proposals for new and emerging issues relating to the conservation and sustainable use of biodiversity and the fair and equitable sharing of benefits arising from the use of genetic resources, to be considered at the twenty-third meeting of the Subsidiary Body, held in November 2019. In response, eight submissions were received. Of these, one submission suggested that synthetic biology should be classified as a new and emerging issue for the future work programmes under the Convention, while another proposed that a specific application of synthetic biology – open-air use of nucleic acids and proteins to alter traits, genes or other kinds of genetic material, which may pose risks to biodiversity and human health – be considered as a new and emerging issue. The submissions are summarized in document CBD/SBSTTA/23/8.

34. Through recommendation SBSTTA-23/7, the Subsidiary Body decided to defer to its twenty-fourth meeting consideration of the submission that synthetic biology should be classified as a new and emerging issue, considering the advice provided by the AHTEG on Synthetic Biology. It also recommended that, pending the outcome of the twenty-fourth meeting of the Subsidiary Body on the subject of synthetic biology, the Conference of the Parties decide not to add to the agenda of the Subsidiary Body in the coming biennium a new and emerging issue, pursuant to the procedure established through decision IX/29.

[13] https://www.cbd.int/meetings/CP-RARM-CB-2019-01.

[14] http://bch.cbd.int/onlineconferences/portal_detection/2019discussions.shtml.

35. As requested in its terms of reference, the AHTEG provided advice on the relationship between synthetic biology and each of the criteria for identifying new and emerging issues as set out in decision IX/29, paragraph 12. The outcomes of this discussion can be found in section VI of annex I.

36. As part of its discussions in this regard, the AHTEG recognized the challenge in bringing the criteria into context and in understanding the criteria, and the lack of guidance as to how the criteria should be applied. The AHTEG noted the difficulty in applying the criteria to a broad topic, such as synthetic biology, and there were questions regarding the suitability and wording of the criteria for identifying new and emerging issues.[15]

37. In the light of the outcomes of the AHTEG's discussions on the relationship between synthetic biology and the criteria for identifying new and emerging issues as set out in decision IX/29, paragraph 12, as well as the proposals related to synthetic biology considered at the twenty-third meeting of the Subsidiary Body, the Subsidiary Body should make a recommendation to the Conference of the Parties as to whether or not synthetic biology should be considered a new and emerging issue.

38. In addition, the Subsidiary Body may wish to recognize the challenges experienced by the AHTEG in bringing the criteria for new and emerging issues into context, understanding the criteria, and the lack of guidance on how the criteria should be applied. It may wish to recommend that the Conference of the Parties invite the submission of views on proposals for improving the criteria for identifying new and emerging issues and how these criteria should be applied. Furthermore, as requested in paragraph 18 (b) of decision 14/19, the Subsidiary Body may wish to note the preliminary analysis done by the Executive Secretary against the criteria for identifying new and emerging issues.[16]

V. SUGGESTED RECOMMENDATION

39. The Subsidiary Body on Scientific, Technical and Technological Advice may wish to recommend that the Conference of the Parties at its fifteenth meeting adopt a decision along the following lines:

The Conference of the Parties,

Recalling decision 14/19, in which it 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 on Biosafety and the Nagoya Protocol on Access and Benefit-sharing,

Welcoming the outcomes of the meeting of the Ad Hoc Technical Expert Group on Synthetic Biology held in Montreal, Canada, from 4 to 7 June 2019,[17]

1. *Establishes* a process for broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology as set out in annex II, section A;

2. *Establishes* the Multidisciplinary Technical Expert Group on Synthetic Biology to support the process for broad and regular horizon scanning, monitoring and assessment in accordance with the terms of reference contained in annex II, section B;

3. *Decides* that the trends in new technological developments in synthetic biology identified by the Ad Hoc Technical Expert Group on Synthetic Biology[18] will inform the horizon scanning, monitoring and assessment for the next biennium;

[15] See paragraph 44 of annex I.

[16] SBSTTA/22/INF/17.

[17] See annex I.

[18] See annex I.

4. *Invites* Parties, other Governments, indigenous peoples and local communities, and relevant organizations to submit to the Executive Secretary information relevant to the trends to inform the horizon scanning, monitoring and assessment;

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

(a) To commission technology assessments on the trends identified by the Ad Hoc Technical Expert Group on Synthetic Biology;

(b) To convene online discussions to support the work of the Multidisciplinary Technical Expert Group as needed;

(c) To synthesize the information submitted in response to paragraph 4 above as well as the information provided through the online discussions;

(d) To convene at least one meeting of the Multidisciplinary Technical Expert Group to consider the technology assessments and the synthesis of information referred to in subparagraphs (a) and (c) above, and to review the components, products and organisms being developed through the trends referred to in paragraph 3 above and consider their possible impacts on the objectives of the Convention;

6. *Requests* the Subsidiary Body on Scientific, Technical and Technological Advice to consider the outcomes of the work of the Multidisciplinary Technical Expert Group and make recommendations for the consideration of the Conference of the Parties at its sixteenth meeting and, as appropriate, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its eleventh meeting and the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol at its fifth meeting;

7. *Also requests* the Executive Secretary to continue pursuing cooperation with other organizations, conventions and initiatives, including academic and research institutions, on issues related to synthetic biology.

40. The Subsidiary Body on Scientific, Technical and Technological Advice may also wish to recommend that the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol and the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol each take note of the decision of the Conference of the Parties on this matter.

Annex I

OUTCOMES OF THE MEETING OF THE AD HOC TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY (MONTREAL, CANADA, 4-7 JUNE, 2019)

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[19] 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.

[19] 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.

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.

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.[20]

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;

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

(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;

(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 table 1 below[21].

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,[22] the AHTEG noted that it would be for the Subsidiary Body on Scientific, Technical and Technological Advice

[21] Table 1 below is a modified version of the appendix to the report of the AHTEG. The changes made are as follows: the title has been revised, the reference to the role of consultants in supporting the work of the Secretariat has been moved to the column on coordinating actors, the reference to commissioning technology assessments exercises and/or collaborative activities has been moved from step "c" to step "a" and the language of Multidisciplinary Technical Expert Group has been used throughout. The original version of the table can be found in the report of the AHTEG, CBD/SYNBIO/AHTEG/2019/1/3.

[22] 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".

and the Conference of the Parties to take its advice into account in considering whether synthetic biology should be a new and emerging issue.

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.

Annex II

BROAD AND REGULAR HORIZON SCANNING, MONITORING AND ASSESSMENT OF THE MOST RECENT TECHNOLOGICAL DEVELOPMENTS IN SYNTHETIC BIOLOGY

A. Process for the horizon scanning, monitoring and assessment

1. The process for broad and regular horizon scanning, monitoring and assessment consists of the following steps:

(a) Information gathering;

(b) Compilation, organization and synthesis of information;

(c) Assessment;

(d) Reporting on outcomes.

2. For each step, the coordinating actors, other actors and main considerations for the process are as set out in table 1.

3. The Subsidiary Body on Scientific, Technical and Technological Advice shall review the outcomes of the horizon scanning, monitoring and assessment and prepare conclusions and recommendations on technological developments in synthetic biology and their potential positive and negative impacts for the objectives of the Convention.

4. The effectiveness of the process for broad and regular horizon scanning, monitoring and assessment of technological developments in synthetic biology shall be reviewed four years following its adoption.

B. Terms of reference for the Multidisciplinary Technical Expert Group on Synthetic Biology to support the process for broad and regular horizon scanning, monitoring and assessment

1. The Multidisciplinary Technical Expert Group shall:

(a) Employing tools and approaches to enable a participatory assessment process, review and assess the information gathered through the process for broad and regular horizon scanning, monitoring and assessment and, on this basis, consider technological developments in synthetic biology and their implications for the objectives of the Convention;

(b) Identify issues identified during one cycle that may need to continue to be considered in subsequent cycles, as well as additional issues that may be considered priorities for the next intersessional period;

(c) Prepare a report on the outcomes of its assessment to be presented to the Subsidiary Body on Scientific, Technical and Technological Advice;

(d) Make recommendations to the Subsidiary Body on Scientific, Technical and Technological Advice on specific issues that may require further consideration by the Conference of the Parties and/or the Parties to the Cartagena Protocol and the Parties to the Nagoya Protocol.

2. The Multidisciplinary Technical Expert Group on Synthetic Biology will be constituted according to section H of the consolidated modus operandi of Subsidiary Body on Scientific, Technical and Technological Advice, including whenever possible, expertise from a broad range of disciplines, as well as interdisciplinary and intercultural expertise.

3. The procedure for avoiding or managing conflicts of interest in expert groups set out in the annex to decision 14/33 shall apply to the Multidisciplinary Technical Expert Group.

4. The Multidisciplinary Technical Expert Group on Synthetic Biology will work through a combination of face to face meetings, held physically and/or online, supported, as needed by online discussions.

Table 1. Process for broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology

Process and steps		Coordinating actors	Other actors and considerations
Horizon scanning, monitoring and assessment process	**(a) Information gathering**	• Secretariat, with the support of consultants as necessary	• Possible mechanisms include submissions of information through notifications; outreach to relevant institutions and intergovernmental organizations; online forums; commissioning technology assessment exercises and/or collaborative activities with regional and national technology assessment platforms; 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. • 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, with the support of consultants as necessary	• The information compiled and synthesized will be made available, including through the clearing-house mechanism.
	(c) Assessment	• Multidisciplinary Technical Expert Group on Synthetic Biology • 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 will be undertaken in accordance with the consolidated modus operandi of the Subsidiary Body on Scientific, Technical and Technological Advice. • Key actors in the horizon scanning, monitoring and assessment process, including consultants and members of the Multidisciplinary Technical Expert Group, will be subject to the procedure for avoiding or managing conflicts of interest set out in decision 14/33.

Process and steps		Coordinating actors	Other actors and considerations
	(d) Reporting on outcomes	• Multidisciplinary Technical Expert Group 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 the meeting of the Parties to the Cartagena Protocol, the meeting of the 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 the meeting of the Parties to the Cartagena Protocol, the meeting of the 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 periodic review by Subsidiary Body on Scientific, Technical and Technological Advice	