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Item 5 of the provisional agenda*

ANALYSIS AGAINST THE CRITERIA SET OUT IN PARAGRAPH 12 OF DECISION IX/29

Note by the Executive Secretary

1. In its terms of reference, the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology was requested to provide for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), at a meeting held prior to the fourteenth meeting of the Conference of the Parties, among other things, an analysis against the criteria set out in paragraph 12 of decision IX/29 to contribute to the completion by SBSTTA of the assessment requested in paragraph 2 of decision XII/24.

2. At the meeting of the AHTEG, the Secretariat noted that SBSTTA would consider, at its twenty-first meeting, a note prepared by the Executive Secretary (CBD/SBSTTA/21/8) on the basis of views submitted by Parties and relevant organizations 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 well as a suggested recommendation on a way forward. On that basis, the Secretariat proposed that the AHTEG defer consideration of an analysis against the criteria pending further guidance and did not include such consideration in the draft provisional agenda. Under item 2 of the agenda, following a proposal from a participant, the Group agreed to consider the issue of further analysing of synthetic biology against the criteria set out in paragraph 12 of decision IX/29 under agenda item 5 on "Other matters". The provisional agenda was adopted with this amendment. Accordingly, under item 5, "some members of the AHTEG noted that SBSTTA is considering how to apply the criteria for selection of new and emerging issues. The AHTEG agreed to defer the analysis requested in paragraph 1(e) of its terms of reference until further guidance is provided by the Conference of the Parties."

3. However, at its twenty-first meeting, SBSTTA, in its recommendation XI/7, did not provide further guidance on how to apply the criteria for the selection of new and emerging issues.

4. To contribute to the request in paragraph 2 of decision XII/24 the Secretariat has prepared an analysis of the reports of 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 was performed by linking relevant statements in the AHTEG reports to the criteria. The analysis includes only statements reflecting statements across the AHTEG, avoiding using statements that clearly reflected the views of only some members.

5. The aim of this analysis is to support the further deliberation on whether or not further assessment of synthetic biology against the criteria set out in paragraph 12 of decision IX/29 is needed. The analysis

* CBD/SBSTTA/22/1.

is not intended to provide final evidence as to whether or not synthetic biology should be considered a new and emerging issue, and does not imply that the AHTEG reached any conclusions on this matter.

ID	Elements from the AHTEG reports	Source[1]
Criterion 1: Relevance of the issue to the implementation of the objectives of the Convention and its existing programmes of work		
1	"The AHTEG noted that the conservation and sustainable use of biodiversity, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources may be affected, both positively and negatively, by living organisms resulting from synthetic biology, as well as by non-living products or components."	Paragraph 28, AHTEG-1
2	"Within the context of Articles 15 and 16 of the Convention and the Nagoya Protocol, the AHTEG also took note of the fact that synthetic biology may have both positive and negative impacts on the fair and equitable sharing of benefits arising from the utilization of genetic resources."	Paragraph 31, AHTEG-1
3	"The AHTEG agreed that living organisms developed through current and near future applications of synthetic biology are similar to LMOs as defined in the Cartagena Protocol."	Paragraph 34, AHTEG-1
4	"[…] the AHTEG noted that living organisms, components and products of synthetic biology fall within the scope of the Convention and its three objectives […]"	Paragraph 38, AHTEG-1
5	"Furthermore, the relationship between synthetic biology and its ethical implications for societal views towards nature, as well as the relationship between mankind and ecosystems, were noted as cross-cutting issues with respect to all three objectives of the Convention."	Paragraph 47, AHTEG-1
6	"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."	Paragraph 20, AHTEG-2
7	"[…] 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	Paragraph 26, AHTEG-2

[1] AHTEG-1 refers to the report of the meeting of the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology held from 21 to 25 September 2015 in Montreal, Canada; available at https://www.cbd.int/meetings/SYNBIOAHTEG-2015-01; AHTEG-2 refers to the report of the meeting of the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology held from 5 to 8 December 2017, in Montreal, Canada; available at https://www.cbd.int/meetings/SYNBIOAHTEG-2017-01.

[2] Paragraph 52 of AHTEG 1 contains illustrative examples of potential benefits and potential adverse effects grouped in accordance with the objectives of the Convention.

	communities in decision-making."	
Criterion 2: New evidence of unexpected and significant impacts on biodiversity [(2)]		
8	"Potential benefits as well as the potential adverse effects of synthetic biology applications need to be assessed on a case-by-case basis, with an appropriate balance between reasoning based on evidence and forward-looking scenarios."	Paragraph 46, AHTEG-1
9	"[…] 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."	Paragraph 28, AHTEG-2
10	"[…] 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."	Paragraphs 22, AHTEG-2
11	"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. 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."	Paragraphs 23 and 24, AHTEG-2
Criterion 3: 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		
12	"The AHTEG also noted that regulators and decision makers may face challenges in fully addressing the potential positive and negative impacts of synthetic biology on biodiversity due to the rate at which the technologies of synthetic biology are evolving. Another aspect of the relationship between synthetic biology and biological diversity that was noted was its potential positive and negative indirect effects, which also have to be taken into account in the adoption and use of organisms, products and components of synthetic biology in order to ensure that the sustainable use of biodiversity is maintained "	Paragraph 30, AHTEG-1

13	"[…] the current and foreseeable future applications of synthetic biology being considered in the assessment of potential benefits and potential adverse effects are at various stages of development, ranging from the theoretical to early or active areas of research to those that are already on the market. Consequently, the timeframe within which the potential benefits and potential adverse effects associated with those applications may be realized would vary considerably."	Paragraph 51, AHTEG-1
14	"In reviewing the recent technological developments of synthetic biology, the AHTEG noted, inter alia, the following: (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; (h) Combining new biotechnology tools and automation allows the more rapid production of modified organisms;"	Paragraph 15 (f, h), AHTEG-2
15	"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."	Paragraph 16, AHTEG-2
16	"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. […]"	Paragraph 25, AHTEG-2
Criterion 4: Actual geographic coverage and potential spread, including rate of spread, of the identified issue relating to the conservation and sustainable use of biodiversity		
17	"In reviewing the recent technological developments of synthetic biology, the AHTEG noted, inter alia, the following: (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;"	Paragraph 15(e), AHTEG-2
18	"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, […]"	Paragraph 21, AHTEG-2
19	"[…] The AHTEG also noted the potential for the unintended transboundary movements and geographic spread of organisms released into the environment. […]"	Paragraph 25, AHTEG-2
Criterion 5: 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		
20	"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 considered for release into the environment, including into lands and territories of indigenous peoples and local communities. […]"	Paragraph 25, AHTEG-2
21	"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."	Paragraph 33, AHTEG-2
22	"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"	Paragraph 34, AHTEG-2
23	"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"	Paragraph 37, AHTEG-2
24	"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"	Paragraph 40, AHTEG-2
25	"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	Paragraph 41, AHTEG-2

	engineered gene drives into natural populations"	
26	"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"	Paragraph 43, AHTEG-2
27	"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"	Paragraph 44, AHTEG-2
28	"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"	Paragraph 48, AHTEG-2
29	"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"	Paragraph 51(a), AHTEG-2
Criterion 6: Magnitude of actual and potential impact of the identified issue on human well-being		
30	"[…] the AHTEG noted that organisms, components and products of synthetic biology are expected to have similar positive and negative impacts on biological diversity as those of classical genetic engineering. However, the potential positive and negative impacts of synthetic biology may be broader and more wide-ranging due to the potential of synthetic biology to engineer more complex organisms and biological systems for use in a varied range of applications."	Paragraph 44, AHTEG-1
31	"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"	Paragraph 17, AHTEG-2
32	"The AHTEG recalled the conclusion reached at its previous meeting that the organisms, components and products of synthetic biology are expected to have similar positive and negative impacts on biological diversity as those of classical genetic engineering. However, the potential positive and negative impacts of synthetic biology may be broader and more wide-ranging due to the potential of	Paragraph 22, AHTEG-2

	synthetic biology to engineer more complex organisms and biological systems for use in a varied range of applications"	
Criterion 7: 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		
33	"In its deliberations the Group highlighted several applications, such as bioenergy, agriculture, pharmaceuticals and chemical production, where organisms, components and products of synthetic biology may interact with biological diversity. Those applications, the Group noted, may have both positive and negative impacts on biological diversity at different levels, including genes, species and ecosystems."	Paragraph 26, AHTEG-1
34	"With respect to the issue of potential benefits and potential adverse effects that may affect biological diversity, and, in particular, its sustainable use, the AHTEG noted that synthetic biology, due to its higher level of complexity, must be placed in the context of other ongoing developments and national strategies, such as existing strategies and approaches on bio-economy, biotechnology, agriculture and biodiversity."	Paragraph 49, AHTEG-1
35	"The assessment of the potential benefits and potential adverse effects of synthetic biology is challenged by the difficulty of distinguishing which socioeconomic changes result from the introduction of synthetic biology. Under such circumstances, it may be necessary to introduce appropriate methods from relevant scientific disciplines to take socioeconomic considerations into account."	Paragraph 50, AHTEG-1

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