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Twenty-second meeting
Montreal, Canada, 2-7 July 2018
Item 5 of the provisional agenda*

SYNTHETIC BIOLOGY

Note by the Executive Secretary

BACKGROUND

1. At its thirteenth meeting, the Conference of the Parties adopted decision [XIII/17](#) on synthetic biology, reaffirming its earlier decision [XII/24](#), in which it had urged Parties and invited other Governments to take a precautionary approach, and noting that paragraph 3 of decision XII/24 could also apply to some living modified organisms containing gene drives. The Conference of the Parties commended the work of the online forum and the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology, and welcomed the conclusions and recommendations contained in the report of the Group as a basis for further discussion.
2. The Conference of the Parties acknowledged that the outcome of the work of the AHTEG on Synthetic Biology on an operational definition was “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” and considered it useful as a starting point for the purpose of facilitating scientific and technical deliberations under the Convention and its Protocols.
3. The Conference of the Parties invited Parties, in accordance with their applicable domestic legislation or national circumstances, to take into account, as appropriate, socioeconomic, cultural and ethical considerations when identifying the potential benefits and potential adverse effects of organisms, components and products resulting from synthetic biology techniques in the context of the three objectives of the Convention. It also encouraged Parties and invited other Governments and relevant organizations, to undertake certain activities related to research, dialogue and awareness-raising, and to cooperate in the development of guidance and capacity-building.
4. The Conference of the Parties also invited Parties, other Governments, relevant organizations and indigenous peoples and local communities to submit to the Executive Secretary information and supporting documentation on synthetic biology.
5. In the same decision, the Conference of the Parties extended the mandate of the AHTEG on Synthetic Biology in accordance with the terms of reference annexed to the decision and also to contribute to the completion of the assessment pursuant to decision XII/24, paragraph 2. The Conference of the Parties also extended the open-ended online forum to support the work of the AHTEG.
6. Furthermore, the Conference of the Parties requested the Subsidiary Body on Scientific, Technical and Technological Advice to review the recommendations of the AHTEG on Synthetic Biology

* CBD/SBSTTA/22/1.

and make further recommendation to the Conference of the Parties, including on the analysis using the criteria set out in decision [IX/29](#), paragraph 12.

7. Accordingly, the Executive Secretary established a process comprising: (a) the submission of information on synthetic biology; (b) an open-ended online forum with discussions on specific topics of synthetic biology; (c) one face-to-face meeting of the AHTEG; and (d) peer review of the report of the AHTEG, as detailed in section II of the present note. The outcomes of the AHTEG are provided in the annex, and the full report is available on the CBD website.¹ The present note is also supplemented by information documents as indicated in section II.

I. OVERVIEW OF ACTIVITIES

A. Submission of information on synthetic biology

8. In response to decision XIII/17, paragraph 10, the Executive Secretary issued a [notification](#) inviting Parties, other Governments, relevant organizations and indigenous peoples and local communities to submit information and supporting documentation on the following:

(a) Research on the benefits and adverse effects of organisms, components and products of synthetic biology on biodiversity; public and multi-stakeholder dialogues and awareness-raising activities; and cooperation in the development of guidance and capacity-building activities as noted in paragraph 9 of the decision;

(b) Evidence of benefits and adverse effects of synthetic biology vis-à-vis the three objectives of the Convention;

(c) Experiences in conducting risk assessments of organisms, components and products of synthetic biology, including any challenges encountered, lessons learned and implications for risk assessment frameworks;

(d) Examples of risk management and other measures that have been put in place to avoid or minimize the potential adverse effects of organisms, components and products of synthetic biology, including experiences of safe use and best practices for the safe handling of organisms developed through synthetic biology;

(e) Regulations, policies and guidelines in place or under development which are directly relevant to synthetic biology;

(f) Knowledge, experience and perspectives of indigenous peoples and local communities in the context of living in harmony with nature for comparison and better understanding of the potential benefits and adverse effects of synthetic biology.

9. A total of 29 submissions were received by the Secretariat. Among the submissions, 15 were from Parties, 1 from a non-Party, and 13 from organizations. The original submissions are available through the Biosafety Clearing-House at <https://bch.cbd.int/synbio/submissions/2017-2018.shtml>. A synthesis of views extracted from the submissions is presented in [CBD/SYNBIO/AHTEG/2017/1/2](#), paragraphs 7 to 24.

B. Open-ended Online Forum on Synthetic Biology

10. The Open-ended Online Forum on Synthetic Biology was convened through the Biosafety-Clearing House between July and September 2017. A total of 410 interventions were made during that period.²

11. The topics of discussion were drawn from the terms of reference of the AHTEG as follows:

¹ [CBD/SYNBIO/AHTEG/2017/1/3](#).

² The discussions under the Open-ended Online Forum on Synthetic Biology are available at <https://bch.cbd.int/synbio/open-ended/discussion>.

(a) Reviewing recent technological developments within the field of synthetic biology to assess if the developments could lead to impacts on biodiversity and the three objectives of the Convention, including unexpected and significant impacts (moderated by Mr. Casper Linnestad from Norway);

(b) Further analysis of evidence of benefits and adverse effects of organisms, components and products of synthetic biology vis-à-vis the three objectives of the Convention (moderated by Ms. María Andrea Orjuela Restrepo from Mexico);

(c) Identifying any living organisms already developed or currently under research and development through techniques of synthetic biology which do not fall under the definition of living modified organisms under the Cartagena Protocol and evaluating the availability of tools to detect and monitor the organisms, components and products of synthetic biology (moderated by Mr. Nikolai Tsvetkov from Bulgaria);

(d) Gathering information on risk management measures, safe use and best practices for safe handling of organisms, components and products of synthetic biology (moderated by Mr. Benson Kinyagia from Kenya).

12. A synthesis of views shared through the online forum is presented in [CBD/SYNBIO/AHTEG/2017/1/2](#), paragraphs 25 to 69.

C. Face-to-face meeting of the Ad Hoc Technical Expert Group

13. The AHTEG on Synthetic Biology held its face-to-face meeting in Montreal, Canada, from 5 to 8 December 2017.

14. The terms of reference of the AHTEG were to:

(a) Review recent technological developments within the field of synthetic biology to assess if the developments could lead to impacts on biodiversity and the three objectives of the Convention, including unexpected and significant impacts;

(b) Identify any living organisms already developed or currently under research and development through techniques of synthetic biology which do not fall under the definition of living modified organisms under the Cartagena Protocol;

(c) Further analyse evidence of benefits and adverse effects of organisms, components and products of synthetic biology vis-à-vis the three objectives of the Convention, and gather information on risk management measures, safe use and best practices for safe handling of organisms, components and products of synthetic biology;

(d) In order to avoid or minimize any potential negative effects on the conservation and sustainable use of biodiversity, evaluate the availability of tools to detect and monitor the organisms, components and products of synthetic biology;

(e) Provide, for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice at a meeting held prior to the fourteenth meeting of the Conference of the Parties, recommendations on the basis of its deliberations to facilitate future discussions and actions on synthetic biology under the Convention, as well as an analysis against the criteria set out in paragraph 12 of decision IX/29 to contribute to the completion of the assessment requested in paragraph 2 of decision XII/24 by the Subsidiary Body on Scientific, Technical and Technological Advice.

15. This was to be done by building on the previous work of the Online Forum and the AHTEG, and drawing upon relevant information submitted by Parties, other Governments, relevant organizations and indigenous peoples and local communities, as well as information made available through the online forum and by the Secretariat, and in coordination with other bodies of the Convention and its Protocols.

16. The outcomes of the deliberations of the AHTEG in response to paragraphs 1(a) to (d) of its terms of reference in decision XIII/17 are set out in paragraphs 14 to 53 of its report³ and reproduced in the annex to the present document.

17. The AHTEG recommended that the Subsidiary Body on Scientific, Technical and Technological Advice at its twenty-second meeting consider the outcomes of this meeting to facilitate future discussions and actions on synthetic biology under the Convention. Furthermore, in relation to paragraph 1(e) of the terms of reference of the AHTEG, the Secretariat noted that the Subsidiary Body would consider, at its twenty-first meeting, information on how to apply the criteria, as set out in paragraph 12 of decision IX/29, for the selection of new and emerging issues relating to the conservation and sustainable use of biological diversity. As a result, under its consideration of other matters, the AHTEG decided to defer the analysis requested in paragraph 1(e) until further guidance was provided by the Conference of the Parties. However, at its twenty-first meeting, the Subsidiary Body did not provide further guidance on how to apply the criteria for the selection of new and emerging issues.⁴ Subsequently, the Secretariat prepared an analysis of the reports on the first and second meetings of the AHTEG against the seven criteria for the selection of new and emerging issues, as set out in paragraph 12 of decision IX/29. The analysis is available as information document CBD/SBSTTA/22/INF/17.

18. Also under its consideration of other matters, the importance of addressing the potential socioeconomic impacts of the commercialization of products of synthetic biology that replaced naturally occurring products was noted by the AHTEG. Further, the participation of representatives of indigenous peoples and local communities at the meeting was acknowledged by the AHTEG and the Secretariat was encouraged to continue facilitating their full and effective participation in all meetings that were relevant to the three objectives of the Convention.

D. Peer review of the outcomes of the process

19. In response to paragraph 14(d) of decision XIII/17, the Executive Secretary issued a notification⁵ inviting Parties, other Governments, relevant organizations and indigenous peoples and local communities to peer review the report of the AHTEG on Synthetic Biology. A total of 21 reviews were received by the Secretariat. Among the submissions, 8 were from Parties, 1 was from a non-Party, and 12 were from organizations. The original submissions are available at <https://bch.cbd.int/synbio/peer-review>. A synthesis of the comments provided through the peer-review process is provided in the information document CBD/SBSTTA/22/INF/18.

II. SUGGESTED RECOMMENDATIONS

20. The Subsidiary Body on Scientific, Technical and Technological Advice may wish to consider a recommendation along the following lines:

The Conference of the Parties,

Recalling decisions XII/24 and XIII/17,

1. *Takes note* of the outcomes of the meeting of the Ad Hoc Technical Expert Group on Synthetic Biology held in Montreal, Canada, from 5 to 8 December 2017;⁶

2. *Notes* that synthetic biology is a cross-cutting issue that may concern all three objectives of the Convention on Biological Diversity, and *recognizes* the need to thoroughly consider the potential benefits and potential adverse effects of synthetic biology applications vis-à-vis the three objectives of the Convention;

³ [CBD/SYNBIO/AHTEG/2017/1/3](https://www.cbd.int/doc/2017/1/3/cbd-synbio-ahteg-2017-1-3.pdf).

⁴ See Subsidiary Body recommendation [XXI/7](#).

⁵ [SCBD/SPS/DC/MPM/MW/87112](#).

⁶ CBD/SBSTTA/22/4, annex.

3. *Also notes* that regular horizon scanning, monitoring and assessing of developments in the field of synthetic biology is needed for reviewing new information regarding the positive and negative impacts of synthetic biology vis-à-vis the three objectives of the Convention and those of its Protocols;

4. *Recognizes* that rapid advances arising from research and development in the field of synthetic biology may pose challenges to the ability of some countries, in particular those with limited experience or resources, to assess the full range of potential impacts of synthetic biology applications;

5. *Also recognizes* the need for a coordinated and non-duplicative approach on issues related to synthetic biology under the Convention and its Protocols, as well as among other conventions and relevant organizations and initiatives;

6. *Further recognizes* that, while there could be potential benefits to the development of organisms containing engineered gene drives, additional research and guidance is needed before any organism containing engineered gene drives is considered for release into the environment, including the lands and territories of indigenous peoples and local communities, and, given the current uncertainties regarding engineered gene drives, *urges* Parties and other Governments to take a precautionary approach in the development and release of organisms containing engineered gene drives, including experimental releases, in order to avoid potentially significant and irreversible adverse effects to biodiversity;

7. *Calls upon* Parties, other Governments and relevant organizations to develop and implement well-designed strategies in order to prevent or minimize the exposure of the environment to organisms, components and products of synthetic biology under contained use;

8. *Also calls upon* Parties, other Governments and relevant organizations to disseminate information and share their experiences on scientific assessments of the potential benefits and adverse impacts of synthetic biology, including that of organisms containing engineered gene drives, taking into account but not limiting themselves to information based on modelling and scenarios, data from experiments performed under contained use, and experience gained through the management of pests and invasive alien species and from the use of living modified organisms that have been released into the environment;

9. *Decides* to extend the mandate of the Ad Hoc Technical Expert Group on Synthetic Biology and that it should work primarily online and in coordination with the process under the Cartagena Protocol, as appropriate, to: (a) take stock of new developments in synthetic biology since the Ad Hoc Technical Expert Group's last meeting in order to support a regular horizon scanning process; (b) prepare a comprehensive review of the current state of knowledge by compiling and analysing information, including but not limited to peer-reviewed published literature, on the potential positive and negative environmental, cultural, and socioeconomic impacts of current and near future applications of synthetic biology, including genome editing and organisms containing engineered gene drives; (c) prepare a forward-looking analysis on potential positive and negative impacts of synthetic biology applications that are in early stages of research and development; and (d) prepare a report on the outcomes of its work for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice;

10. *Also decides* to extend the Open-ended Online Forum on Synthetic Biology to support the deliberations of the Ad Hoc Technical Expert Group on Synthetic Biology, and *invites* Parties, other Governments, indigenous and local communities and relevant organizations to continue to nominate experts to take part in the online forum on synthetic biology;

11. *Invites* Parties, other Governments, relevant organizations, indigenous peoples and local communities, and other relevant stakeholders to provide the Executive Secretary with relevant information for inclusion in the review referred to in paragraph 9 above;

12. *Requests* the Executive Secretary:

(a) To convene moderated online discussions under the Open-ended Online Forum on Synthetic Biology;

(b) To facilitate the work of the Ad Hoc Technical Expert Group on Synthetic Biology, subject to the availability of funds, by, among other things, collecting and synthesizing and arranging for peer review of relevant information, and convening at least one face-to-face meeting;

(c) To further pursue cooperation with other organizations, conventions and initiatives, including academic and research institutions, from all regions, on issues related to synthetic biology and how it may contribute to progress towards the 2030 Agenda for Sustainable Development;⁷

(d) To explore ways to facilitate, promote and support capacity-building and knowledge sharing regarding synthetic biology, taking into account the needs of Parties and of indigenous peoples and local communities, including through necessary funding, and the co-design of training materials in the official languages of the United Nations and, where possible, in local languages.

13. *Requests* the Subsidiary Body on Scientific, Technical and Technological Advice to consider the work of the Ad Hoc Technical Expert Group on Synthetic Biology and submit a recommendation to the Conference of the Parties at its fifteenth meeting.

⁷ [General Assembly resolution 70/1](#), annex.

*Annex***OUTCOMES OF THE AD HOC TECHNICAL EXPERT GROUP (AHTEG) ON SYNTHETIC BIOLOGY⁸****3.1. Recent technological developments in the field of synthetic biology**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

⁸ Reproduced from the report of the Ad Hoc Technical Expert Group ([CBD/SYNBIO/AHTEG/2017/1/3](https://www.cbd.int/doc/2017/1/3/cbd-synbio-ahteg-2017-1-3.pdf)).

under contained use.⁹ These strategies should be commensurate to the risk posed by the organisms, components and products.

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

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

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

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

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

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

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

25. The AHTEG noted that consideration of the potential benefits and adverse effects of organisms produced through synthetic biology could be particularly relevant and urgent for those organisms that had been developed to contain engineered gene drives, in the light of the impacts that such organisms might have on the conservation and sustainable use of biological diversity, as well as the knowledge, innovations and practices of indigenous peoples and local communities, particularly if they were released into the environment. Uncertainties related to the efficacy and safety of engineered gene drive systems, as well as the relative risks that could be posed by the different applications of engineered gene drive systems (for example, for population replacement or suppression) were noted. Furthermore, while there could be potential benefits to the development of such organisms, it was noted that additional research and guidance were needed before any organism containing engineered gene drives could be

⁹ Insofar as they are consistent with Conference of the Parties [decision V/5](#), para. 23.

considered for release into the environment, including into lands and territories of indigenous peoples and local communities. The AHTEG also noted the potential for the unintended transboundary movements and geographic spread of organisms released into the environment. Given the current uncertainties regarding engineered gene drives, a precautionary approach and cooperation with all countries and stakeholders that could be affected, taking into account the need for the free, prior and informed consent of indigenous peoples and local communities, might be warranted in the development and release of organisms containing engineered gene drives, including experimental releases, in order to avoid potential significant and irreversible adverse effects to biodiversity.

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

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

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

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

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

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

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

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

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

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

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

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

36. It was suggested that the Network of Laboratories for the Detection and Identification of LMOs,¹⁰ among others, might be able to contribute to the assessment of the availability of tools for the detection of organisms developed through synthetic biology techniques and the identification of best practices as well as any gaps and challenges in existing methodologies that might need to be addressed. It was also suggested that the Network could be expanded to bring together experts in the field of analytical chemistry in order to facilitate the assessment of the availability of tools for the detection and monitoring of components and products of synthetic biology.

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

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

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

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

Risk assessment

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

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

(a) The lack of suitable comparators in cases whereby organisms developed through techniques of synthetic biology contain features that are significantly different from existing organisms;

(b) Knowledge gaps in assessing unintended effects that might result from complex changes and novel traits;

(c) Knowledge gaps in assessing interactions of combinatorial and cumulative effects of multiple organisms developed through synthetic biology being released in the same environment;

(d) Lack of experience with the introduction of organisms containing engineered gene drives into natural populations.

42. The AHTEG also noted the existence of voluntary guidance documents that could be taken into account in the risk assessment of organisms developed through synthetic biology.¹¹

¹⁰ Accessible through http://bch.cbd.int/onlineconferences/portal_detection/lab_network.shtml.

¹¹ Such as the Guidance on Risk Assessment developed by the AHTEG on Risk Assessment and Risk Management and other relevant guidance documents as per decision [CP VIII/12](#).

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

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

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

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

Risk management

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

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

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

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

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

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

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

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

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

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