



Building International Capacity in Synthetic Biology Assessment and Governance

Key decisions adopted by the Convention on Biological Diversity and the Cartagena Protocol on Biosafety related to 'synthetic biology'

The issue of synthetic biology first appeared on the agenda of the Convention on Biological Diversity (CBD) in 2010. The Conference of the Parties (COP) adopted a decision on new and emerging issues, which called for the application of the precautionary approach “to the field release of synthetic life, cell or genome into the environment.” Another decision on biofuels and biodiversity reaffirmed this, and added that the precautionary approach should also be applied to the introduction and use of living modified organisms (LMOs) for the production of biofuels while acknowledging the rights of Parties to suspend the release of synthetic life, cell, or genome into the environment.

DECISION ADOPTED BY THE CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY

X/13. New and emerging issues

The Conference of the Parties

1. *Decides* not to add any of the proposed new and emerging issues relating to the conservation and sustainable use of biodiversity to the agenda of the Subsidiary Body on Scientific, Technical and Technological Advice;
2. *Noting* decision IX/29 which sets out the criteria for new and emerging issues, and *recognizing* that the issues of ocean acidification, Arctic biodiversity, ocean noise, and ground level ozone meet the criteria set out by the Conference of the Parties for consideration as new and emerging issues and *further recognizing* that ocean acidification and ocean noise do not constitute new issues, *requests* the Subsidiary Body on Scientific, Technical and Technological Advice to:
 - (a) Consider the impacts of ocean acidification on marine biodiversity and habitats as part of the ongoing activities under the programme of work on marine and coastal biological diversity, in accordance with the provision in paragraph 4 of decision IX/20;
 - (b) Take into account, in the implementation of the programmes of work on protected areas and on marine and coastal biodiversity, the impact of ocean noise on marine protected areas and to consider the scientific information on underwater noise and its impacts on marine and coastal biodiversity and habitats that will be made available by the Executive Secretary prior to the eleventh meeting of the Conference of the Parties;
3. *Invites* the Arctic Council to provide relevant information and assessments of Arctic biodiversity, in particular information generated through the Circumpolar Biodiversity Monitoring Program (CBMP) of the Arctic Council's Conservation of Arctic Flora and Fauna Working

Group, for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice;

4. *Invites* Parties, other Governments and relevant organizations to submit information on synthetic biology and geo-engineering, for the consideration by the Subsidiary Body on Scientific, Technical and Technological Advice, in accordance with the procedures of decision IX/29, while applying the precautionary approach to the field release of synthetic life, cell or genome into the environment;
5. *Invites* Parties, other Governments and relevant organizations to consider the issues identified as possible new and emerging issues relating to the conservation and sustainable use of biodiversity and the fair and equitable sharing of benefits arising from the use of genetic resources when implementing existing programmes of work, guidelines and principles under the Convention as well as under other forums and processes;

[...]

DECISION ADOPTED BY THE CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY

X/37. Biofuels and biodiversity

The Conference of the Parties,

Recalling its decision IX/2, in which it decided to consider at its tenth meeting ways and means to promote the positive and minimize the negative impacts of the production and use of biofuels on biodiversity,

Recognizing that improved scientific, environmental and socio-economic research and assessments, open and transparent consultation, with the full and effective participation of the concerned indigenous and local communities, and sharing of best practices, are crucial needs for the continuing improvement of policy guidance and decision-making to promote the positive and minimize or avoid the negative impacts of biofuels on biodiversity and impacts on biodiversity that affect

related socioeconomic conditions and to address the gaps in scientific knowledge and concerns that exist regarding such impacts,

Noting the rapid pace of development of new technologies that enable conversion of biomass into a broader and more flexible range of fuels,

Acknowledging concerns that deployment of biofuel technologies, may result in increased demand for biomass and aggravate drivers of biodiversity loss, such as land use change, introduction of invasive alien species, bearing in mind paragraph 6 of decision X/38 of the Conference of the Parties, and resource over-consumption,

Also acknowledging the potential for biofuel technologies to make a positive contribution to mitigating climate change, another of the main drivers of biodiversity loss, and generating additional income in rural areas,

Aware in particular of the potential positive and negative impacts of the production and use of biofuels on the conservation and customary use of biodiversity by indigenous and local communities, and the consequences for their well-being,

[...]

16. *Urges* Parties and other Governments to apply the precautionary approach in accordance with the Preamble to the Convention, and the Cartagena Protocol, to the introduction and use of living modified organisms for the production of biofuels as well as to the field release of synthetic life, cell, or genome into the environment, acknowledging the entitlement of Parties, in accordance with domestic legislation, to suspend the release of synthetic life, cell, or genome into the environment;
17. *Recognizes* that the consideration by the Subsidiary Body on Scientific, Technical and Technological Advice, in accordance with paragraph 4 of decision X/12, should assist in providing guidance and clarity on synthetic biology, and *encourages* Parties to include relevant information on synthetic biology and biofuels when submitting information in response to paragraph 4 of decision X/12.

By COP 11 in 2012, discussions had matured such that Parties asked for additional relevant information on 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. This information was to be synthesized, together with a consideration of possible gaps and overlaps with the provisions of the Convention, its Protocols and other relevant agreements. The precautionary approach to synthetic biology was reaffirmed, given the scientific uncertainties of the potential impacts. It is important to note that the language refers not only to organisms resulting from synthetic biology techniques, but also to the components and products, which are regarded as non-living, as well as includes not only impacts on biodiversity, but socio-economic and cultural considerations.

DECISION ADOPTED BY THE CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY

XI/11. New and emerging issues relating to the conservation and sustainable use of biodiversity

The Conference of the Parties

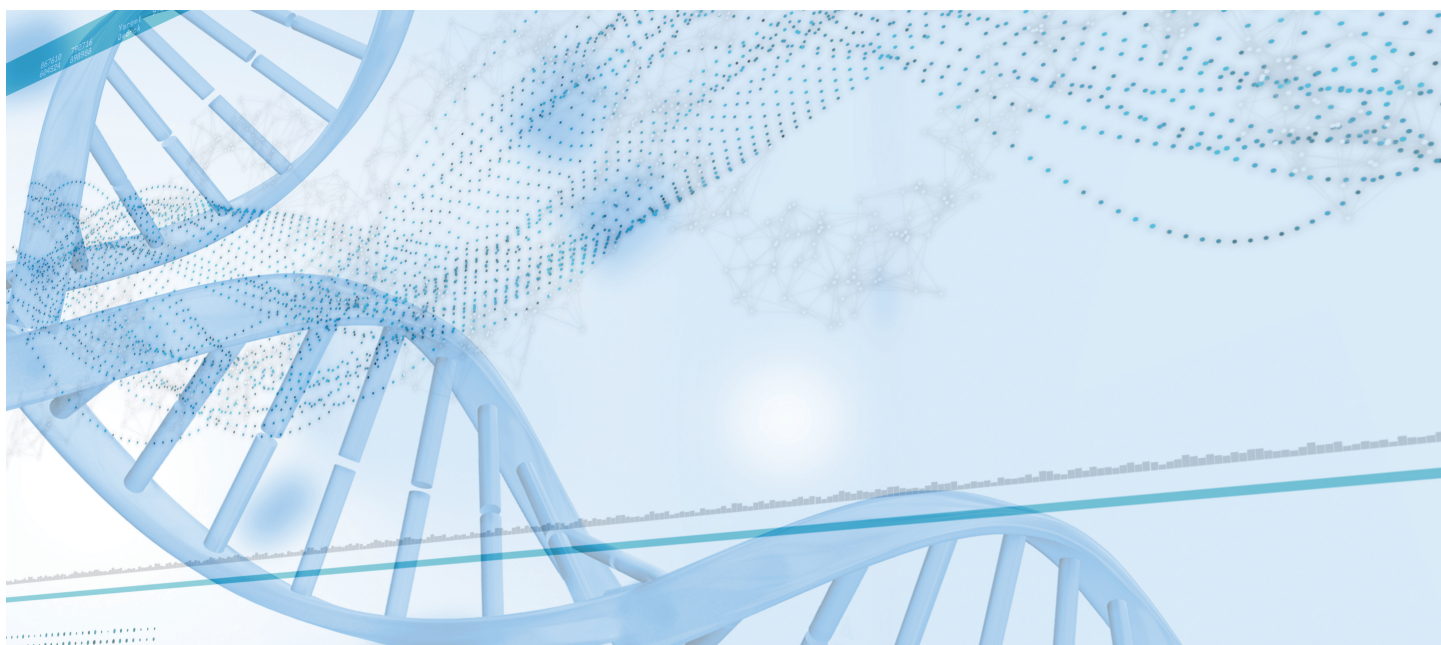
1. *Takes note* of the proposals for new and emerging issues relating to the conservation and sustainable use of biodiversity as contained in the note by the Executive Secretary on new and emerging issues relating to the conservation of biodiversity prepared for the sixteenth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (UNEP/CBD/SBSTTA/16/13);

[...]

3. *Noting*, based on the precautionary approach, the need to consider the potential positive and negative impacts of components, organisms

and products resulting from synthetic biology techniques on the conservation and sustainable use of biodiversity, *requests* the Executive Secretary, subject to availability of resources, to:

- (a) Invite Parties, other Governments, relevant international organizations, indigenous and local communities and other stakeholders to submit, in accordance with paragraphs 11 and 12 of decision IX/29, additional relevant information on 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;
 - (b) Compile and synthesize relevant available information, together with the accompanying information;
 - (c) Consider possible gaps and overlaps with the applicable provisions of the Convention, its Protocols and other relevant agreements related to components, organisms and products resulting from synthetic biology techniques;
 - (d) Make a synthesis of the above information, including an analysis of how the criteria set out in paragraph 12 of decision IX/29 apply to this issue, available for peer review and subsequent consideration by a meeting of the Subsidiary Body on Scientific, Technical and Technological Advice prior to the twelfth meeting of the Conference of the Parties, in accordance with paragraph 13 of decision IX/29;
4. *Recognizing* the development of technologies associated with synthetic life, cells or genomes, and the scientific uncertainties of their potential impact on the conservation and sustainable use of biological diversity, *urges* Parties and *invites* other Governments to take a precautionary



approach, in accordance with the preamble of the Convention and with Article 14, when addressing threats of significant reduction or loss of biological diversity posed by organisms, components and products resulting from synthetic biology, in accordance with domestic legislation and other relevant international obligations;

5. In line with decision IX/29, *requests* the Executive Secretary to include, with the compilation of original submissions and the information and views on each proposed new and emerging issue relating to the conservation and sustainable use of biodiversity, a review of information applying the criteria contained in paragraph 12 of decision IX/29, where this has not otherwise been provided, with a view to enabling the Subsidiary Body on Scientific, Technical and Technological Advice to consider the proposals.

At COP 12 in 2014, a landmark decision on synthetic biology was adopted that emphasized the need for precaution. The decision called for effective risk assessment and management procedures and/or regulatory systems for synthetic biology organisms, products and components, and the assessment of not only potential effects on the conservation and sustainable use of biodiversity, but also of human health, food security and socio-economic considerations. Importantly, it highlighted that the full participation of indigenous peoples and local communities is needed in such assessments.

Parties also established an online forum and Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology to address seven questions, in particular to examine the gaps and overlaps in regulatory systems and to provide an operational definition to allow further work on the issue.

At the same time, a decision by the Parties of the Cartagena Protocol on Biosafety recommended a coordinated approach on the issue of synthetic biology, taking into account that the provisions of the Protocol may also apply to living organisms resulting from synthetic biology.

DECISION ADOPTED BY THE CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY

XII/24. New and emerging issues: synthetic biology

The Conference of the Parties,

Reaffirming paragraph 4 of decision XI/11, in which it recognized the development of technologies associated with synthetic life, cells or genomes, and the scientific uncertainties of their potential impact on the conservation and sustainable use of biological diversity, urged Parties and invited other Governments to take a precautionary approach, in accordance with the preamble of the Convention and with Article 14, when addressing threats of significant reduction or loss of biological diversity posed by organisms, components and products resulting from synthetic biology, in accordance with domestic legislation and other relevant international obligations,

Noting decision BS-VII/12 of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, recommending a coordinated approach on the issue of synthetic biology taking into account that the provisions of the Cartagena Protocol may also apply to living organisms resulting from synthetic biology,

1. *Takes note* of the conclusions of the Subsidiary Body on Scientific, Technical and Technological Advice at its eighteenth meeting, as contained in paragraph 1 of recommendation XVIII/7, *recognizes* that this issue is of relevance to the Convention and *concludes* that there is currently insufficient information available to finalize an analysis, using the criteria set out in paragraph 12 of decision IX/29, to decide whether or not this is a new and emerging issue related to conservation and sustainable use of biodiversity;
2. *Awaits* the completion of a robust analysis using the criteria set out in paragraph 12 of decision IX/29;
3. *Urges* Parties and *invites* other Governments to

take a precautionary approach, in accordance with paragraph 4 of decision XI/11, and:

- (a) 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;
- (b) To approve organisms resulting from synthetic biology techniques for field trials only after appropriate risk assessments have been carried out in accordance with national, regional and/or international frameworks, as appropriate;
- (c) To carry out scientific assessments concerning organisms, components and products resulting from synthetic biology techniques with regard to potential effects on the conservation and sustainable use of biodiversity, taking into account risks to human health and addressing, as appropriate, and according to national and/or regional legislation, other issues such as food security and socioeconomic considerations with, where appropriate, the full participation of indigenous and local communities;
- (d) To encourage the provision of funding for research into synthetic biology risk assessment methodologies and into the positive and negative impacts of synthetic biology on the conservation and sustainable use of biodiversity, and to promote interdisciplinary research that includes related socioeconomic considerations;
- (e) To cooperate in the development and/or strengthening of human resources and institutional capacities, including on methodologies for risk assessments in synthetic biology and its potential impacts on biodiversity, in developing countries, in particular the least developed countries



and small island developing States, and countries with economies in transition, including through existing global, regional and national institutions and organizations and, as appropriate, by facilitating civil society involvement. The needs of developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, for financial resources; access to and transfer of technology consistent with Article 16 of the Convention; establishing or strengthening regulatory frameworks; and the management of risks related to the release of organisms, components and products resulting from synthetic biology techniques, should be taken fully into account in this regard;

4. *Decides*, subject to the availability of resources, to establish an Ad Hoc Technical Expert Group, with terms of reference contained in the annex to the present decision, to be convened after the Executive Secretary has completed the requests in paragraph 7 below;
5. *Invites* Parties, other Governments, relevant organizations and stakeholders to submit

information to the Executive Secretary relevant to the work of the Ad Hoc Technical Expert Group established by the present decision, as well as on measures undertaken in accordance with paragraph 3 above, including the identification of needs for guidance;

6. *Invites* Parties, other Governments, relevant international organizations, indigenous and local communities and relevant stakeholders to continue to provide further information to the Executive Secretary in response to decision XI/11, paragraph 3 (a);
7. *Requests* the Executive Secretary, subject to the availability of financial resources:
 - (a) To make available the information reported in accordance with paragraphs 5 and 6 above, through the clearing-house mechanism of the Convention and other means;
 - (b) To convene a moderated open-ended online forum¹ to support the work of the Ad Hoc Technical Expert Group established in paragraph 4 above in meeting its terms of reference;
 - (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 paragraphs 5 and 6 above and a synthesis of the outcomes of the process mentioned in paragraph 7 (b) and to submit these for consideration by the Ad Hoc Technical Expert Group;
 - (d) To submit for consideration by a meeting of the Subsidiary Body on Scientific, Technical and Technological Advice prior to the thirteenth meeting of the Conference of the Parties, the peer-reviewed reports of the outcomes of the process mentioned in paragraphs 7 (b) and 7 (c) above;
8. *Invites* relevant organizations, including relevant United Nations organizations and bodies, to consider the possible implications of synthetic biology as it relates to their mandates.

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

The Ad Hoc Technical Expert Group will include balanced representation of Parties from all regions and include representation of indigenous and local communities and all relevant stakeholders, including other Governments, with knowledge of the Convention and its Protocols,² and will report on its work to a meeting of the Subsidiary Body on Scientific, Technical and Technological Advice prior to the thirteenth meeting of the Conference of the Parties.

The Ad Hoc Technical Expert Group will:

- (a) Take note of the exchange of views on how to address the relationship between synthetic biology and biological diversity;
- (b) Identify the similarities and differences between living modified organisms (as defined in the Cartagena Protocol) and organisms, components and products of synthetic biology techniques to determine if living modified organisms derived from synthetic biology fall under the scope of the Cartagena Protocol;
- (c) Identify if other national, regional and/or international instruments adequately regulate the organisms, components or products derived from synthetic biology techniques in so far as they impact on the objectives of the Convention and its Protocols;
- (d) Work towards an operational definition of synthetic biology, comprising inclusion and exclusion criteria, using all relevant information, based on scientific and peer-reviewed studies;
- (e) Identify the 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) Building on the work on risk assessment and risk management undertaken by the Cartagena Protocol, compile information on best practices on risk assessment and monitoring regimes currently used by Parties to the Convention and other Governments, including transboundary movement, to inform those who do not have national risk assessment or monitoring regimes, or are in the process of reviewing their current risk assessment or monitoring regimes and to help those Parties and other Governments to regulate organisms, components and products from synthetic biology techniques appropriately;
- (g) Identify if the existing arrangements constitute a comprehensive framework in order to address impacts of organisms, components and products resulting from synthetic biology relevant to the objectives of the Convention on Biological Diversity and its Protocols, in particular threats of significant reduction or loss of biological diversity.

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

2 The Ad Hoc Technical Expert Group will be convened in accordance with the modus operandi of the Subsidiary Body on Scientific, Technical and Technological Advice, except that there will be 5 to 8 experts nominated by each of the five regions.



DECISION ADOPTED BY THE CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY

BS-VII/12. Risk assessment and risk management (Articles 15 and 16)

The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety,

Recalling paragraph 1(d)(ii) of the annex to decision BS-IV/11 and paragraph 2 of decision BS-V/12,

Also recalling decision BS-VI/12, in particular that the Guidance on Risk Assessment of Living Modified Organisms¹ is not prescriptive and does not impose any obligations on Parties,

Further recalling that the Guidance is intended as a “living document” that may be revised and improved as appropriate and when mandated by the Parties to the Cartagena Protocol on Biosafety,

1. *Welcomes* the results of the testing of the Guidance on Risk Assessment of Living Modified Organisms;
2. *Invites* Parties, other Governments and relevant organizations to test or use, as appropriate, the

Guidance in actual cases of risk assessment and as a tool for capacity-building activities in risk assessment;

3. *Establishes* the mechanism outlined in the annex to this decision for revising and improving the Guidance on the basis of the feedback provided through the testing with a view to having an improved version of the Guidance by its eighth meeting;
4. *Extends* the Open-ended Online Expert Forum (Online Forum) on Risk Assessment and Risk Management and the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management to work, primarily online and, subject to the availability of funds, through a face-to-face meeting, with revised terms of reference as annexed to this decision, and *expands* the composition of the AHTEG to add one new member from each region;
5. *Invites* Parties to submit (a) information on their needs and priorities for further guidance on specific topics of risk assessment of living modified organisms, and (b) existing guidance on specific topics of risk assessment of living modified organisms;
6. *Requests* the Executive Secretary to synthesize the views submitted through paragraph 5

above for consideration of the eighth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol;

7. *Agrees* to consider, at its eighth meeting, the need for the development of further guidance on topics prioritized on the basis of the needs indicated by the Parties with a view to moving towards operational objectives 1.3 and 1.4 of the Strategic Plan and its outcomes;
8. *Invites* Parties, other Governments and relevant organizations to confirm the nominations of their experts who are currently participating in the Online Forum on risk assessment and risk management, *requests* the Executive Secretary to remove the records of experts whose nominations have not been confirmed, and further *invites* Parties, other Governments and relevant organizations to nominate additional experts to join the Online Forum using the format for the nomination of experts to the Roster of Experts;
9. *Requests* the Executive Secretary to continue facilitating the work of the Online Forum and the AHTEG;
10. *Also requests* the Executive Secretary to improve the mechanism established in paragraph 6 of decision BS-VI/12 for updating background documents to the Guidance as follows:
 - (a) Extend the period for commenting on the background documents to three weeks and send an automatic reminder after two weeks to the group operating the mechanism;
 - (b) Raise awareness of the background documents linked to the Guidance by, for example, adding information and links in the Biosafety Clearing-House and inviting experts in the specific topics of the Guidance to submit background documents;
 - (c) Index the background documents for author affiliation, for example, government, academic institutions, non-governmental organizations and business;
11. *Welcomes* the package that aligns the Guidance and Training Manual;
12. *Invites* Parties and other Governments and relevant organizations to test or use, as appropriate, the package as a tool for, inter alia, capacity-building in risk assessment;
13. *Requests* the Executive Secretary, subject to the availability of funds, to conduct capacity-building activities in risk assessment using the aligned package;
14. *Invites* Parties, other Governments and international organizations to provide funds and in-kind assistance to implement the capacity-building activities referred to in paragraph 13 above;
15. *Welcomes* the creation of sections in the Biosafety Clearing-House where scientific information can be submitted and retrieved regarding living modified organisms or specific traits that may have or that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health;
16. *Invites* Parties, other Governments and relevant organizations to continue submitting, through the Biosafety-Clearing House, the information referred to in paragraph 15 above;
17. *Recommends* to the Conference of the Parties to the Convention on Biological Diversity a coordinated approach with the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety on the issue of synthetic biology, taking into account that the provisions of the Protocol may also apply to living organisms resulting from synthetic biology.

TERMS OF REFERENCE FOR THE OPEN-ENDED ONLINE FORUM AND AD HOC TECHNICAL EXPERT GROUP ON RISK ASSESSMENT AND RISK MANAGEMENT

Methodology

1. Taking into account the results of the testing process, established in decision BS-VI/12, the Guidance on Risk Assessment of LMOs shall be revised and improved in accordance with the following mechanism:
 - (a) After the seventh meeting of the COP-MOP, the Secretariat will group the original comments provided through the testing of the Guidance. The grouping will be done in the form of a matrix based on the following categories: statements that do not trigger changes; editorial and translational changes; suggestions for changes without a specified location in the Guidance; and suggestions for changes to specific sections of the Guidance (sorted by line numbers);
 - (b) The AHTEG shall review the grouping of comments done by the Secretariat and work on the suggestions for changes;
 - (c) The AHTEG shall streamline the comments by identifying which suggestions may be taken on board and providing justification for those suggestions that may not be taken on board. The AHTEG will also provide concrete text proposals for the suggestions to be taken on board with a justification where the original suggestion was modified;
 - (d) The Open-ended Online Forum and the AHTEG shall subsequently review all comments and suggestions with a view to having an improved version of the Guidance for consideration by the COP-MOP at its eighth meeting.
2. While revising and improving the Guidance, an attempt should be made to take into account the topics prioritized by the AHTEG, on the basis of the needs indicated by the Parties with a view to moving towards operational objectives 1.3 and 1.4 of the Strategic Plan and its outcomes, for the development of further guidance.
3. The AHTEG shall continue to operate the mechanism for regularly updating the list of background documents to the Guidance as established in decision BS-VI/12, paragraph 6, and improved as per paragraph 10 of this decision.
4. Subject to the availability of funds, the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management shall meet face-to-face, at least once, prior to the eighth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

Expected outcome

5. An improved version of the Guidance on Risk Assessment of Living Modified Organisms.

Reporting

6. The Online Forum and the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management shall submit their reports detailing the activities, outcomes and recommendations for consideration by the eighth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

1 UNEP/CBD/BS/COP-MOP/6/13/Add.1 available at <http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=4715>.

At COP 13 in 2016, the decision on synthetic biology accepted the operational definition of synthetic biology developed by the AHTEG on Synthetic Biology, which facilitates further work on the issue. The decision extended the mandate of the AHTEG, to continue working and updating on this fast-developing field, including identifying risk management measures, safe use and best practices for safe handling, and evaluating the availability of tools to detect and monitor the organisms, components and products of synthetic biology. Parties were also asked to take socio-economic, cultural and ethical considerations into account. The decision further explicitly mentioned LMOs containing gene drives, noting the need for precaution, effective risk assessment and management, and regulation.

However, while the Parties to the CBD noted that the methodologies for risk assessment of LMOs may need to be updated and adapted for synthetic biology, the Parties to the Cartagena Protocol on Biosafety dissolved the AHTEG on Risk Assessment and Risk Management, which had been expected to develop guidance on synthetic biology. The relevant decision does not mention synthetic biology, even though further specific risk assessment guidance on LMOs produced through synthetic biology had been requested by Parties and recommended by the AHTEG.

DECISION ADOPTED BY THE CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY

XIII/17. Synthetic biology

The Conference of the Parties

1. *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;
2. *Reiterates* paragraph 3 of decision XII/24 and notes that it can also apply to some living modified organisms containing gene drives;
3. *Commends* the work of the online forum and the Ad Hoc Technical Expert Group on Synthetic Biology, and *welcomes* the conclusions and recommendations of the report of the Group as a basis for further discussion;
4. *Acknowledges* that the outcome of the work of the Ad Hoc Technical Expert Group on Synthetic Biology on the operational definition is “synthetic biology is a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems”, and *considers* it useful as a starting point for the purpose of facilitating scientific and technical deliberations under the Convention and its Protocols;
5. *Takes note* of the conclusion of the Ad Hoc Technical Expert Group on Synthetic Biology that living organisms developed through current applications of synthetic biology, or that are currently in the early stages of research and development, are similar to living modified organisms as defined in the Cartagena Protocol;
6. *Notes* that the general principles and methodologies for risk assessment under the Cartagena Protocol and existing biosafety frameworks provide a good basis for risk assessment regarding living organisms developed through current applications of synthetic biology, or that are currently in the early stages of research and development, but such methodologies may need to be updated and adapted for current and future developments and applications of synthetic biology;
7. *Also notes* that it is not clear, given the current state of knowledge, 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 living modified organisms under the Cartagena Protocol, and *further notes* that there are cases in which there may be no consensus on whether the result of a synthetic biology application is “living” or not;

8. *Invites* Parties, in accordance with their applicable domestic legislation or national circumstances, to take into account, as appropriate, socio-economic, cultural and ethical considerations when identifying the potential benefits and potential adverse effects of organisms, components and products resulting from synthetic biology techniques in the context of the three objectives of the Convention;
9. *Encourages* Parties and *invites* other Governments and relevant organizations, in the context of the three objectives of the Convention and taking into account, if appropriate and in accordance with domestic legislation or national circumstances, socio-economic, cultural and ethical considerations:
 - (a) To conduct research on the benefits and adverse effects of organisms, components and products of synthetic biology on biodiversity, with a view to filling knowledge gaps and identifying how those effects relate to the objectives of the Convention and its Protocols;
 - (b) To promote and enable public and multi-stakeholder dialogues and awareness-raising activities on the potential benefits and potential adverse effects of organisms, components and products of synthetic biology on biodiversity, involving all relevant stakeholders and with the full and effective engagement of indigenous peoples and local communities;
 - (c) To cooperate in the development of guidance and capacity-building activities with a view to assessing the potential benefits and potential adverse effects of organisms, components and

products of synthetic biology and, if necessary, updating and adapting current methodologies for risk assessment of living modified organisms to organisms resulting from synthetic biology, as appropriate;

10. *Invites* Parties, other Governments, relevant organizations and indigenous peoples and local communities to submit to the Executive Secretary information and supporting documentation on:
 - (a) Research, cooperation and activities noted in paragraph 9 above;
 - (b) Evidence of benefits and adverse effects of synthetic biology vis-à-vis the three objectives of the Convention;
 - (c) Experiences in conducting risk assessments of organisms, components and products of synthetic biology, including any challenges encountered, lessons learned and implications for risk assessment frameworks;
 - (d) Examples of risk management and other measures that have been put in place to avoid or minimize the potential adverse effects of organisms, components and products of synthetic biology, including experiences of safe use and best practices for the safe handling of organisms developed through synthetic biology;
 - (e) Regulations, policies and guidelines in place or under development which are directly relevant to synthetic biology;
 - (f) Knowledge, experience and perspectives of indigenous peoples and local communities in the context of living in harmony with nature for comparison and better understanding of the potential benefits and adverse effects of synthetic biology;
11. *Decides* to extend the mandate of the current Ad Hoc Technical Expert Group on Synthetic Biology in accordance with the

terms of reference annexed hereto and also to contribute to the completion of the assessment as requested in paragraph 2 of decision XII/24;

12. *Also decides* to extend the open-ended online forum to support the work of the Ad Hoc Technical Expert Group on Synthetic Biology, and invites Parties, other Governments, indigenous peoples and local communities and relevant organizations to continue nominating experts to take part in the open-ended online forum;
13. *Requests* the Subsidiary Body on Scientific, Technical and Technological Advice to review the recommendations of the Ad Hoc Technical Expert Group on Synthetic Biology and make further recommendation to the Conference of the Parties, including on the analysis using the criteria set out in paragraph 12 of decision IX/29;
14. *Requests* the Executive Secretary, subject to the availability of resources:
 - (a) Continue to facilitate moderated discussions under the open-ended online forum on synthetic biology through the Biosafety Clearing-House, and to continue to invite Parties, other Governments, indigenous peoples and local communities and relevant organizations to nominate experts to take part in the forum;
 - (b) To make the information received through paragraph 10 above available online;
 - (c) 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;
 - (d) To convene moderated online discussions under the open-ended online forum and, subject to the availability of funds, a face-to-face meeting of the Ad Hoc Technical Expert Group on Synthetic Biology 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;

- (e) To cooperate and establish synergies with other United Nations and international organizations whose mandates are relevant to synthetic biology;
 - (f) To promote the full and effective engagement of indigenous peoples and local communities in future activities relating to synthetic biology under the Convention;
 - (g) To facilitate, in collaboration with relevant research institutions and organizations, capacity-building and support to developing countries, in particular the least developed countries, small island developing States and countries with economies in transition, on undertaking the activities outlined in paragraph 9 above;
15. *Welcomes* the recommendation of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, in its decision BS-VII/12, on a coordinated approach on the issue of synthetic biology, taking into account that the provisions of the Protocol may also apply to living organisms resulting from synthetic biology, and *invites* the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety to take into account in its future deliberations relevant information resulting from the processes under the Convention.

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

1. Building on the previous work of the Online Forum and Ad Hoc Technical Expert Group, and drawing upon relevant information submitted by Parties, other Governments, relevant organizations and indigenous peoples and local communities through paragraph 10 above, as well as information made available through the online forum and by the Secretariat, the Ad Hoc Technical Expert Group on Synthetic Biology shall, in coordination with other bodies of the Convention and its Protocols:
 - (a) Review recent technological developments within the field of synthetic biology to assess if the developments could lead to impacts on biodiversity and the three objectives of the Convention, including unexpected and significant impacts;
 - (b) Identify any living organisms already developed or currently under research and development through techniques of synthetic biology which do not fall under the definition of living modified organisms under the Cartagena Protocol;
 - (c) Further analyse evidence of benefits and adverse effects of organisms, components and products of synthetic biology vis-à-vis the three objectives of the Convention, and gather information on risk management measures, safe use and best practices for safe handling of organisms, components and products of synthetic biology;
 - (d) In order to avoid or minimize any potential negative effects on the conservation and sustainable use of biodiversity, evaluate the availability of tools to detect and monitor the organisms, components and products of synthetic biology;
 - (e) Provide, for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice at a meeting held prior to the fourteenth meeting of the Conference of the Parties, recommendations on the basis of its deliberations to facilitate future discussions and actions on synthetic biology under the Convention, as well as an analysis against the criteria set out in paragraph 12 of decision IX/29 to contribute to the completion of the assessment requested in paragraph 2 of decision XII/24 by the Subsidiary Body on Scientific, Technical and Technological Advice;
2. Subject to the availability of funds, the Ad Hoc Technical Expert Group 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.