|  |  |  |
| --- | --- | --- |
| Macintosh HD:Users:bilodeau:Desktop:logos:template 2017:un.emf | Macintosh HD:Users:bilodeau:Desktop:logos:template 2017:unep-old.emf | **CBD** |

|  |  |  |
| --- | --- | --- |
|  |  | Distr.  GENERAL  CBD/SBSTTA/22/INF/17  12 May 2018  ORIGINAL: ENGLISH |

SUBSIDIARY BODY ON SCIENTIFIC, TECHNICAL AND TECHNOLOGICAL ADVICE

Twenty-second meeting

Montreal, Canada, 2-7 July 2018

Item 5 of the provisional agenda[[1]](#footnote-1)\*

# 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](https://www.cbd.int/doc/decisions/cop-09/cop-09-dec-29-en.pdf) to contribute to the completion by SBSTTA of the assessment requested in paragraph 2 of decision [XII/24.](https://www.cbd.int/doc/decisions/cop-12/cop-12-dec-24-en.pdf)
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](https://www.cbd.int/doc/meetings/sbstta/sbstta-21/official/sbstta-21-08-en.doc)) 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](https://www.cbd.int/doc/decisions/cop-09/cop-09-dec-29-en.pdf), 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](https://www.cbd.int/doc/decisions/cop-12/cop-12-dec-24-en.pdf) 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](https://www.cbd.int/doc/decisions/cop-09/cop-09-dec-29-en.pdf). 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](https://www.cbd.int/doc/decisions/cop-09/cop-09-dec-29-en.pdf) is needed. The analysis 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[[2]](#footnote-2)** |
| ***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.”  Canada acknowledges that living organisms that are products of synthetic biology are already covered by the CPB and therefore are not ‘new and emerging’. | 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.”  This quotation is evidence that the issue is NOT ‘new and emerging’ for this criterion with respect to living organisms that are products of synthetic biology as they are already covered by CPB. | 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 communities in decision-making.” | Paragraph 26,  AHTEG-2 |
| ***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.”  This quotation does not provide evidence the criterion of ‘unexpected and significant impacts on biodiversity’ is met. It simply reinforces the need for risk assessment. | 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.”  This quotation is evidence that the issue is NOT ‘new and emerging’ for this criterion with respect to living organisms that are products of synthetic biology as they are already covered by CPB. | 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.”  This quotation does not provide evidence the criterion of ‘unexpected and significant impacts on biodiversity’ is met. | 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.”  This quotation does not provide evidence the criterion of ‘unexpected and significant impacts on biodiversity’ is met. It simply states that information can come from a variety of sources. | 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 ”  The AHTEG did say 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” but recognized, when saying so, that rapid change is not unique and not inherent to this technology. In addition, experts identified this aspect as primarily administrative in nature (eg. hiring enough risk assessors with the appropriate expertise, etc.) and not related to risk assessment as such. This quotation does not support this criterion as being met. | 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.”  This quotation does not address this criterion. There is a range of timelines. There is no urgency or imminent risk that is not already addressed by existing mechanisms. | 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;”  This quotation does not address this criterion. There is a range of timelines. There is no urgency or imminent risk that is not already addressed by existing risk assessment procedures and containment mechanisms. | 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.”  The AHTEG did note the above, but recognized, when saying so, that rapid change is not unique and not inherent to this technology. Experts identified this aspect as primarily administrative in nature (eg. hiring enough risk assessors with the appropriate expertise, etc.) and not related to risk assessment as such. This quotation does not support this criterion as being met and speaks more to the need for capacity building and not the need to identify the issue as new and emerging. | 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. […]”  The AHTEG (and COP 14 for that matter) made note of concerns around gene drives; however, genetically engineered gene drive modified organisms are LMOs and therefore are covered by the CPB and therefore are not ‘new and emerging’. There is no imminent ‘risk’ to biodiversity; only the need to conduct a rigourous, case-by-case risk assessment with appropriate consultation as determined by national circumstances. | 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;”  This is not relevant as para 15(e) in AHTEG 2 refers to spread of knowledge not spread of organisms. This is certainly not ‘new and emerging’! Criterion 4 is not met. | 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, […]”  The issues raised in para 21 of AHTEG-2 are not relevant to and do not address criterion 4. Criterion 4 is not met. This quotation is related to the need for capacity building. | 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. […]”  This quotation is not relevant to this criterion; the quotation supports the role of the CPB and therefore is not evidence of the issue being ‘new and emerging’. | 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. […]”  Prudence is important in research and in risk assessment, but there is no evidence of absence or limited availability of tools to limit or mitigate potential negative impacts of organisms with genetically engineered gene drives. In addition, such organisms are LMOs and are covered by the CPB and therefore are not ‘new and emerging’. Criterion 5 is not met. | 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.”  This again is not evidence of the absence or limited availability of tools to manage risk. In some jurisdictions, such organisms may not be regulated at all as there would not be a novel trait. If the jurisdiction required identification for reasons unrelated to risk to biodiversity, then that is beyond the scope of the Convention.  This quotation notes a resulting LMO may be indistinguishable from naturally occurring / conventionally bred counterparts – in which case the negative impacts on biodiversity of these organisms would be similarly indistinguishable from the counterparts. Criterion 5 is not met because there is no impact on biodiversity. Note that if the jurisdiction required it for non-risk related reasons, conventional identity preservation tracking systems (bar codes, RFID, etc.) would work and are available. | 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”  The so-called absence of tools is relevant where there is a need to identify the issue in order to manage a risk; the quotation above is not related to risk management and does not address this criterion. In addition, for example, current tools to identify ‘real’ vanilla from ‘synthesized’ vanilla for non-risk purposes already exist and are used. This quotation does not support this criterion. | 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”  This quotation speaks to the need for capacity building and not to the question of whether or not the issue is new and emerging. Criterion is not supported. | 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”  This quotation does not support that the issue is new and emerging with respect to the lack of tools for risk management. | 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 engineered gene drives into natural populations”  This quotation does not support that the issue is new and emerging with respect to the lack of tools for risk management. Rather, the quotation reinforces the need to keep **risk assessment** up to date. | Paragraph 41, AHTEG-2 |
| 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”  We share the concern about losses to biodiversity, species extinctions and Mother Nature, but these have nothing to do with synthetic biology and nothing to do with alleged lack of tools for risk management. This quotation does not support this criterion. | 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”  This quotation speaks to the need to update **risk assessment** for genetically engineered gene drives and not about the lack of tools for risk management. Such organisms, with respect to potential impacts on the “…conservation and sustainable use of biodiversity…” are also covered by the CPB and therefore cannot be ‘new and emerging’ for this objective. | 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”  This quotation supports that current risk management strategies for LMOs are (might be) a good basis but might need to be adapted and complemented. There is no evidence of the lack to tools for risk management. This quotation does not support the criterion. | 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”  This quotation does not support the criterion. “Best practices…should be adapted” does not mean there is evidence of a lack of tools for risk management. In fact, where risks are identified, the containment may well be the risk management. This quotation does not support the criterion. | 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.”  The quotation is simply an expression of what might be - including some extremely profound positive impacts on human well-being. | 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”  The quotation refers to genetically engineered gene drives which we know to be LMOs and therefore covered by the CPB. | 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 synthetic biology to engineer more complex organisms and biological systems for use in a varied range of applications”  Circular quotation so therefore a circular response: The quotation is simply an expression of what might be - including some extremely profound positive impacts on human well-being. | Paragraph 22, AHTEG-2 |
| ***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.”  Yes but is this ‘new and emerging’? | 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.”  Yes but is this ‘new and emerging’? | 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.”  So the quotation says we might have a difficulty distinguishing cause from effect… does that make the issue ‘new and emerging’? The quotation “…it may be necessary to introduce appropriate methods…” does not sound like there is a ‘magnitude’ to be concerned about. Socioeconomic considerations, consistent with the CPB, should only be considered where this is an adverse effect on biodiversity. | Paragraph 50, AHTEG-1 |

\_\_\_\_\_\_\_\_\_\_

1. \* CBD/SBSTTA/22/1. [↑](#footnote-ref-1)
2. 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. [↑](#footnote-ref-2)