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Item 6 of the provisional agenda**

SYNTHETIC BIOLOGY

Note by the Executive Secretary

I. BACKGROUND

1. At its twelfth meeting, the Conference of the Parties adopted a decision on synthetic biology by which, among other things, it urged Parties to take a precautionary approach, and to establish, or have in place, effective risk assessment and management procedures and/or regulatory systems to regulate environmental release of any organisms, components or products resulting from synthetic biology techniques, consistent with Article 3 of the Convention (decision XII/24,[1] paragraph 3). The decision also addressed scientific assessments, funding for research and cooperation.

2. In paragraph 4 of the decision, the Conference of the Parties to the Convention on Biological Diversity established an ad hoc technical expert group (AHTEG) on synthetic biology with terms of reference contained in the annex to the decision.

3. In paragraphs 5 and 6 of the same decision, the Conference of the Parties invited Parties, other Governments, relevant organizations, indigenous and local communities and relevant stakeholders to submit information to the Executive Secretary relevant to the work of the AHTEG, as well as on measures undertaken in accordance with paragraph 3 of decision XII/24, including the identification of needs for guidance, and further information in response to paragraph 3(a) of decision XI/11.

4. Furthermore, in paragraph 7 of the same decision, the Conference of the Parties requested the Executive Secretary:

(a) To make available the information submitted by Parties, other Governments, relevant organizations, indigenous and local communities and relevant stakeholders through the clearing-house mechanism of the Convention and other means;

(b) To convene a moderated open-ended online forum[2] to support the work of the AHTEG in meeting its terms of reference;

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[1] Full text of the decision can be found at http://www.cbd.int/doc/decisions/cop-12/cop-12-dec-24-en.pdf.

[2] The open-ended online forum will be open to all interested participants and will continue for a finite period of time.

(c) To prepare an updated report on the work specified in paragraphs 3(a), 3(b) and 3(c) of decision XI/11, taking into account information submitted in paragraph 2 above and a synthesis of the outcomes of the process mentioned in paragraph (b) above, and to submit these for consideration by the AHTEG;

(d) To submit for consideration by a meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) prior to the thirteenth meeting of the Conference of the Parties, the peer-reviewed reports of the outcomes of the process mentioned in paragraphs (b) and (c) above.

5. In the light of the decision, the Executive Secretary established a continuous process comprising of: (a) the submission of information on synthetic biology; (b) an open-ended online forum with online discussions on specific topics of synthetic biology; (c) one face-to-face meeting of the AHTEG; and (d) peer review of the outcomes of the process.[3]

6. The present note presents, in section II, a procedural summary of each step of the process outlined above. Section III reproduces the outputs and conclusions of the AHTEG; section IV provides an overview of the comments provided through the peer-review process; and section V contains suggested recommendations for consideration by SBSTTA.

II. PROCEDURAL SUMMARY

A. Submission of information on synthetic biology

7. In response to paragraphs 5 and 6 of decision XII/24, the Executive Secretary issued a notification on 6 February 2015 inviting Parties, other Governments, relevant organizations and stakeholders to submit information (a) relevant to the work of the AHTEG as established in the decision; (b) on measures undertaken in accordance with paragraph 3 of the decision, including the identification of needs for guidance; and (c) on the components, organisms and products resulting from synthetic biology techniques that may have impacts on the conservation and sustainable use of biological diversity and associated social, economic and cultural considerations.

8. A total of 27 submissions were received by the Secretariat. Among the submissions, 15 were from Parties, 1 was from a non-Party, and 11 were from organizations.[4]

B. Open-ended online forum on synthetic biology

9. In response to paragraph 7(b) of decision XII/24, the Executive Secretary issued a notification inviting Parties, other Governments, relevant international organizations, indigenous and local communities and other relevant stakeholders to nominate experts to participate in the Open-ended Online Forum on Synthetic Biology.[5]

10. A total of 235 experts were nominated to participate in the open-ended online forum. Among these, 146 were from Parties, nine from a non-Party, and 80 from organizations.

11. The Open-ended Online Forum on Synthetic Biology was launched through the Biosafety Clearing-House and a total of 402 interventions were made during the online discussions that took place between April and July 2015. The topics of discussion were drawn from the terms of reference of the AHTEG.[6]

12. The views emerging from the submissions under section III and the main outcomes of the online discussion held by the Online Forum were summarized into a report (UNEP/CBD/SBSTTA/20/INF/11).

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[3] The calendar of activities for the entire process is available at https://bch.cbd.int/calendar_synbio.shtml.

[4] The submissions are available online at http://bch.cbd.int/synbio/submissions/.

[5] Notification SCBD/BS/CG/MPM/DA/84355 (https://www.cbd.int/doc/notifications/2015/ntf-2015-019-synth-en.pdf).

[6] The discussions under the Open-ended Online Forum on Synthetic Biology are available at http://bch.cbd.int/synbio/open-ended/discussion.shtml.

C. Face-to-face meeting of the ad hoc technical expert group on synthetic biology

13. In accordance with paragraph 4 of decision XII/24, establishing an AHTEG on synthetic biology, the Executive Secretary, in consultation with the SBSTTA Bureau, selected experts in accordance with the consolidated modus operandi of SBSTTA[7] and decision XII/24, from among the nominations submitted by Parties as per paragraph 10 above, taking into consideration geographical distribution and gender balance and nominees' active participation in the Open-ended Online Forum. A limited number of experts nominated by other Governments and relevant organizations were also selected using the same criteria and approval process.

14. The AHTEG held its face-to-face meeting in Montreal, Canada, from 21 to 25 September 2015.

15. During the meeting, the AHTEG deliberated on each of the following substantive issues, as per its terms of reference:

(a) Relationship between synthetic biology and biological diversity;

(b) Similarities and differences between living modified organisms (as defined in the Cartagena Protocol) and organisms, components and products of synthetic biology techniques;

(c) Adequacy of existing national, regional and/or international instruments to regulate the organisms, components or products derived from synthetic biology techniques;

(d) Towards an operational definition of synthetic biology comprising inclusion and exclusion criteria;

(e) Potential benefits and risks of organisms, components and products arising from synthetic biology techniques to the conservation and sustainable use of biodiversity and related human health and socioeconomic impacts relevant to the mandate of the Convention and its Protocols;

(f) Best practices on risk assessment and monitoring regimes currently used by Parties to the Convention and other Governments;

(g) Degree to which the existing arrangements constitute a comprehensive framework in order to address impacts of organisms, components and products resulting from synthetic biology, in particular threats of significant reduction or loss of biological diversity.

16. Section III reproduces the outputs and conclusions of the AHTEG. The full report of the AHTEG has been issued as UNEP/CBD/SBSTTA/20/INF/12.

D. Peer-review process

17. In response to paragraph 7(d) of decision XII/24, the Executive Secretary issued a notification[8] inviting Parties, other Governments, relevant organizations and indigenous people and local communities to peer review the reports referred to in paragraphs 11 and 15 above for consideration by SBSTTA.

18. A total of 32 submissions were received by the Secretariat. Among the submissions sixteen were from Parties, one was from a non-Party, and fifteen were from organizations.[9]

19. An overview of views that were shared by several Parties is provided in section IV below. A detailed synthesis of the peer-review comments will be available as document UNEP/CBD/SBSTTA/20/INF/13.

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[7] Decision VIII/10 of the Conference of the Parties, annex III, para. 18.

[8] Notification SCBD/BS/CG/MPM/DA/58140 (https://www.cbd.int/doc/notifications/2015/ntf-2015-139-bs-en.pdf).

[9] The peer-review submissions are available online at http://bch.cbd.int/synbio/peer-review/.

III. OUTPUTS OF THE AD HOC TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY

20. This section is reproduced from paragraphs 20 to 66 of the report of the AHTEG.[10]

A. Substantive issues

1. Towards an operational definition of synthetic biology comprising inclusion and exclusion criteria

21. In its deliberations under the agenda item, the AHTEG recognized that synthetic biology is a broad term that refers to a wide range of disciplines, techniques, potential applications and end products, and has a degree of overlap with modern biotechnology.

22. It was also noted that an operational definition must be understood in the context of the objectives of the Convention[11] and that the purpose of such a definition is to assist Parties in their implementation of the provisions of the Convention.

23. In the light of the above, there was support for the development of an operational definition that would express the notions of both continuity and novelty in relation to modern biotechnology and would draw on elements from the text of the definition developed by three scientific committees of the European Commission12 and included by the European Union in its response to the notification issued by the Secretariat inviting submissions on information relevant to the work of the AHTEG.13

24. Taking into account the deliberations of the AHTEG and the shared views of its members, the Chair proposed a draft operational definition for the consideration of the Group. The following is the outcome of the deliberations of the Group:

25. "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."

2. Relationship between synthetic biology and biological diversity

26. Under the agenda item, the AHTEG took note of the exchange of views during the open-ended online discussions and the submissions[14] on how to address the relationship between synthetic biology and biological diversity.

27. 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.

28. In addressing the relationship between synthetic biology and biological diversity, the Group worked within the context of the operational definition agreed on and each of the specific three objectives of the Convention. It was noted that, in order to facilitate discussions on the relationship between

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[10] Document UNEP/CBD/SBSTTA/20/INF/12.

[11] The objectives of the Convention are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

[12] SCENIHR, SCCS, SCHER (2014). Final Opinion on Synthetic Biology I Definition. Available at http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_044.pdf.

[13] Notification SCBD/BS/CG/MPM/DA/84279 available at http://www.cbd.int/doc/notifications/2015/ntf-2015-013-synthetic-biology-en.pdf.

[14] Available at http://www.cbd.int/doc/notifications/2015/ntf-2015-013-synthetic-biology-en.pdf and http://bch.cbd.int/synbio/open-ended/discussion.shtml.

synthetic biology and biological diversity, an appropriate baseline for measuring the potential positive and negative impacts of synthetic biology on each of the objectives of the Convention needs to be considered or developed and, where possible, supported by evidence-based information, including peer-reviewed data, as well as specialized knowledge, indigenous and traditional knowledge.

29. 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.

30. On the one hand, some members of the AHTEG noted that there is a potentially higher level of uncertainty due to the increased depth of intervention of synthetic biology in living organisms and biological systems, and emphasized, in accordance with paragraph 3 of decision XII/24, the need for Governments to take a precautionary approach when addressing threats of significant reduction or loss of biological diversity posed by organisms, components and products resulting from synthetic biology, in accordance with their domestic legislation and relevant international obligations. On the other hand, some members of the AHTEG noted that there are mechanisms built into existing risk assessment frameworks which take into account such uncertainties in a stepwise manner while building on past experience with the existing frameworks. In that context, those AHTEG members also noted that the nature of synthetic biology research and development may lead to more predictability in the characteristics of the resulting organism, thereby facilitating the risk assessment process and reducing uncertainty.

31. 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.

32. 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. Some AHTEG members further noted the potential for the unequitable use of digital genetic information.

3. Similarities and differences between living modified organisms (as defined in the Cartagena Protocol) and organisms, components and products of synthetic biology techniques

33. In considering the agenda item, the AHTEG arrived at a common understanding 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). Both terms were considered as referring to non-living entities. On the basis of that understanding, the Group agreed that those non-living components and products of synthetic biology do not fall under the scope of the Cartagena Protocol on Biosafety.

34. The AHTEG deliberated on whether living organisms derived from synthetic biology fall under the scope of the Cartagena Protocol by considering both the similarities and the differences between living modified organisms (LMOs) and the living organisms developed through current and near future applications of synthetic biology.

35. 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.

36. The AHTEG noted, however, that it is not clear at the current stage whether or not some organisms of synthetic biology, which are currently in the early stages of research and development, would fall under the definition of LMOs under the Cartagena Protocol.

37. It was also noted that there are cases in which there may be no consensus on whether the result of a synthetic biology application is “living” or not (for example, protocells).

4. Adequacy of other existing national, regional and/or international instruments to regulate the organisms, components or products derived from synthetic biology techniques

38. Under the agenda item, the AHTEG first examined the issues on whether the organisms, components and products of synthetic biology fall under the scope of existing laws and regulations, whether the existing laws and regulations can adequately address the technology, and whether there are any gaps.

39. Following discussions under item 3.3, the AHTEG noted that living organisms, components and products of synthetic biology fall within the scope of the Convention and its three objectives. However, only living organisms of synthetic biology would fall under the scope of the Cartagena Protocol and the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress.15 It was therefore noted by some members of the AHTEG that many components and products of synthetic biology, while covered by the Convention, are not covered under the scope of the two Protocols and possibly not by some national biosafety frameworks either.

40. The Nagoya Protocol was noted as a relevant international instrument providing a framework for the fair and equitable sharing of the benefits arising from the utilization of genetic resources in synthetic biology. Nevertheless, the lack of clarity on how the provisions of Articles 15 and 16 of the Convention and the Nagoya Protocol apply, in practice, to synthetic biology was noted.

41. Some members of the AHTEG noted that products of synthetic biology fall under the scope of international, regional or national instruments addressing, among other things, chemicals, human pharmaceuticals and veterinary products. At the national level, while some AHTEG members considered the sectoral regulations in their countries adequate to address products of synthetic biology, other members considered such national legislation to be fragmented and/or lacking the necessary operational provisions.

42. Some members of the AHTEG noted the following needs with regard to international regimes: (a) provisions to address the socioeconomic impacts of the components and products of synthetic biology; (b) measures to minimize the likelihood of unintentional transboundary movements of organisms of synthetic biology after their release into the environment; and (c) traceability tools to ensure the fair and equitable sharing of the benefits arising from the utilization of genetic resources in synthetic biology.

43. Some members of the AHTEG noted that some countries have policies and regulations for controlling the exchange, distribution and commercialization of the products of modern biotechnology, which could also be applied to the non-living components of synthetic biology. Other members, however, did not consider the existing national legislation to be adequate for regulating the components of synthetic biology.

5. Potential benefits and risks of organisms, components and products arising from synthetic biology techniques to the conservation and sustainable use of biodiversity and related human health and socioeconomic impacts relevant to the mandate of the Convention and its Protocols

44. Under the agenda item, the AHTEG considered the potential benefits and potential adverse effects[16] of organisms, components and products of synthetic biology within the mandate of the Convention and its Protocols, taking into account the information contained in the background document as well as submissions and interventions in the online forum.

45. In line with the agreed operational definition of synthetic biology, the AHTEG noted 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

[15] Once it enters into force.

[16] In line with the Cartagena Protocol, the AHTEG decided to use the term "potential adverse effects" rather than "risk" in the context of this agenda item.

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.

46. Members of the AHTEG noted that, in comparison with classical genetic engineering, a distinctive quality of synthetic biology is its rate and depth of intervention, which may lead to decreased familiarity of the organisms developed through synthetic biology in comparison with non-modified organisms. From an engineering perspective, synthetic biology aims at achieving more predictability in the characteristics of the resulting organism. However, the level of uncertainty in risk assessment may increase with regard to the impacts on biodiversity and human health as well as the time needed to complete the risk assessment.

47. 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.

48. 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.

49. The potential benefits and potential adverse effects associated with synthetic biology are dependent on the particular circumstances and context in which the application is used: for example, the country in which the technology is being applied, its ecosystem and the relevant production system.

50. 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.

51. The assessment of the potential benefits and potential adverse effects of synthetic biology is therefore 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.

52. Furthermore, 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.

53. The text box below contains illustrative examples of potential benefits and potential adverse effects grouped in accordance with the objectives of the Convention.

Potential benefits

A cross-cutting and key potential benefit of synthetic biology is the contribution to the understanding of biological systems from the molecular to the ecosystems level:

Objective 1: Conservation of biological diversity

(a) Medical and nutritional applications may lead to healthier populations, which is a pre-requisite for the conservation of biological diversity;

(b) Bioremediation may contribute to the restoration of ecosystems;

(c) Resistance or tolerance to various stresses, such as diseases and abiotic stresses, may contribute to species conservation;

(d) Agricultural and agroforestry applications with reduced chemical pesticide/herbicide use may lead to the conservation of pollinators and other non-target organisms;

Objective 2: Sustainable use of biological diversity

(e) Agricultural and agroforestry applications of synthetic biology, such as abiotic stress tolerance or micro-organisms modified for increased nitrogen fixation, may lead to restoring productivity of depleted agricultural land and to increased crop productivity on existing agricultural land;

(f) In the area of bioenergy applications that rely on synthetic biology, some models indicate a potential reduction in greenhouse gas emissions, which would contribute to mitigation of climate change and thereby to the sustainable use of biological diversity;

(g) Application of gene drive systems and other tools of synthetic biology to control agricultural pests and animal and human diseases may improve the sustainable use of biodiversity and human health;

(h) Using microorganisms produced through synthetic biology to utilize biomass waste from agriculture and/or forestry more efficiently. This may reduce reliance on natural environments or land-use for agriculture and forestry;

(i) Industrial applications of synthetic biology may lead to alternative methods to manufacture products, such as chemicals and other materials, which are currently produced from natural sources, thereby reducing the impacts associated with the extraction of natural resources;

Objective 3: Fair and equitable sharing of the benefits of biological diversity

(j) Provisions on the fair and equitable sharing of the benefits arising out of the utilization of genetic resources are covered in Articles 15 and 16 of the Convention and the Nagoya Protocol. The availability of synthetic biology may enable the fair and equitable sharing of benefits with relevant stakeholders in developing countries through greater access to the tools of synthetic biology, thereby facilitating the transfer of knowledge and technology.

Potential adverse effects

Potential adverse effects of synthetic biology with respect to conservation of biological diversity can result from direct and indirect, intended or unintended, as well as immediate or delayed effects. These effects may occur at the genetic, population, or ecosystem level. On this basis, the following examples of potential adverse effects were identified:

Objective 1: Conservation of biological diversity

(a) An engineered fitness advantage may lead to invasiveness;

(b) Enhanced gene flow that leads to loss of biodiversity;

(c) An increased pathogenic potential;

(d) Increased levels of toxic substances, which may lead to disruptive effects on soil, food-webs, and pollinators;

(e) Negative effects on non-target organisms, such as pollinators;

(f) Changes in organisms on the level of basic metabolic pathways, such as altered photosynthesis pathways, carbohydrate metabolism or nitrogen fixation, which, among other effects, may lead to changes in agricultural practice and land-use and may challenge risk assessment;

(g) Applications that are aimed at altering and replacing natural populations (for example, gene drive systems) may have adverse effects at the ecosystem level, and vis-à-vis the other two objectives of the Convention;

Objective 2: Sustainable use of biological diversity

(h) Increased demand for biomass crops, as well as changes in patterns of extraction of biomass, minerals and other sources of energy, may lead to changes in land use;

(i) Replacement of natural products may lead to changes in the agricultural practices of communities, which may adversely affect traditional crops, practices and livelihoods;

(j) Gene flow may lead to adverse effects on agrobiodiversity;

Objective 3: Equitable sharing of the benefits of biological diversity

(k) Loss of market share and income by indigenous and local communities due to the altered exploitation of genetic resources;

(l) A shift in the understanding of what constitutes a genetic resource and the implications thereof, such as the misappropriation of the original source of the DNA information and, consequently — if benefits are derived from the use of such DNA information without prior informed consent and mutually agreed terms — the fair and equitable sharing of the benefits would not be possible;

(m) Inappropriate access without benefit-sharing due to the use of sequenced data without material transfer agreements under the Nagoya Protocol;

(n) Patent-driven and open-source approaches to synthetic biology may have different implications in the context of access and benefit sharing;

(o) Indigenous peoples and local communities will not necessarily support or benefit from the utilization of genetic resources in synthetic biology.

6. Best practices on risk assessment and monitoring regimes currently used by Parties to the Convention and other Governments

54. Under the agenda item, the AHTEG took into account the examples of best practices provided through the submissions of information[17] and online discussions,[18] and considered whether additional efforts are needed to compile information on best practices. The AHTEG also considered possible ways forward with regard to facilitating the sharing, dissemination and use of that information by Parties and other Governments.

55. The AHTEG noted that the examples of best practices provided through the submissions were primarily based on experiences with LMO risk assessment within the context of Annex III of the Cartagena Protocol.

56. The AHTEG concluded that it would be useful to compile the existing body of knowledge on relevant best practices on risk assessment and monitoring in a single and easily accessible online portal under, for example, the Biosafety-Clearing House of the Cartagena Protocol or the clearing-house mechanism of the Convention.

57. With regard to additional topics on which best practices may need to be complied, the AHTEG noted that best practices on the standardization of risk assessment methodologies and on monitoring are underrepresented, and an invitation for submission of those topics would be useful.

[17] Available at http://www.cbd.int/doc/notifications/2015/ntf-2015-013-synthetic-biology-en.pdf.

[18] Available at http://bch.cbd.int/synbio/open-ended/discussion.shtml.

7. Degree to which the existing arrangements constitute a comprehensive framework in order to address impacts of organisms, components and products resulting from synthetic biology, in particular threats of significant reduction or loss of biological diversity

58. Under the agenda item, the AHTEG agreed that, in order to be considered comprehensive, a framework should include arrangements that address the impacts of organisms, components and products of synthetic biology in the context of the three objectives of the Convention, in line with Article 8(g) and decision XII/24.

59. In considering the degree to which existing risk assessment principles and methodologies constitute a comprehensive framework to address the impact of organisms of synthetic biology, some members of the AHTEG noted that risk assessment practices currently in place to evaluate LMOs are sufficient and appropriate to evaluate organisms of synthetic biology, and could be modified to accommodate new specific considerations related to synthetic biology should the need arise.

60. Some members noted, however, that current risk assessment approaches and methodologies must be adapted to address matters that are of particular relevance to synthetic biology. Those members identified the lack of familiarity in comparison with non-modified organisms, challenges in establishing meaningful comparators, and possibly higher levels of uncertainty as gaps in the existing methodologies for assessing the environmental impacts of organisms of synthetic biology, and identified a need for guidelines and capacity-building to be developed and made available.

61. The views of the members of the AHTEG diverged with regard to whether or not current methodologies to address the environmental impacts of the components and products of synthetic biology are adequate or even needed.

62. With regard to the socioeconomic considerations of the impacts of synthetic biology on the three objectives of the Convention, some members of the Group noted that the issues are not sufficiently addressed by existing frameworks.

63. With regard to the fair and equitable sharing of the benefits of synthetic biology, some members of the AHTEG noted that there is no comprehensive framework to assess the added value of synthetic biology applications to society.

64. Some members of the AHTEG further noted the lack of relevant methodologies for integrating ethical values that are relevant to society in the assessment of the added value of synthetic biology applications.

65. The need for coordination with current processes under the Cartagena Protocol on Biosafety was noted, in particular with the AHTEG on Socio-economic Considerations and the AHTEG on Risk Assessment and Risk Management.

66. Some members of the AHTEG noted that the existing arrangements to address the impacts of organisms, components and products resulting from synthetic biology are fragmented and do not constitute a comprehensive framework.

B. Conclusions and ways forward, including elements to facilitate future discussions and actions on synthetic biology under the Convention

67. Reaffirming decision XII/24, in which the Conference of the Parties urged Parties and invited other Governments to take a precautionary approach in accordance with paragraph 4 of decision XI/11, and having deliberated on the tasks mandated by the Conference of the Parties, the AHTEG made the following proposals on the ways forward for future actions on synthetic biology for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice in formulating its recommendations to the Conference of the Parties:

(a) Consider the adoption of the operational definition of synthetic biology: “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";

(b) Take note of the conclusion of the AHTEG that living organisms developed through current and near future applications of synthetic biology are similar to LMOs as defined in the Cartagena Protocol;

(c) Establish a process to monitor and assess the state of knowledge within the field of synthetic biology on a regular basis, review new information regarding the positive and negative impacts of synthetic biology vis-à-vis the three objectives of the Convention, and update the proposed operational definition as appropriate;

(d) Urge Parties to address synthetic biology in a coordinated manner within the context of the objectives of the Convention and its Protocols, particularly by tapping into existing processes, such as the AHTEG on Risk Assessment and Risk Management and the AHTEG on Socio-economic Considerations under the Cartagena Protocol;

(e) Coordinate and establish synergies with other United Nations and international organizations, whose mandates are relevant to synthetic biology, such as the World Health Organization, the Food and Agriculture Organization of the United Nations, including its Committee on World Food Security and Codex Alimentarius, the World Intellectual Property Organization, the World Organisation for Animal Health, the Permanent Forum on Indigenous Issues and the Technology Facilitation Mechanism of the United Nations;

(f) Create or expand existing online platforms to facilitate knowledge and information sharing on risk assessment research, positive and negative impacts of synthetic biology through, among other things, the Biosafety-Clearing House or the clearing-house mechanism;

(g) Promote the use of online tools to facilitate work on synthetic biology in the context of the Convention and its Protocols;

(h) Promote capacity-building and encourage cooperation among Parties, other Governments and relevant organizations;

(i) Invite the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol to set up mechanisms for clarifying the issue of digital genetic resource information as it relates to access and benefit-sharing;

(j) Assess potential gaps in oversight under the Convention and its Protocols with regard to components and products of synthetic biology;

(k) Urge the Convention to promote the full engagement of indigenous peoples and local communities in future activities relating to synthetic biology;

(l) Promote engagement among Parties, other Governments and relevant stakeholders to discuss, among other things, the potential benefits and potential adverse effects of synthetic biology, the development of guidelines, public awareness, communication and education, and ethical considerations in the context of the three objectives of the Convention.

IV. OVERVIEW OF COMMENTS PROVIDED THROUGH THE PEER-REVIEW PROCESS

68. The following views were shared by several Parties following their peer review of documents UNEP/CBD/SBSTTA/20/INF/11 and UNEP/CBD/SBSTTA/20/INF/12:

(a) In general, the reports provide an accurate and balanced overview of the discussions held by the Open-ended Online Forum and the AHTEG on synthetic biology and may serve as the foundation for further discussions at the twentieth meeting of SBSTTA;

(b) The operational definition as proposed by the AHTEG will be useful in guiding and facilitating further discussions on synthetic biology under the Convention. Nevertheless, given the broad

scope of the proposed definition, it is also important to identify cases where synthetic biology and modern biotechnology may differ;

(c) Living organisms, components and products of synthetic biology fall within the scope of the Convention and its three objectives: conservation of biological diversity, sustainable use of biological diversity, and fair and equitable sharing of the benefits of biological diversity/utilization of genetic resources;

(d) Living organisms developed through current and near future applications of synthetic biology are similar to LMOs as defined in the Cartagena Protocol, whereas non-living components (such as a DNA molecule) and products (such as a chemical substance) of synthetic biology do not fall under the scope of the Cartagena Protocol;

(e) The general principles and methodology of risk assessment as per the Cartagena Protocol and existing biosafety frameworks provide a good basis for the risk assessment of living organisms developed through current and near future applications of synthetic biology. However, the methodology may need to be updated or adjusted in order to fully address the potential environmental and societal impacts of synthetic biology and ensure that sufficient information is available to support rigorous and scientifically sound risk assessments. Therefore, building on existing international, regional and national biosafety frameworks is considered to be the best approach for assessing, managing and preventing potential adverse effects arising from components, organisms and products of synthetic biology.

69. Several Parties supported the following possible ways forward for future actions:

(a) Further discussing the "boundary" between modern biotechnology and synthetic biology, including their similarities and differences, by first determining which, if any, living organisms developed through synthetic biology would be outside the scope of the Cartagena Protocol;

(b) Sharing knowledge and experience, among Parties, on their experiences and challenges in implementing the provisions of the Cartagena Protocol to ensure the safe use of components, organisms and products of synthetic biology, while taking into account other relevant definitions and regulations in place;

(c) Establishing a process through the Convention to regularly monitor and assess the scientific and technological developments in synthetic biology as it applies to the objectives of the Convention with a view to enhancing the state of knowledge and capacity of different countries;

(d) Cooperating with relevant international organizations to assess the potential benefits and adverse effects of synthetic biology;

(e) Assessing the potential gaps under the Convention's framework with regard to components and products, as well as organisms developed through synthetic biology.

70. A detailed synthesis of the peer-review comments is available as document UNEP/CBD/SBSTTA/20/INF/13.

VI. SUGGESTED RECOMMENDATIONS

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

The Subsidiary Body on Scientific, Technical and Technological Advice,

Having considered the information submitted by Parties, other Governments, relevant organizations and stakeholders, the outcomes of the Open-ended Online Forum on Synthetic Biology and the AHTEG on Synthetic Biology, as well as the comments from the peer-review process, *notes* that:

(a) The operational definition "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" is useful as a basis for facilitating further deliberations under the Convention;

(b) Living organisms, components and products of synthetic biology fall within the scope of the Convention and its three objectives, and 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 components and products of synthetic biology;

(c) Living organisms developed through current and near future applications of synthetic biology are similar to living modified organisms as defined in the Cartagena Protocol on Biosafety, whereas non-living components (such as a DNA molecule) and products/outputs of synthetic biology (such as a chemical substance) do not fall under the scope of the Cartagena Protocol;

(d) The general principles and methodology for risk assessment under the Cartagena Protocol and existing biosafety frameworks provide a good basis for risk assessment regarding living organisms developed through current and near future applications of synthetic biology, but such methodologies may need to be updated and adapted for future developments and applications of synthetic biology;

(e) The sharing of experience and information among Parties is crucial and needs to be encouraged, including information on actual risk assessments and gaps in existing national, regional and/or international instruments to regulate the organisms, components or products derived from synthetic biology techniques;

(f) Scientific and technological developments in the field of synthetic biology need to be reviewed regularly to ensure adequacy of regulatory oversight and risk assessment methodologies;

(g) Coordination is needed among current and future processes under the Convention and its Protocols, and in particular with the AHTEG on Risk Assessment and Risk Management and the AHTEG on Socio-economic Considerations under the Cartagena Protocol, as appropriate;

(h) Coordination is needed to with other United Nations and international organizations considering, whose mandates are relevant to synthetic biology.

Recommendation to the Conference of the Parties

72. The Subsidiary Body on Scientific, Technical and Technological Advice *recommends* that the Conference of the Parties, at its thirteenth meeting, adopt a decision along the following lines:

The Conference of the Parties

(a) *Reaffirms* decision XII/24, in which it urged Parties and invited other Governments to take a precautionary approach in accordance with decision XI/11, paragraph 4;

(b) *Decides* to use the following operational definition of synthetic biology to facilitate further deliberations in the context of the Convention: "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";

(c) *Takes note* of the conclusion of the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology that living organisms developed through current and near future applications of synthetic biology are similar to LMOs as defined in the Cartagena Protocol;

(d) *Encourages* Parties, other Governments and relevant organizations to:

(i) Conduct research on the positive and negative impacts of synthetic biology, on biodiversity, with a view to filling knowledge gaps and identifying how those impacts relate to the objectives of the Convention and its Protocols;

(ii) Promote and enable public and multi-stakeholder dialogues and awareness-raising activities on the potential positive and negative impacts of synthetic biology on biodiversity, taking into account ethical considerations in the context of the three objectives of the Convention, with the full engagement of indigenous peoples and local communities;

(iii) Cooperate in the development of guidelines and capacity-building activities with a view to assessing the potential benefits and potential adverse effects of synthetic biology and adapting current methodologies for risk assessment of living modified organisms to organisms resulting from synthetic biology;

(iv) Share and exchange, through the appropriate online platform under the Convention, information and experience arising from research, cooperation, capacity-building activities and regulatory processes;

(e) *Invites* Parties, other Governments, relevant organizations and indigenous people and local communities to submit information and supporting documentation to the Executive Secretary on:

(i) Evidence of positive and negative impacts of synthetic biology vis-à-vis the three objectives of the Convention;

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

(iii) Examples of risk management and other measures that have been put in place to minimize the potential adverse effects of the components, organisms and products of synthetic biology;

(iv) Views on how the use of digital sequence information on genetic resources relates to access and the fair and equitable sharing of benefits arising from their utilization in the context of the Nagoya Protocol;

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

(f) *Requests* the Executive Secretary:

(i) To extend the open-ended online forum on synthetic biology through the Biosafety Clearing-House or the clearing-house mechanism in order to facilitate knowledge- and information sharing regarding the research on the positive and negative impacts of synthetic biology, and to continue to invite Parties, other Governments, indigenous and local communities and relevant organizations to nominate experts to take part in the forum;

(ii) To compile and synthesize the information received through paragraph (e) above;

(iii) To commission updated studies to (a) review recent technological developments in synthetic biology and (b) assess the extent to which existing national, regional and/or international instruments are adequate to regulate the non-living components and products of synthetic biology techniques, and identify any possible gaps that are relevant to the objectives of the Convention;

(iv) To compile and synthesize the results of the work referred to in the paragraphs above and make them available for further discussion through the online forum and the Ad Hoc Technical Expert Group;

(v) To convene moderated online discussions under the open-ended online forum and, subject to the availability of funds, a face-to-face meeting of an ad hoc technical expert group with the terms of reference annexed to the present decision, and submit the report of the ad hoc technical expert group to peer review by Parties 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;

(vi) To cooperate with other United Nations and international organizations whose mandates are relevant to synthetic biology, such as the World Health Organization, the Food and Agriculture Organization of the United Nations, including its Committee on World Food Security and Codex Alimentarius, the World Intellectual Property Organization, the World Organisation for Animal Health, the Permanent Forum on Indigenous Issues and the Technology Facilitation Mechanism of the United Nations;

(vii) To promote the full engagement of indigenous peoples and local communities in future activities relating to synthetic biology under the Convention.

(g) *Invites* the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety to address synthetic biology in a coordinated manner, particularly by tapping into existing processes, such as the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management for the development of guidance dedicated to risk assessment regarding living modified organisms developed through synthetic biology and the Ad Hoc Technical Expert Group on Socio-economic Considerations under the Cartagena Protocol, as appropriate.

Annex

TERMS OF REFERENCE FOR THE AD HOC TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY

1. The Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology shall:

(a) Monitor and assess the current state of knowledge within the field of synthetic biology by reviewing recent technological developments;

(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) Analyse evidence of positive and negative impacts of synthetic biology, vis-à-vis the three objectives of the Convention, including documented cases of incidents that may lead to potential adverse effects, such as cases of organisms that were intended for contained use being introduced into the environment and of unintentional transboundary movements;

(d) Assess potential gaps in oversight under the Convention and its Protocols with regard to components, organisms and products of synthetic biology;

(e) Provide clarity on how the use digital sequence information on genetic resources could have impacts, both positive and negative, on the fair and equitable sharing of benefits arising from their utilization within the context of the Nagoya Protocol;

(f) Provide recommendations on the basis of its deliberations to facilitate future discussions and actions on synthetic biology under the Convention 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.

2. The AHTEG will draw 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, as referred to in this decision.

3. The AHTEG will be convened in accordance with the modus operandi of the Subsidiary Body on Scientific, Technical and Technological Advice (decision VIII/10). Subject to the availability of funds, the AHTEG shall meet at least once face-to-face prior to the fourteenth meeting of the Conference of the Parties and make use of online tools to facilitate its work, as appropriate.

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