From: Tim Strabala <Tim.Strabala@epa.govt.nz>
Sent: Wednesday, 17 February 2021 8:31 pm
To: GALVIN, Liese (ENV)
Cc: PATERSON, Rosemary (ENV); Manda Safavi; 'Andy Morgan'
Subject: RE: CBD notifications: SBSTTA and SBI meeting dates and preparatory webinars
Attachments: SBSTTA24_Agenda_Item_5_Risk_Assessment_and_Risk_Management_of_LMOs-R1.docx

This attachment is withheld in full under S9(2)(g)(i), it is a draft document, the final version has been provided

Follow Up Flag: Follow up
Flag Status: Completed

Hi, Liese.

Attached is the revised version addressing the issue of specificity in the talking points. I've made the concomitant changes in the changes for submission to the secretariat, as well as in paragraph 6 of the draft decision, and Annex paragraph 1, subparagraph c.

Please let me know if there are any other issues.

Thanks, Tim

Tim Strabala, PhD
Principal Scientist, New Organisms

s9(2)(a)

From: GALVIN, Liese (ENV) [mailto:Liese.Galvin@mfat.govt.nz]
Sent: Tuesday, 19 January 2021 11:36 a.m.
To: Tim Strabala <Tim.Strabala@epa.govt.nz>
Subject: RE: CBD notifications: SBSTTA and SBI meeting dates and preparatory webinars

[UNCLASSIFIED]

Hi Tim,

Many thanks for the draft RARM brief.

Rosie has now reviewed and tracked in one question around the need for guidance to be 'specific' – see attached. Any elaboration on that requirement would be appreciated.

I've also just included the text change proposals in a dedicated section so these can be easily handed over to the secretariat.

Many thanks,
Liese

From: Tim Strabala <Tim.Strabala@epa.govt.nz>
Sent: Monday, 18 January 2021 11:06 AM
To: GALVIN, Liese (ENV) <Liese.Galvin@mfat.govt.nz>
Subject: RE: CBD notifications: SBSTTA and SBI meeting dates and preparatory webinars

Thanks Liese. I'm hoping to get the SynBio brief to you within the next couple of days. I still have to run it past MfE, which I hope they can do quickly tomorrow.

While I'm thinking of such things, do you have any comments on the RARM brief, or are you and Rosie happy with it as it is?

Cheers, Tim

Out of scope

Following two pages removed as out of scope

From: Tim Strabala <Tim.Strabala@epa.govt.nz>
Sent: Wednesday, 17 February 2021 7:32 pm
To: PATERSON, Rosemary (ENV)
Cc: GALVIN, Liese (ENV); Manda Safavi; 'Andy Morgan'
Subject: Agenda Item 4 - SynBio brief
Attachments: SBSTTA24_Agenda_Item_4_SynBio_Brief.docx

This attachment is withheld in full under S9(2)(g)(i), it is a draft document, the final version has been provided

Follow Up Flag: Follow up
Flag Status: Completed

Hi Rosie,

Please find attached the SynBio brief. I apologise it's taken so long. I timed the talking points, and I went 3:17. I can probably talk a little faster. It's a little unconventional looking, as I've left some comments in to point to some of the long-running technologies that are now being included as part of Synthetic Biology to refer back to in any future discussion.

Andy, I apologise for the short notice, but if you have any comment, I'll need it tomorrow before COB.

Thanks all, Tim

Tim Strabala, PhD
Principal Scientist, New Organisms

s9(2)(a)

From: Tim Strabala <Tim.Strabala@epa.govt.nz>
Sent: Tuesday, 8 December 2020 5:28 pm
To: GALVIN, Liese (ENV); PATERSON, Rosemary (ENV)
Cc: Andy Morgan; Mariska Wouters (Mariska.Wouters@mfe.govt.nz); Manda Safavi
Subject: SBSTTA24_Agenda_Item_5_RARM_Brief.docx
Attachments: SBSTTA24_Agenda_Item_5_RARM_Brief_DRAFT_to_MFAT.docx

Follow Up Flag: Follow up
Flag Status: Completed

This attachment is withheld in full under S9(2)(g)(i), it is a draft document, the final version has been provided

Hi all,

Please find attached the RA/RM brief for SBSTTA-24. Liese, I apologise that I'm running late with these things, but I'm trying to get them finished up as quickly as I can, with an prioritisation of SBSTTA documents. Synthetic Biology is next, I believe. Liese & Rosie, please let me know of any changes that you think are needed.

Happy reading!

Tim
Tim Strabala, PhD
Principal Scientist
Regulatory Systems and Operations
New Organisms Applications

s9(2)(a)

From: Tim Strabala <Tim.Strabala@epa.govt.nz>
Sent: Monday, 24 May 2021 1:37 pm
To: GALVIN, Liese (ENV)
Cc: PATERSON, Rosemary (ENV); Manda Safavi
Subject: SBSTTA24_Agenda_Item_4_SynBio_Brief_DRAFT_V4.docx
Attachments: SBSTTA24_Agenda_Item_4_SynBio_Brief_DRAFT_V4.docx

Follow Up Flag: Follow up
Flag Status: Completed

This attachment is withheld in full under S9(2)(g)(i), it is a draft document, the final version has been provided

Hi Liese,

Here is the SynBio brief (not too late for CG). I don't think there are any changes to the RARM brief that Rosie called final a couple of months back, but I'll double check in the context of the informal interventions.

Cheers, Tim

From: Tim Strabala <Tim.Strabala@epa.govt.nz>
Sent: Friday, 19 February 2021 3:06 am
To: PATERSON, Rosemary (ENV); GALVIN, Liese (ENV); Adam van Opzeeland; Manda Safavi; 'Maya Hunt (mhunt@doc.govt.nz)'; Helen Sharpe
Cc: Andy Morgan (Andy.Morgan@mfe.govt.nz)
Subject: SBSTTA24_Agenda_Item_4_SynBio_Brief_DRAFT_V2.docx
Attachments: SBSTTA24_Agenda_Item_4_SynBio_Brief_DRAFT_V2.docx

This attachment is withheld in full under S9(2)(g)(i), it is a draft document, the final version has been provided

Hi all,

Please find attached the current draft brief for Synthetic Biology for your reference. It's a 21 page beast, and as Rosie alluded to, the current bane of my existence.

Cheers, Tim

Tim Strabala, PhD
Principal Scientist, New Organisms
s9(2)(a)

CONVENTION ON BIOLOGICAL DIVERSITY

Informal 24th Meeting of the Subsidiary Body on Scientific, Technical, and Technological Advice (SBSTTA-24)

18-20, 25-27 February 2021

New Zealand Delegation Brief

POLI-58-969

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Out of scope

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Out of scope

Following 27 pages removed as out of scope

4 Synthetic biology

Agenda item 4 – Synthetic Biology

Relevant documents

CBD/SBSTTA/24/4/Rev.1
CBD/SYNBIO/AHTEG/2019/1/INF/2
XII/24
14/19
CBD/SBSTTA/REC/23/7
VIII/10, Annex III, section H28
CBD/SYNBIO/AHTEG/2019/1/2
CBD/SYNBIO/AHTEG/2019/1/3
XIII/17
CBD/SBSTTA/22/INF/17
IX/29 (new and emerging issue criteria)
14/33 (conflicts of interest annex)

Issue

In decision 14/19, Parties agreed that "broad and regular horizon scanning, monitoring and assessing of the most recent technological developments is needed for reviewing new information regarding the potential positive and potential negative impacts of synthetic biology vis-à-vis the three objectives of the Convention and those of the Cartagena Protocol and Nagoya Protocol." To enable this, they authorised a continuation of the AHTEG on Synthetic Biology, under its existing terms of reference albeit with new membership. Parties also decided to continue the open-ended online forum on synthetic biology, to allow the submission of information from various sources to support the AHTEG.

The AHTEG's mandate included:

a) the completion of the analysis requested in decision XII/24, paragraph 2 (synthetic biology as a new and emerging issue as assessed against the criteria laid out in decision IX/29, paragraph 12), and reiterated in decision XIII/17, paragraph 13;

b) taking stock on new technological developments in synthetic biology since its last meeting, including genome editing as it pertains to synthetic biology;

c) undertaking a review of the current state of knowledge on the potential positive and negative impacts of synthetic biology (including organisms with engineered gene drives) on the environment;

d) consideration of whether any living organism developed through synthetic biology falls outside the definition of "Living Modified Organism" in the Cartagena Protocol;

e) compilation and analysis of information including peer-reviewed published literature to prepare a "forward looking report" on synthetic biology applications in the early stages of research and development;

f) recommendation of options for regular horizon scanning and assessment of developments as described in decision 14/19 paragraph 3;

28 AHTEG meetings under the Modus operandi of operations of the SBSTTA.

g) preparation of a report on the outcomes of its work for consideration by the SBSTTA prior to COP15.

The Secretariat was also requested to carry out a range of activities in support of the AHTEG, including the convening of the Open-Ended Online Forum on Synthetic Biology, and the generation of a report (CBD/SYNBIO/AHTEG/2019/1/INF/2) for consideration by the AHTEG.

The AHTEG produced a report (task g)), covering tasks a) through f) and made a number of recommendations, based on its findings. The SBSTTA is now being asked to consider the AHTEG's report, in addition to the Secretariat's Terms of Reference for the activities of a proposed "Multidisciplinary Technical Expert Group" and make a recommendation for a draft decision to be considered by Parties at COP15.

New Zealand objectives

- To support a reasonable and science-based approach to synthetic biology that is consistent with our existing domestic framework. To only support mechanisms, such as horizon scanning, "technology assessments" and reporting, that are non-duplicative and add value.
- To ensure a mechanism by which the horizon scanning and reporting function is subject to periodic review as to its relevance and usefulness, and thus to limit the duration of existence of the proposed new Multidisciplinary Technical Expert Group (MTEG), as is required of an AHTEG in section H of the consolidated modus operandi of the SBSTTA.
- To resist calls for certain activities as described in the AHTEG report (Annex I) to be considered as aspects of synthetic biology, particularly as new and emerging issues.
- To resist calls to have synthetic biology or open-air use of nucleic acids to be considered a 'new and emerging issue' under the Convention, consistent with CBD/SBSTTA/REC/23/7 to add no additional new and emerging issues for consideration by the COP.
- To encourage the consideration of some issues identified in the AHTEG's horizon scanning exercise to be more appropriately considered to be part of the definition of 'biotechnology' under the Convention, and therefore subject to its provisions of "aiding the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.", and concomitant considerations of its potential benefit to the environment, in addition to any risks.

Talking points

- Although it has a new name, the proposed Multidisciplinary Technical Expert Group is simply an AHTEG. This is alluded to in paragraph 2 of the draft decision,

in that the membership of the proposed multidisciplinary group is to be selected in accordance with section H of the consolidated modus operandi of the SBSTTA. Section H describes the establishment of Ad Hoc Technical Expert Groups. Indeed, the consolidated modus operandi of the SBSTTA only allows for the creation of AHTEGs. To ensure future clarity that the SBSTTA is recommending the creation of a new AHTEG, we suggest that the proposed multidisciplinary expert group be identified as a multidisciplinary AHTEG, if the multidisciplinary nature of the group must be emphasised. To accomplish this, we propose the insertion of the words "Ad Hoc" after "multidisciplinary" at all points in the draft decision, Annex II, and Table 1 of Annex II.

- Further to this point, Section H also states that ad hoc technical expert groups must be of limited duration. Thus, we suggest the addition of a new paragraph 5 to the draft Annex II, Part B, requiring the periodic review of the continuing need for the existence of the group.
- The operational definition of synthetic biology that was agreed in decision XIII/17 covers a very broad range of current and future trends and applications, including the use of organisms with engineered gene drives. As noted in decision 14/19, such organisms require case-by-case risk assessment. The same is true of the seven trends and 17 applications of synthetic biology identified by the AHTEG in its horizon-scanning exercise[29], with the note that the lists are not exhaustive. We note that many of the applications identified by the AHTEG have research histories dating back as far as the 1970s and 1980s[30].
- We disagree with the proposed move of commissioning technology assessments exercises and/or collaborative activities from step "c" to step "a", in Table 1 of Annex II, as explained in footnote 21 of CBD/SBSTTA/24/4/Rev.1. The initial commissioned technology assessment reports called for in the assessment step of the Multidisciplinary AHTEG's Terms of Reference appears to be unnecessarily duplicative to the responsibilities of the multidisciplinary AHTEG for technology assessment. If a commissioned technology report is required, it should only be authorised if the multidisciplinary AHTEG decides it lacks sufficient capacity and/or expertise to carry out the assessment itself, and requests such reports to be commissioned by the Secretariat. Therefore, we suggest the commissioning of technology assessments be moved to the "Assessment" section of Table 1 in Annex II, as was recommended by the AHTEG in the report of its outcomes[31].

Text changes proposed (for the Secretariat)

Uniformly replace the term "Multidisciplinary Technical Expert Group" with "Multidisciplinary *Ad Hoc* Technical Expert Group" in the draft decision, as well as in the Terms of Reference for the Group, and the table therein (Annex II). This text is found in the draft decision paragraphs 2, 5b, 5d, and 6, Annex II, Part B Header, and paragraphs 1, 2, 3, and 4. The text is also found at several points in Table 1 of Annex II, which I will list by column. In the "Coordinating actors" column, it is found in the first bullet point of row (c) Assessment, and in row (d) reporting outcomes in the first bullet point. In the

29 Annex I, paragraphs 5 and 12, respectively

30 Annex I, paragraphs 12(a)(ix); 12(b)(i, ii, iii), 12(c)(iii)

31 Annex I, paragraph 41(i)

"Other actors and considerations" column, it is found in the fourth and sixth bullet points of row (c) assessment.

NB: Given that text changes will not be acted upon from interventions at the informal meetings, I will finish this section at a later time.

Draft recommendation

The Subsidiary Body on Scientific, Technical and Technological Advice may wish to recommend that the Conference of the Parties at its fifteenth meeting adopt a decision along the following lines: *The Conference of the Parties,* *Recalling* decision 14/19, in which it agreed that broad and regular horizon scanning, monitoring and assessing of the most recent technological developments is needed for reviewing new information regarding the potential positive and potential negative impacts of synthetic biology vis-à-vis the three objectives of the Convention and those of the Cartagena Protocol on Biosafety and the Nagoya Protocol on Access and Benefit-sharing, *Welcoming* the outcomes of the meeting of the Ad Hoc Technical Expert Group on Synthetic Biology held in Montreal, Canada, from 4 to 7 June 2019,32	No comment
1. *Establishes* a process for broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology as set out in annex II, section A;	no comment.
2. *Establishes* the Multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology to support the process for broad and regular horizon scanning, monitoring and assessment in	no comment.

32 See annex I.

accordance with the terms of reference contained in annex II, section B;	
3. *Decides* that the trends in new technological developments in synthetic biology identified by the Ad Hoc Technical Expert Group on Synthetic Biology33 will inform the horizon scanning, monitoring and assessment for the next biennium;	Agree.
4. *Invites* Parties, other Governments, indigenous peoples and local communities, and relevant organizations to submit to the Executive Secretary information relevant to the trends to inform the horizon scanning, monitoring and assessment;	agree.
5. *Requests* the Executive Secretary, subject to the availability of resources:	
(a) To commission technology assessments on the trends identified and requested by the Ad Hoc Technical Expert Group on Synthetic Biology;	(a) to bring this work in line with the recommendation of the AHTEG report.
(b) To convene online discussions to support the work of the Multidisciplinary Ad Hoc Technical Expert Group as needed;	(b) agree.
(c) To synthesize the information submitted in response to paragraph 4 above as well as the information provided through the online discussions;	(c) no comment
(d) To convene at least one meeting of the Multidisciplinary Ad Hoc Technical Expert Group to consider the technology assessments and the synthesis of information referred to in subparagraphs (a) and (c) above, and to review the components, products and organisms being developed through the trends referred to in paragraph 3 above	(d) agree.

33 See annex I.

and consider their possible impacts on the objectives of the Convention;	
6. *Requests* the Subsidiary Body on Scientific, Technical and Technological Advice to consider the outcomes of the work of the Multidisciplinary Ad Hoc Technical Expert Group and make recommendations for the consideration of the Conference of the Parties at its sixteenth meeting and, as appropriate, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its eleventh meeting and the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol at its fifth meeting;	agree.
7. *Also requests* the Executive Secretary to continue pursuing cooperation with other organizations, conventions and initiatives, including academic and research institutions, on issues related to synthetic biology.	No comment.
8. The Subsidiary Body on Scientific, Technical and Technological Advice may also wish to recommend that the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol and the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol each take note of the decision of the Conference of the Parties on this matter.	agree.

Annex I

Outcomes of the meeting of the Ad Hoc Technical Expert Group on Synthetic Biology (Montreal, Canada, 4-7 June, 2019)

I. The AHTEG recognized that the different elements of its mandate were interrelated and that there may be some overlap in the discussions on these elements. It considered that new technological developments (addressed under its agenda item 3.1) was a broad topic while synthetic biology applications in early stages of research and developments (addressed under item 3.2) was more concrete. It also noted that the discussions under a number of items, particularly 3.1, 3.2 and 3.4, could inform

consideration of the process for broad and regular horizon scanning, monitoring and assessment[34] addressed under item 3.5.

2. The AHTEG recognized that the submissions of information and the online forum had provided important and useful information for its deliberations. It also recognized, however, that the online forum may have had limitations, for example, for those who come from an oral tradition of communication or whose mother tongue is not English.

3. The AHTEG also expressed its appreciation for the compilation of the bibliographic references (CBD/SYNBIO/AHTEG/2019/1/INF/3), which had served as a useful source of information. It agreed that it would be beneficial if the Secretariat continued to update this document as new research on synthetic biology was published.

I. New technological developments in synthetic biology

4. The AHTEG recalled the discussions on recent technological developments in the field of synthetic biology during its 2017 meeting, and noted that the outcomes of that discussion remain relevant.

5. The AHTEG noted that new technological developments could be grouped into trends that could inform a process for horizon scanning, monitoring and assessment. The Group identified a number of trends as follows, recognizing that this list is not exhaustive:

(a) Increased field testing of organisms, components and products derived from new developments in synthetic biology;

(b) Increased development of technologies that genetically modify organisms directly in the field;

(c) A shift to the development of synthetic biology for environmental, conservation, agricultural and health uses (some examples are provided in paragraph 12 below);

(d) Increasing sophistication of methods, including, for example, new genome editing techniques, more complex metabolic engineering, the recoding of genomes, and the use of artificial intelligence/machine learning for the redesign of biological systems;

(e) The use of transient modification of organisms, including, for example, through the use of synthetic double-stranded RNA molecules, nano-particles and genetically modified viruses;

(f) Ability to produce new synthetic biomolecules using non-canonical nucleotides and amino acids;

(g) The use of synthetic biology for non-biological purposes, for example in data storage.

6. It was noted that the technological developments mentioned within the various trends referred to above could be at different stages of progress and may be more advanced in some countries than in others.

7. The potential dual use nature of some advances in synthetic biology might raise biosecurity concerns in relation to the three objectives of the Convention.[35]

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[34] In decision 14/19, paragraph 3, the Conference of the Parties agreed "that broad and regular horizon scanning, monitoring and assessing of the most recent technological developments is needed for reviewing new information regarding the potential positive and potential negative impacts of synthetic biology vis-à-vis the three objectives of the Convention and those of the Cartagena Protocol and Nagoya Protocol". The phrase "horizon scanning, monitoring and assessment" is used in the text that follows to refer to this process.

[35] See also paragraph 19 of the 2017 AHTEG report (CBD/SYNBIO/AHTEG/2017/1/3).

8. In taking stock of new technological developments in synthetic biology, the AHTEG acknowledged the importance of considering the speed of development, geographic spread and availability and accessibility of tools and expertise. These factors may, among other things, pose challenges to the capacity to conduct risk assessment and the ability to understand the full range of possible impacts.

II. Synthetic biology applications that are in early stages of research and development, vis-à-vis the three objectives of the Convention

9. The AHTEG recognized that synthetic biology applications are at different stages of research and development and that, therefore, their relation to the objectives of the Convention should not be generalized.

10. The AHTEG recalled that, in decision 14/19, paragraph 5, the Conference of the Parties had recognized that synthetic biology applications could pose challenges to the ability of some countries, especially developing countries which might lack the necessary capacity, to assess the potential impacts in relation to the three objectives of the Convention. Such applications could, for example, have cultural and socioeconomic impacts over a large geographic area and in locations far from the place of use.

11. It was noted that indigenous peoples and local communities could have different perspectives, different ways of perceiving potential impacts and be impacted differently by synthetic biology applications in relation to the objectives of the Convention, since, for indigenous peoples and local communities, natural elements are living entities. It was recalled that the free, prior informed consent of potentially affected indigenous peoples and local communities should be sought or obtained.

12. Recognizing the similarities between this topic and the discussion on new technological developments in synthetic biology (see section I above), the AHTEG identified the following as examples of specific synthetic biology applications, chosen primarily from those that are in early stages of research and development (R and D), that may be relevant to the three objectives of the Convention:

(a) Applications intended for use in the environment in managed and wild populations:

(a) Genetically engineered nitrogen-fixing bacteria and other genetically engineered bacteria/viruses for agriculture – some close to or at field trials;

(b) Genetically engineered bacteria for such environmental applications as bioremediation, biodegradation and biomining – various stages of R and D;

(c) Engineered gene drive system in mice for conservation purposes, control of vector-borne disease and agricultural pests, medical research – early laboratory R and D stage;

(d) Engineered gene drives in a few mosquito species for potential control of vector-borne diseases through either population collapse or to interrupt the ability to transmit disease – laboratory R and D stage;

(e) Engineered gene drive for an agricultural pest (spotted wing *Drosophila*) – laboratory R and D stage;

(f) Genetically engineered sorghum to produce a new synthetic protein to improve digestibility for food and feed – early field trial stage;

(g) Insect delivery of modified viruses for the modification of crops (horizontal environmental genetic alteration agents (HEGAAs)) for biodefense, agriculture – early laboratory R and D stage;

(h) Improving the resilience of wild animal and plant populations, for example the ability of genetically engineered corals to withstand stress – early laboratory R and D stage;

(i) Transient modification of agricultural plants through, for example RNAi spray (non-living biopesticide) – laboratory R and D stage;

(j) Cyanobacteria production platforms (i.e. engineered for the photosynthetic production of fuels and fine chemicals) in contained environmental facilities – laboratory R and D stage;

(b) Applications intended for use in the laboratory:

(a) Development of protocells and minimal cells for basic research – early stage laboratory research;

(b) Applications to produce non-native nucleotides and amino acids inside the cell (novel engineered synthetic pathways) for basic research and production of pharmaceuticals – early stage R and D;

(c) Development of synthetic virus-like assemblies for drug delivery and vaccine applications (synthetic nucleocapsids) for human health and perhaps animal health – early laboratory R and D stage;

(d) Re-creation of an extinct infectious horsepox virus from chemically synthesized DNA fragments, for the purpose of creating a smallpox vaccine. This demonstrated proof of concept of *de novo* synthesis of a complex virus (health implications, biosecurity concerns);

(c) Applications with intended use in both the environment and the laboratory:

(a) Genetically engineered bio-containment systems within the cell, primarily for use in the environment but also some laboratory applications – various stages of R and D;

(b) Biofoundries (i.e., highly automated service laboratories) that engineer microbes for a variety of purposes – biofoundries exist now, products in various stages of R and D and on the market;

(c) Genetically engineered plants to produce recombinant polyclonal antibodies against snake venom toxins – early laboratory R and D stage.

III. Synthetic biology organisms that may fall outside the definition of living modified organisms as per the Cartagena Protocol

13. The AHTEG noted that both legal and technical considerations inform the question of whether a synthetic biology organism falls within or outside the definition of "living modified organism" as per the Cartagena Protocol.

14. The AHTEG recalled the statement from its 2017 report whereby it had noted that "indigenous peoples and local communities regarded all components of Mother Nature as living entities."

15. The AHTEG discussed a number of examples that had been identified through the submissions and the online forum, of synthetic biology organisms that may fall outside the definition of "living modified organism" (see CBD/SYNBIO/AHTEG/2019/1/2, para. 17).

16. From these examples, it was acknowledged that both virus-like macromolecular assemblies and protocells were not living organisms.

17. Views differed on whether organisms whose genomes had been edited without the use of nucleic acids using only protein reagents introduced into the cell, for example

by ZFN/TALEN/MN applications, would fall under the definition of "living modified organism".

18. In addition, the AHTEG considered that it was unclear whether some transiently modified organisms fall within or outside the definition of "living modified organism".

19. In this light, the AHTEG recalled the related discussion reflected in its 2017 report in which the AHTEG concluded "that most living organisms already developed or currently under research and development through techniques of synthetic biology, including organisms containing engineered gene drives, fell under the definition of LMOs as per the Cartagena Protocol." The AHTEG agreed that this conclusion was still valid.

20. The AHTEG also noted, however, that, given the rapid developments in the field, it may be possible that synthetic biology organisms developed in the future could fall outside the definition of "living modified organism" in the Protocol. Were such a situation to arise, it was recognized that the relevant obligations in the Convention would continue to apply.

21. In discussing the use of terms in Article 3 of the Cartagena Protocol, the AHTEG considered how interpretations of these definitions are now being challenged by new technological developments. It was noted, however, that the Convention contains a definition of "biotechnology" which is broader than the definition of "modern biotechnology" in the Cartagena Protocol, and it was recognized that all Parties to the Convention have obligations with regard to biotechnology and living modified organisms and that the Conference of the Parties has adopted decisions with regard to organisms, components and products of synthetic biology.

22. The AHTEG agreed that it would be important to take a coordinated, complementary and non-duplicative approach on issues related to synthetic biology under the Convention and the Cartagena Protocol.

IV. The current state of knowledge by analysing, including but not limited to peer reviewed published literature, on the potential positive and negative environmental impacts of current and near future applications of synthetic biology, including those applications that involve organisms containing engineered gene drives, taking into account human health, cultural and socioeconomic impacts, especially with regard to the value of biodiversity to indigenous peoples and local communities

23. The AHTEG highlighted the challenges associated with addressing its mandate under point (c) of its terms of reference, noting that undertaking a review of the current state of knowledge is a complex task.

24. The AHTEG noted that the review of the current state of knowledge may provide valuable contributions towards a broad and regular horizon scanning, monitoring and assessment exercise.

25. It also noted that there were multiple factors highlighted in the terms of reference which may require a structured approach or framework in order to undertake this task in a proper way. A consideration of potential benefits and risks is useful but would not be sufficient; it would also be important to identify knowledge gaps in a broad perspective that would continue to be relevant in the future.

26. It was pointed out that multiple dimensions need to be considered when assessing the current state of knowledge, including environmental, human heath, cultural, socioeconomic and ethical dimensions as well as the implications for indigenous peoples and local communities. Likewise, the need to consider what kind of technology assessment tools should be used was highlighted as an important aspect that could inform a proper assessment of potential impacts.

27. The following current challenges were pointed out concerning the identification of potential gaps with respect to data and information as well as tools and instruments as a basis for compiling and assessing the state of knowledge:

(a) Information on the potential receiving environment and its interaction with some organisms, products and components of synthetic biology intended for release into the environment;

(b) Analytical tools to detect, identify and monitor some organisms, products and components of synthetic biology;

(c) Tools to complement risk assessment methods, e.g. regarding assessment of ethical, cultural and socioeconomic factors, including potential benefits, in addition to environmental and human health factors.

28. The AHTEG recalled its discussion on risk assessment and risk management during its 2017 meeting as reflected in section 3.5 of the report on that meeting and agreed that these considerations were still valid.

29. The AHTEG noted that more information for assessing potential impacts may become available in the future (e.g. during contained use experiments, field trials, at the time of release, by modelling), highlighting that the state of knowledge will be constantly evolving as new information becomes available.

30. The AHTEG also pointed out that experience from the risk assessment of LMOs as well as other fields, such as technology assessment and experience with and management of invasive alien species, could be a useful source of information to anticipate potential impacts. The usefulness of the Biosafety Clearing-House as a source of information was also highlighted.

31. The AHTEG noted that some applications of synthetic biology aimed at biodiversity conservation could raise a number of conceptual and legal issues with regard to the status of protected or threatened species, regulation of trade in wildlife products and the compatibility of these approaches with conservation and the cultural practices of indigenous peoples and local communities. These issues may warrant further consideration in cooperation with the appropriate bodies, e.g. CITES.

32. The AHTEG also noted that synthetic biology could raise more general issues regarding the nature of biological diversity.

33. The AHTEG recognized that the state of knowledge on potential impacts of current and near future applications of synthetic biology should consider that, for indigenous peoples and local communities, those applications that may impact their traditional knowledge, innovation, practices, livelihoods and use of land, resources and water should seek their free, prior and informed consent, and the assessment of those applications is usually undertaken in a participatory manner involving the whole community.

34. The AHTEG noted that the online forum and the submissions on synthetic biology raised a number of general considerations related to potential positive and negative impacts from current and near-future applications of synthetic biology, recognizing that these were similar to the points reflected in the 2015 meeting of the AHTEG. These considerations are summarized in CBD/SYNBIO/AHTEG/2019/INF/4, paragraph 3.

V. Options for regular horizon scanning, monitoring and assessment

35. The AHTEG recalled that the Conference of the Parties, in decision 14/19, paragraph 3, agreed that broad and regular horizon scanning, monitoring and assessment of the most recent technological developments was needed for reviewing new information regarding the potential positive and potential negative impacts of synthetic biology vis-à-vis the three objectives of the Convention and those of the

Cartagena Protocol and Nagoya Protocol, and had mandated the AHTEG to recommend options in this regard.

36. The AHTEG considered this agenda item in the light of the other agenda items which provided some relevant experience in reviewing information regarding the potential impacts of synthetic biology vis-à-vis the Convention and the protocols.

37. The AHTEG considered that the process for horizon scanning, monitoring and assessment requires the following steps:

(a) Information gathering;

(b) Compilation, organization and synthesis of information;

(c) Assessment;

(d) Reporting on outcomes.

38. The AHTEG suggested that:

(a) The steps of information gathering and of compiling, organizing and synthesizing of information, should be coordinated by the Secretariat;

(b) The steps of assessing the information and of reporting on outcomes should be undertaken primarily by a multidisciplinary technical expert group, and/or another assessment body. The Subsidiary Body on Scientific, Technical and Technological Advice may have a role in approving the main conclusions of the process;

(c) Other actors could be involved in the steps as further elaborated in paragraph 41 and the table in the appendix.

39. The outcomes of the process would be reviewed by the Subsidiary Body on Scientific, Technical and Technological Advice, and its conclusions and recommendations would be submitted to the Conference of the Parties and, where appropriate, the Parties to the Cartagena Protocol and/or the Parties to the Nagoya Protocol, for consideration. The outcomes of the assessment, related conclusions and recommendations of the Subsidiary Body on Scientific, Technical and Technological Advice, and related decisions of the Conference of the Parties and the Parties to the protocols, may also be used by other bodies under the Convention and the protocols (such as the compliance committees), may be communicated to relevant bodies in the United Nations system, may be used to inform decision-making by individual Parties and others, and may be used to support capacity-building.

40. The process, comprising the four steps, would be a periodic one, with each cycle occurring over an intersessional period (i.e. a biennium). The process would be kept under review by the Subsidiary Body on Scientific, Technical and Technological Advice and the Conference of the Parties with a periodic review of the effectiveness of the process.

41. The AHTEG also noted the following considerations:

(a) Possible mechanisms for the step of information gathering include: submissions of information through notifications, outreach to relevant institutions and intergovernmental organizations, online forums and other existing tools, such as national reports, and the clearing-house mechanism;

(b) Mechanisms for information gathering should seek inputs from a diverse range of actors, facilitate the engagement of indigenous peoples and local communities, among other major groups, and build on the work done by other processes (including relevant horizon scanning or technology assessment processes, such as those under United Nations bodies and processes);

(c) All of the information compiled and synthesized could be made available, including through the clearing-house mechanism;

(d) Some issues identified during one cycle may need to continue to be considered in subsequent cycles with a view to supporting ongoing monitoring of these issues;

(e) Consistency in the way the process is carried out would be important with a view to obtaining results that could be comparable over time;

(f) Expertise from a broad range of disciplines, as well as interdisciplinary and intercultural expertise, would be necessary, especially for the assessment step;

(g) The selection of experts for the multidisciplinary technical expert group, and/or another assessment body will be undertaken in accordance with the consolidated modus operandi of Subsidiary Body on Scientific, Technical and Technological Advice;

(h) The assessment step should employ tools and approaches to enable a participatory assessment process;

(i) The assessment step may be supported by, among other things, commissioning technology assessment exercises and/or collaborative activities with regional and national technology assessment platforms;

(j) Key actors in the horizon scanning, monitoring and assessment process, including consultants and members of any assessment body, should be subject to the procedure for avoiding or managing conflicts of interest set out in decision 14/33;

(k) Online mechanisms could support the various steps of the process, but face-to-face meetings would be necessary for the assessment step;

(l) External review of the draft outcomes of the process would be desirable to ensure their quality;

(m) Efforts would be needed to communicate the outputs effectively to a broad range of potential users, in a culturally appropriate format and in the official languages of the United Nations and, where possible, in local languages;

(n) The capacity, cost implications and effectiveness of the process, including the foregoing considerations, would need to be taken into account;

(o) Collaboration with other bodies in the United Nations system could be explored to support the horizon scanning, monitoring and assessment process;

(p) Efforts should be made to ensure the transparency of the process;

(q) Other bodies under the Convention and the protocols (e.g. the Informal Advisory Committee to the Clearing-House Mechanism, the Informal Advisory Committee on Biosafety Clearing-House) should contribute to various steps of the process and make use of the outcomes, as appropriate.

42. An overview of the options for the process is also presented in table 1 below[36].

VI. Relationship between synthetic biology and the criteria set out in decision IX/29, paragraph 12

43. The AHTEG deliberated extensively on how synthetic biology developments could be related to each of the criteria listed below as per decision IX/29.

[36] Table 1 below is a modified version of the appendix to the report of the AHTEG. The changes made are as follows: the title has been revised, the reference to the role of consultants in supporting the work of the Secretariat has been moved to the column on coordinating actors, the reference to commissioning technology assessments exercises and/or collaborative activities has been moved from step "c" to step "a" and the language of Multidisciplinary Technical Expert Group has been used throughout. The original version of the table can be found in the report of the AHTEG, CBD/SYNBIO/AHTEG/2019/1/3.

44. The AHTEG recognized the challenge in bringing the criteria into context, understanding the criteria and the lack of guidance as to how they should be applied. The AHTEG noted the difficulty in applying the criteria to a broad topic, such as synthetic biology. There were questions regarding the suitability and wording of the criteria for identifying new and emerging issues. Recalling its mandate,[37] the AHTEG noted that it would be for the Subsidiary Body on Scientific, Technical and Technological Advice and the Conference of the Parties to take its advice into account in considering whether synthetic biology should be a new and emerging issue.

Criterion (a)
Relevance of the issue to the implementation of the objectives of the Convention and its existing programmes of work

45. The AHTEG agreed that organisms, products and components developed through the use of synthetic biology were relevant to the implementation of the Convention and its programmes of work.

Criterion (b)
New evidence of unexpected and significant impacts on biodiversity

46. Experts had a range of perspectives regarding this criterion. There was an extensive discussion on the nature of evidence and what is considered evidence.

Criterion (c)
Urgency of addressing the issue/imminence of the risk caused by the issue to the effective implementation of the Convention as well as the magnitude of actual and potential impact on biodiversity

47. Experts had a range of perspectives regarding this criterion, including with respect to the imminence of possible release of organisms, components and products of synthetic biology. The interconnections between criteria (c), (d) and (e) were noted.

48. It was acknowledged that current regulatory mechanisms, including the Cartagena Protocol, already provide a framework for addressing the potential adverse effects of most organisms resulting from synthetic biology, including organisms that are likely to be produced by synthetic biology in the near future. On the other hand, some experts identified the lack of control strategies for engineered gene drives, including those with a greater potential for transboundary movement, as well as the lack of traceability and detectability methods for certain genome edited organisms and products thereof.

Criterion (d)
Actual geographic coverage and potential spread, including rate of spread, of the identified issue relating to the conservation and sustainable use of biodiversity

49. Views differed on the actual geographical coverage and potential spread, including the rate of spread, of organisms, components and products produced from synthetic biology. It was noted that some of the applications of synthetic biology, such as engineered gene drives, have not been released, and, thus, the actual geographical spread of these cannot be assessed. It was also noted that applications, such as gene drives or horizontal engineered genetic alteration agents, may have the potential for rapid spread over a wide geographical range.

50. It was noted that, for genome-edited organisms, the current lack of tools to detect these organisms could lead to them spreading more widely.

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37 Decision 14/19, annex, paragraph (a): "The Ad Hoc Technical Expert Group on Synthetic Biology shall provide advice on the relationship between synthetic biology and the criteria set out in decision IX/29, paragraph 12, in order to contribute to the completion of the assessment requested in decision XII/24, paragraph 2, building on the preliminary analysis prepared by the Executive Secretary in document CBD/SBSTTA/22/INF/17".

51. The continued expansion of access to the tools of synthetic biology was highlighted with regard to its potential to enable rapid spread and development of synthetic biology and its applications. Likewise, the increased accessibility of these tools could facilitate the release of organisms, components and products of synthetic biology by new actors (e.g. for example, do it yourself (DIY) practitioners and artists), which could pose challenges to the conservation and sustainable use of biodiversity.

Criterion (e)
Evidence of the absence or limited availability of tools to limit or mitigate the negative impacts of the identified issue on the conservation and sustainable use of biodiversity

52. Experts had a range of perspectives regarding this criterion.

53. It was acknowledged that current regulatory mechanisms, including the Cartagena Protocol, provide a framework for addressing the potential adverse effects of most organisms resulting from synthetic biology. However, some experts highlighted the lack of analytical tools for the detection, identification, and monitoring of some products and organisms of synthetic biology, and the lack of control measures as posing challenges for the mitigation of negative impacts. It was noted that the detectability of single nucleotide or small genomic changes could pose further challenges for some countries. Further, some noted that there is a lack of appropriate tools for performing risk assessment to address the specific challenges from some organisms, products and components of synthetic biology.

Criteria (f) and (g)
Magnitude of actual and potential impacts of the identified issue on human well-being

Magnitude of actual and potential impact of the identified issue on productive sectors and economic well-being as related to the conservation and sustainable use of biodiversity

54. The AHTEG considered criteria (f) and (g) together. Experts had a range of perspectives regarding these criteria.

55. Potential health impacts were noted with respect to the reduction in vector-borne diseases, the reduction of the cost of pharmaceuticals through the utilization of synthetic biology, and the production of new vaccines. Potential impacts were noted regarding the challenges of shifting land use, lack of informed consent for society and lack of free, prior informed consent for indigenous peoples and local communities, and economic losses for small farmers. However, it was noted that the magnitude of impacts of synthetic biology, positive or negative, cannot be predicted in a generalized manner and should be assessed on a case-by-case basis, taking into account a broad range of areas beyond an environmental context.

56. The AHTEG recalled that the issue of digital sequence information on genetic resources and fair and equitable benefit-sharing was initially identified during its 2015 meeting and is now being considered through the process set out in decision 14/20. It noted the relevance of the issue to synthetic biology and human and economic well-being.

Annex II

Broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology

A. Process for the horizon scanning, monitoring and assessment	
1. The process for broad and regular horizon scanning, monitoring and assessment consists of the following steps: (a) Information gathering; (b) Compilation, organization and synthesis of information; (c) Assessment; (d) Reporting on outcomes.	No comment.
2. For each step, the coordinating actors, other actors and main considerations for the process are as set out in table 1.	No comment.
3. The Subsidiary Body on Scientific, Technical and Technological Advice shall review the outcomes of the horizon scanning, monitoring and assessment and prepare conclusions and recommendations on technological developments in synthetic biology and their potential positive and negative impacts for the objectives of the Convention.	Support this, particularly for its language pertaining to "the *positive*...impacts for the objectives of the Convention.
4. The effectiveness of the process for broad and regular horizon scanning, monitoring and assessment of technological developments in synthetic biology shall be reviewed four years following its adoption.	Agree.
B. Terms of reference for the Multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology to support the process for broad and regular horizon scanning, monitoring and assessment	
1. The Multidisciplinary Ad Hoc Technical Expert Group shall: (a) Employing tools and approaches to	(a) ongoing concerns regarding the

enable a participatory assessment process, review and assess the information gathered through the process for broad and regular horizon scanning, monitoring and assessment described in Annex II, Part A, and, on this basis, consider technological developments in synthetic biology and their implications for the objectives of the Convention, both positive and negative; (b) Identify and distinguish between developments identified during one cycle that may or may not need to continue to be considered in subsequent cycles, as well as additional developments that may be considered priorities during the next intersessional period; (c) Prepare a report on the outcomes of its assessment to be presented to the Subsidiary Body on Scientific, Technical and Technological Advice; (d) Make recommendations to the Subsidiary Body on Scientific, Technical and Technological Advice on specific issues that may or may not require further consideration by the Conference of the Parties and/or the Parties to the Cartagena Protocol and the Parties to the Nagoya Protocol.	'starting point' definition of synthetic biology (XIII/17, paragraph 4), as a number of identified issues have quite long histories. The second text change here is meant to recognise that examination of the trends and techniques identified are being considered under the convention, not the Cartagena Protocol (if they don't meet its criteria), which only covers risk. (b) changes to connect item 1(b) to the Multidisciplinary AHTEG's activities described in 1(a), as well as edits to ensure pruning of the issues under consideration by the Multidisciplinary AHTEG (c) agree. (d) again, to attempt to ensure that the list of items under consideration by the Multidisciplinary AHTEG remains of a manageable size.
2. The Multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology will be constituted according to section H of the consolidated modus operandi of Subsidiary Body on Scientific, Technical and Technological Advice, including whenever possible, expertise from a broad range of disciplines, as well as interdisciplinary and intercultural expertise.	Agree, with particular attention to the limited duration of the group's existence (see suggested paragraph 5 below).
3. The procedure for avoiding or managing conflicts of interest in expert groups set out in the annex to decision 14/33 shall apply to the Multidisciplinary	Agree.

Ad Hoc Technical Expert Group.	
4. The Multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology will work through a combination of face to face meetings, held physically and/or online, supported, as needed by online discussions.	Agree.
5. The Mandate of the Multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology will be reviewed four years after its establishment, (and if necessary, biennially thereafter) by the Subsidiary Body on Scientific, Technical and Technological Advice, which will make a recommendation on the need for the group's continuation, subject to approval by the Conference of the Parties.	Propose this text to be added to ensure that the multidisciplinary AHTEG does not continue indefinitely, and/or unnecessarily.

Table 1. Process for broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology

Process and steps		Coordinating actors	Other actors and considerations
Horizon scanning, monitoring and assessment process	**(a) Information gathering**	• Secretariat, with the support of consultants as necessary	• Possible mechanisms include submissions of information through notifications; outreach to relevant institutions and intergovernmental organizations; online forums; and other existing tools, such as national reports, and the clearing-house mechanism. • Seek inputs from a diverse range of actors, facilitate engagement of indigenous peoples and local communities, among others, and build on the work done by other relevant horizon scanning or technology assessment processes. • Some issues identified during one cycle may need to continue to be considered in subsequent cycles, with consistency in the way the process is carried out with a view to obtaining results that could be comparable over time.
	(b) Compilation, organization and synthesis	• Secretariat, with the support of consultants as necessary	• The information compiled and synthesized will be made available, including through the clearing-house mechanism.

Process and steps		Coordinating actors	Other actors and considerations
	of information		
	(c) Assessment	• Multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology • Consultants commissioned by the Multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology • Subsidiary Body on Scientific, Technical and Technological Advice (approval of the main conclusions of the process)	• Expertise from a broad range of disciplines, as well as interdisciplinary and intercultural expertise necessary. • Face-to-face meetings with support of online mechanisms. • Employ tools and approaches to enable a participatory assessment process. • Selection of experts for the Multidisciplinary Ad Hoc Technical Expert Group will be undertaken in accordance with the consolidated modus operandi of the Subsidiary Body on Scientific, Technical and Technological Advice. • commissioned technology assessment reports and/or collaborative activities with regional and national technology assessment platforms; • Key actors in the horizon scanning, monitoring and assessment process, including consultants and members of the Multidisciplinary Ad Hoc Technical Expert Group, will be subject to the procedure for avoiding or managing conflicts of interest set out in decision 14/33.
	(d) Reporting on outcomes	• Multidisciplinary Ad Hoc Technical Expert Group reports to Subsidiary Body on Scientific, Technical and Technological Advice • Subsidiary Body on Scientific, Technical and Technological Advice reports to Conference of the Parties (and/or the meeting of the Parties to the Cartagena Protocol, the meeting of the Parties to the Nagoya Protocol)	• External review of the draft outcomes. • Communicate the outputs effectively to a broad range of potential users, in a culturally appropriate format and languages.
Use of outcomes in support of decision-making		• Subsidiary Body on Scientific, Technical and Technological	

Process and steps	Coordinating actors	Other actors and considerations
	Advice (review of outcomes, preparation of conclusions and recommendations) • Conference of the Parties and/or the meeting of the Parties to the Cartagena Protocol, the meeting of the Parties to the Nagoya Protocol (decision-making) • Parties and others, including other United Nations bodies	
Review of process and its effectiveness	• Conference of the Parties on basis of periodic review by Subsidiary Body on Scientific, Technical and Technological Advice	

Background

The operational definition of synthetic biology that was agreed in decision XIII/17 covers a very broad range of current and future trends and applications, including the use of organisms with engineered gene drives. As noted in decision 14/19, such organisms require case-by-case risk assessment. The same is true of the seven trends and 17 applications of synthetic biology identified by the AHTEG in its horizon-scanning exercise38, with the note that the lists are not exhaustive. We note that many of the applications identified by the AHTEG have research histories dating back as far as the 1970s and 1980s39. This demonstrates that "synthetic biology" as we have defined it is neither new, nor emerging, but simply a name given to cover long-standing activities that often now have engineering principles applied to them. Thus, we endorse SBSTTA23's recommendation "not to add to the agenda of the Subsidiary Body in the coming biennium a new and emerging issue".40

EPA February 2021

38 Annex I, paragraphs 5 and 12, respectively

39 Annex I, paragraphs 12(a)(ix); 12(b)(i, ii, iii), 12(c)(iii)

40 CBD/SBSTTA/REC/23/7, paragraph 3.

5 Risk assessment and risk management of living modified organisms

Agenda item 5 – Risk Assessment and Risk Management

Relevant documents

BS-VIII/12 CP-9/13
CP/RA/AHTEG/2020/1/5

Issue

In decision CP-9/13, Parties decided to establish a process for the identification and prioritization of specific issues regarding risk assessment of living modified organisms for consideration at COP-MOP10, with a view to as to whether or not the development of further guidance on the risk assessment of living modified (LM) fish and LM gene drive organisms is needed. To achieve this, Parties also decided to convene a new AHTEG on Risk Assessment to consider these two topics, as well as requesting the Secretariat to commission studies to assist the new AHTEG in informing the decision-making criteria of CP-9/13's Annex I, which sets out requirements that must be met before the development of new guidance may be considered.

Due to the COVID-19 pandemic, the AHTEG met virtually, using live sessions and an online forum from 30 March to 3 April 2020. As stated in the second annex below, the AHTEG evaluated LM fish and LM gene drive organisms against the criteria established in CP-9/13 (Annex I). The AHTEG concluded that the development of further guidance for LM fish was not required, but that the development of guidance on the risk assessment of LM gene drive organisms should be undertaken.

The AHTEG further recommended that no adjustment to its terms of reference as described in CP-9/13 Annex I was required, in accordance with paragraph (c)(ii) of its Terms of reference (CP-9/13 Annex II).

Based on these conclusions, the draft decision calls for the formation of a new AHTEG to develop guidance for the risk assessment of LM gene drive organisms. While it was recognised at COP-MOP9 that this recommendation was a fait accompli, it was useful to see the criteria applied to both LM gene drive organisms and LM fish, and to arrive at different conclusions on the two issues.

New Zealand position

New Zealand is supportive of the AHTEG's conclusions and recommendations on the whole, with some strong reservations regarding the resulting draft decision as prepared by the Secretariat. These are addressed in the Talking Points and in tracked changes in the text of the draft decision below.

New Zealand objectives

- To avoid a repetition of the eight-year process undertaken by the AHTEG established after COP-MOP4 (BS-IV/11) which failed to produce a Guidance document on LM mosquitos and LM trees that was considered acceptable by the Parties (BS-VIII/12). We consider that the development of risk assessment guidance on "gene drive organisms" has great potential to follow the same path, given the range of gene drive technologies, organisms that may be modified, and scenarios under which such organisms may be released.
- To support the conclusion of the AHTEG that additional guidance for the risk assessment of living modified fish is not required.
- To support the conclusion of the AHTEG for the development of guidance for the risk assessment of living modified gene drive organisms, provided that the guidance is ~~specific~~ pertinent to organisms currently under development, scientifically- and evidence-based, and supports case-by-case risk assessments.

Talking points

- New Zealand commends the substantial effort undertaken by the Risk Assessment AHTEG, notes its report and endorses its conclusion that the development of further guidance for living modified fish is not required at this time. Further, New Zealand supports the AHTEG's conclusion that the development of guidance regarding living modified gene drive organisms is warranted, with certain reservations.
- Recalling that both decisions 14/19 on synthetic biology and CP-9/13 on risk assessment of LMOs contain the statement "*...as there could be potential adverse effects arising from organisms containing engineered gene drives, before these organisms are considered for release into the environment, research and analysis are needed, and specific guidance may be useful, to support case-by-case risk assessment.*"[41] We are particularly concerned that the draft decision and Terms of Reference for the AHTEG, as written, do not account for the development of "specific guidance" to support "case by case" risk assessments of living modified gene drive organisms. It is New Zealand's view that the purpose of the new AHTEG described in paragraph 6 must be clarified to align it with the original intention of decisions 14/19 and CP-9/13 in this draft decision and its supporting annex.
- To this end, we propose textual changes to paragraphs 6 and 9 of the draft decision, as well as paragraph 1(c) of the annex to the decision, which we will submit in writing to the Secretariat, to account clearly for the intent of decisions 14/19 and CP-9/13 for guidance that supports case-by-case risk assessment.
- In addition to these changes, New Zealand suggests two minor changes to the text to correct a grammatical error and a possibly erroneous internal reference. Specifically:

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[41] Paragraphs 9 and 3, respectively.

- In paragraph 1, the phrase '*Recalling* of' should simply be '*Recalling*'.
- In paragraph 8(c), we note a reference to paragraph 5, which we believe should be a reference to paragraph 7.

- Finally, we note that the draft decision does not provide a mechanism by which Parties may submit information regarding their needs on issues of risk assessment. We propose changes to the text of paragraph 10 to enable the submission of identified needs to the Secretariat. We will submit this suggested change to the text to the Secretariat in writing.

Text changes proposed (for the Secretariat)

Preamble to recommendation: *Recalling* decision CP-9/13, paragraph 7, in which it decided to consider, at its tenth meeting, whether additional guidance materials on risk assessment are needed for (a) living modified organisms containing engineered gene drives, and (b) living modified fish,
6. *Decides* to establish an Ad Hoc Technical Expert Group on Risk Assessment to develop guidance materials that are pertinent to organisms currently under development, that are scientifically- and evidence-based, and which support case-by-case risk assessment of living modified organisms containing engineered gene drives, as described in decisions 14/19 and CP-9/13 and in accordance with the terms of reference annexed hereto;

9. *Requests* the Subsidiary Body on Scientific, Technical and Technological Advice to consider the outcomes of the Ad Hoc Technical Expert Group on Risk Assessment in the context of paragraph 3 of decision 14/19 and paragraph 9 of decision CP-9/13, and make a recommendation for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its eleventh meeting;

10. *Invites* Parties to submit to the Executive Secretary, including through their national reports,42 additional issues on which guidance materials on risk assessment may be needed, further to the process for the identification and prioritization of specific issues of risk assessment of living modified organisms established in decision CP-9/13, and *decides* to consider them, at its eleventh meeting.

Annex to draft decision: 1(c). Develop guidance that is pertinent to organisms currently under development, is scientifically- and evidence-based, and supports case-by-case risk assessments of living modified organisms containing engineered gene drives in accordance with decisions 14/19, CP-9/13, and annex III of the Protocol;

Draft recommendation (if there is one)

57. Further to the request of the Conference of the Parties serving as the meeting of the Parties to the Protocol in decision CP-9/13, paragraph 12, and in the light of the outcomes of the	No comment.

42 A synthesis of relevant information provided in the fourth national reports is available as CBD/CP/--

discussions of the AHTEG, the Subsidiary Body on Scientific, Technical and Technological Advice may wish to recommend that the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, at its tenth meeting, adopt a decision along the following lines:	
The Conference of the Parties serving as the meeting to the Parties to the Cartagena Protocol on Biosafety, *Recalling* decision CP-9/13, paragraph 7, in which it decided to consider, at its tenth meeting, whether additional guidance materials on risk assessment are needed for (a) living modified organisms containing engineered gene drives, and (b) living modified fish,	'*Recalling* of' should simply be '*Recalling*'. See Talking Points.
1. *Welcomes* the outcomes of the discussions of the Ad Hoc Technical Expert Group on Risk Assessment;44	No comment.
2. *Takes note* of the clarifications made by the Ad Hoc Technical Expert Group to annex I of decision CP-9/13 regarding the process for identification and prioritization of specific issues of risk assessment of living modified organisms that may warrant consideration;45	No changes were recommended. No comment.
3. *Notes* the analysis done by the Ad Hoc Technical Expert Group on the topics of (a) living modified organisms containing engineering gene drives and (b) living modified fish according to decision CP-9/13, annex I;	Agree.
4. *Notes* the range of perspectives on the need for the development of guidance on risk assessment of living modified fish, and *decides* not to develop, at this stage, additional guidance materials on risk assessment regarding living modified fish;	Support. Oppose any call to ignore this recommendation and to add language to the draft decision for the development of guidance on LM fish. If this is unsuccessful, then our fallback position must be that any guidance developed must be pertinent to organisms currently under development, is scientifically- and evidence-based, and supports support case-by-case risk

44 CBD/CP/RA/AHTEG/2020/1/5.

45 See CBD/CP/RA/AHTEG/2020/1/5, annex I, sect. III.

	assessment, consistent with the intent of 14/19 and CP-9/13, as we are saying with gene drive organisms.
5. *Endorses* the recommendation of the Ad Hoc Technical Expert Group that guidance for the risk assessment on living modified organisms containing engineered gene drives should be developed;	Support any proposal to change to "*Takes note*", or "*Accepts*", because while we commend the effort of the AHTEG (see first Talking Point), we have reservations regarding the draft recommendation as written (see below).
6. *Decides* to establish an Ad Hoc Technical Expert Group on Risk Assessment to develop guidance materials that are pertinent to organisms currently under development, that are scientifically- and evidence-based, and which support case-by-case risk assessment of living modified organisms containing engineered gene drives, as described in decisions 14/19 and CP-9/13 and in accordance with the terms of reference annexed hereto;	Propose the changes at left, as tracked. These changes are necessary to bring the current decision in line with the intent of decisions 14/19 and CP-9/13.
7. *Invites* Parties, other Governments, indigenous peoples and local communities and relevant organizations to submit to the Executive Secretary information relevant to the work of the Ad Hoc Technical Expert Group, prior to its first meeting;	Agree.
8. *Requests* the Executive Secretary:	
(a) To convene online discussions of the Open-ended Online Forum on Risk Assessment and Risk Management to support the work of the Ad Hoc Technical Expert Group;	(a) Agree.
(b) To collect and synthesize relevant information to facilitate the work of the Online Forum and the Ad Hoc Technical Expert Group;	(b) Agree.
(c) To synthesize the views referred to in paragraph 5 above and the discussions in the Online Forum and make them available for the Ad Hoc Technical Expert Group;	(c) Agree, but it appears that the reference here should be to paragraph 7 above, rather than paragraph 5, as stated here. See Talking Points.
(d) To convene, subject to the availability of resources, two meetings of the Ad Hoc Technical Expert Group on Risk Assessment;	(d) Agree.

9. *Requests* the Subsidiary Body on Scientific, Technical and Technological Advice to consider the outcomes of the Ad Hoc Technical Expert Group on Risk Assessment in the context of paragraph 3 of decision 14/19 and paragraph 9 of decision CP-9/13, and make a recommendation for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its eleventh meeting;	Agree, with the addition of the tracked qualifying clause at left.
10. *Invites* Parties to submit to the Executive Secretary, including through their national reports,46 additional issues on which guidance materials on risk assessment may be needed, further to the process for the identification and prioritization of specific issues of risk assessment of living modified organisms established in decision CP-9/13, and *decides* to consider them, at its eleventh meeting.	The paragraph as written does not provide a mechanism for Parties to submit their needs on guidance issues, as Decision CP-9/13 refers specifically to issues identified in BS-VIII/12. Additionally, the phrasing of this paragraph is not ideal. It would be useful to limit the use of national reports to the 4th national reports, to prevent re-hashing of old arguments regarding the development of guidance (refer to LM trees and LM mosquitos which were the subjects of the last guidance development effort rejected by the Parties at COP-MOP8). We should support any intervention of this nature, although it isn't a red line issue for us, and we should focus on ensuring that the guidance is pertinent to organisms currently under development, is scientifically- and evidence-based, and which supports case-by-case risk assessments.

46 A synthesis of relevant information provided in the fourth national reports is available as CBD/CP/--

Annex (to the draft decision)

Terms of reference for the Ad Hoc Technical Expert Group on Risk Assessment

1. The Ad Hoc Technical Expert Group (Group) on Risk Assessment shall:	
(a) Be composed of experts selected in accordance with the consolidated modus operandi of the Subsidiary Body on Scientific, Technical and Technological Advice;	(a) Agree.
(b) Meet twice, subject to the availability of funds and prior to the eleventh meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, and perform necessary tasks between its two meetings;	(b) Agree.
(c) Develop guidance that is pertinent to organisms currently under development, is scientifically- and evidence-based, and supports case-by-case risk assessments of living modified organisms containing engineered gene drives in accordance with decisions 14/19, CP-9/13, and annex III of the Protocol;	(c) Suggest the changes at left. See Talking Points.
(d) Prepare a report, including draft guidance, for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice.	(d) Agree.
2. In undertaking its work, the Group shall consider the synthesis of views from the submissions and discussions in the online forum prepared by the Executive Secretary; existing resources identified in the stock-taking exercise of the "study on risk assessment: application of annex I of decision CP-9/13 to living modified organisms containing engineering gene drives";[48] and any other relevant information collected by the Executive Secretary further to paragraph 6(b) of decision CP-10/--.	Agree.

Annex (NB: this annex is also the annex of CP/RA/AHTEG/2020/1/5)

Outcomes of the meeting of the Ad Hoc Technical Expert Group on Risk Assessment

I. living modified fish

A. Review of the study and analysis according to annex I of decision CP-9/13

[48] CBD/CP/RA/AHTEG/2020/1/4.

58. The AHTEG agreed that the "Study on risk assessment: application of annex I of decision CP-9/13 to living modified fish" was a good basis from which to work in order to conduct its analysis. The AHTEG also identified that more information on the potential impacts of living modified fish on biodiversity would be useful to complement the research presented in the study. As part of the review of the study by the AHTEG, some specific points were raised concerning risk assessment of living modified fish and these points are included as part of the analysis below.

(a) They are identified by Parties as priorities, taking into account the challenges to risk assessment, particularly for developing country Parties and countries with economies in transition.

The AHTEG recognized that the issue of living modified fish has been identified by some Parties as a priority through various sources, including the submissions of information pursuant to decision CP-VIII/12, the online forum in 2018, the survey conducted as part of the study, and the fourth national reports on the implementation of the Cartagena Protocol on Biosafety.

The AHTEG acknowledged that different Parties may have different challenges for risk assessment of living modified fish and that these challenges may result in some Parties placing a higher priority on this topic. Further information on some of the challenges related to risk assessment of living modified fish are included in the analysis by the AHTEG under criterion (c) below.

(b) They fall within the scope and objective of the Cartagena Protocol on Biosafety.

The AHTEG considered that living modified fish fall within the scope and objective of the Cartagena Protocol on Biosafety.

(c) They pose challenges to existing risk assessment frameworks, guidance and methodologies, for example, if the issue at hand has been assessed with existing risk assessment frameworks but poses specific technical or methodological challenges that require further attention.

The AHTEG recognized that existing risk assessment methodologies would apply for living modified fish but noted that there are specific technical or methodological challenges that require further attention. These challenges may be due to:

(a) A lack of data or methods to collect data to inform the risk assessment process;
(b) Limited applicability of some risk assessment methodologies to living modified fish;
(c) Lack of tools to estimate consequences, likelihoods and uncertainty;
(d) Difficulties in establishing comparator baselines;
(e) Difficulties in relation to monitoring;
(f) Lack of experience or capacity;
(g) The specific nature of the biology of fish;
(h) The specific nature of the possible genetic modifications.

Recognizing the linkages between criteria (c) and (d), the AHTEG further described the challenges related to living modified fish, as further detailed under criterion (d) below.

(d) The challenges in addressing the specific issue are clearly described.

Regarding the specific challenges related to the risk assessment of living modified fish, the AHTEG discussed the following potential challenges:

(a) Related to fish biology:

(i) Insufficient knowledge on fish biology, genetics and ecology;
(ii) Fish mobility (for example, ability to swim vast distances), and therefore to enter different ecosystems;
(iii) Fish have the potential to be invasive and to hybridize with wildtype populations;
(iv) Fish demonstrate diverse morphological, genetic, physiological, and behavioural adaptations to highly variable aquatic environments;

(b) Related to genetic modification:

(i) Introduced genetic modification (for example, enhanced growth) may confer competitive advantages within the environment;
(ii) Uncertainties associated with next generation effects, including considerations of evolutionary dynamics;
(iii) Some transformations of fish can result in pleiotropic and secondary effects, which can have pronounced effects on the phenology and behaviour of fish.

(c) Related to data collection and availability:

(i) Challenges in simulating natural environments under experimental conditions;
(ii) Data on environmental behaviour (for example, interactions with different species), environmental factors which influence living modified fish reproduction and monitoring is very limited;
(iii) Knowledge on aquatic environments and genotype-environment interactions;
(iv) Difficulty in determining whether survival, migration, spawning, hybridization and introgression of living modified fish would occur under natural conditions and in different environments.

(d) Related to experience:

(i) Limited experience performing risk assessments of living modified fish;
(ii) The experience in undertaking risk assessment of living modified fish varies among countries;
(iii) Experience with risk assessment of living modified fish is limited to containment conditions.

(e) Related to risk assessment methodologies:

(i) Difficulties in establishing baselines;
(ii) Need for additional tools to estimate consequences and likelihoods of risks and uncertainty because of the complexity of the species and the receiving environment.

(f) Related to monitoring and risk management:

(i) Methods to monitor living modified fish in the environment.

Data on releases of non-modified, non-indigenous fish was noted as being available (for example, the United States Geological Survey's Non-Indigenous Aquatic Species Program). Similarly, it was suggested that data from non-modified fish species, such as invasive alien fish species, and lessons from commercial fish farming may be a source of experience that can inform potential environmental effects of living modified fish, without assuming an equivalence.

It was noted that while some tools exist to predict the survival and dissemination of fish species in the environment (for example, the Fish Invasiveness Screening Kit), it was also suggested that an agreed standard model for estimating dispersal and population dynamics would be useful.

Further, some AHTEG members noted that obtaining reliable data for risk assessment can be a challenge, but it does not necessarily mean a challenge to the risk assessment methodology itself.

(e) The specific issues concerning living modified organisms that:
(i) Have the potential to cause adverse effects on biodiversity, in particular those that are serious or irreversible, taking into account the urgent need to protect specific aspects of biodiversity, such as an endemic/rare species or a unique habitat or ecosystem, taking into account risks to human health and the value of biological diversity to indigenous peoples and local communities;
(ii) May be introduced into the environment either deliberately or accidentally;
(iii) Have the potential to disseminate across national borders;
(iv) Are already, or are likely to be, commercialized or in use somewhere in the world.

The AHTEG noted that the study's analysis of criterion (e)(i) contained relatively little information on potential impacts of living modified fish on biodiversity and additional information would be useful, while also noting the potential relevance of information in section 6.4 of the study. Building on the information in the study, experts identified potential adverse effects of living modified fish on biodiversity, for example, the potential for faster growing living modified salmon to out-compete naturally occurring smaller salmon.

Experts shared perspectives on the importance of many wild fish species to indigenous peoples and local communities and highlighted the importance of the relationship between indigenous peoples and local communities and biodiversity. It was suggested that there is a need to consider sociocultural impacts related to adverse effects on native fish populations resulting from a release of living modified fish, ensuring the full and effective participation of indigenous peoples and local communities.

It was recalled that no living modified fish have been developed for release into the environment and those living modified fish that have been released unintentionally, for example, ornamental fish, were not likely to survive in the environment. It was also suggested, however, that the important consideration was that living modified fish had been released into the environment, and whether or not these fish would persist was not relevant for this criterion.

The AHTEG agreed that living modified fish have the potential to disseminate across national borders.

The AHTEG recognized that several species of living modified ornamental fish as well as living modified Atlantic salmon have been commercialized.

B. Stocktaking of resources on similar issues

The AHTEG recognized that resources related to risk assessment of living modified fish do exist, including documents prepared by the European Food Safety Authority and the Organisation for Economic Co-operation and Development and in the context of the Cartagena Protocol on Biosafety as well as resources on risk assessment of living modified animals in general. For some experts, these documents were sufficient for risk assessment of living modified fish, noting that additional guidance would not be able to address challenges related to the lack of data. Other experts were of the view that specific considerations related, for example, to prolonged exposure or next generation

effects, were missing from these documents and, so, more detailed guidance was needed. It was also suggested that most existing resources are for animals in general and guidance focused on fish would be useful and better adapted to the specific challenges they posed.

The AHTEG also acknowledged the compilation of bibliographic references that had been prepared by the Secretariat as an information document for the meeting (CBD/CP/RA/AHTEG/2020/1/INF/3). It noted that the compilation would be revised and updated with additional references, including those provided by AHTEG members, and made available for the twenty-fourth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice.

C. Need for guidance to be developed on risk assessment of living modified fish

The AHTEG noted a range of perspectives on the need for the development of guidance on risk assessment of living modified fish.

Some experts were of the view that all the criteria in decision CP-9/13, annex I, had been met and that, accordingly, there was a clear need and rationale for guidance to be developed on this topic. It was suggested that there are specific issues and challenges related to risk assessment of living modified fish that would be well suited to guidance and also that the development of guidance would help to pool resources and experiences on risk assessment in this area.

Other experts recognized that there could be a need for guidance but were of the view that existing documents can help to address this need and accordingly, the development of guidance on risk assessment of living modified fish should not prioritized at the moment.

Some experts were of the view that not all the criteria were met and there was no need for the development of guidance on risk assessment of living modified fish. They suggested that the focus should be on capacity-building, sharing of experience as well as sharing of existing guidance materials, including in different languages. Experts suggested that given that approvals are for confined use and there are no indications that commercial fish species are being developed for environmental release to date, the development of guidance on risk assessment of living modified fish was not a priority.

One expert considered that she had insufficient information to reach a decision on the need for the development of guidance on living modified fish.

There were also some questions concerning what was meant by "guidance" in decision CP-9/13 and what types of guidance should be considered.

II. living modified organisms containing engineered gene drives

A. Review of the study and analysis according to annex I of decision CP-9/13

The AHTEG agreed that the "Study on risk assessment: application of annex I of decision CP-9/13 to living modified organisms containing engineered gene drives" was a good basis for its work, and it was noted that it provided a useful overview of the current status of engineered gene drive technologies and potential applications. The AHTEG noted that the scope of the study was engineered (or synthetic) gene drives of sexually reproducing organisms. It noted that some of the terms used in the study, such as "reversibility" and "population replacement drive", were not necessarily used in line with the understanding of some of the experts of the AHTEG. It was also recognized that there was additional information not covered by the study that could support the

AHTEG's deliberations. Specific points relevant to annex I of decision CP-9/13 that were raised during the review are included as part of the analysis below.

The importance of benefit analysis in relation to potential applications of living modified organisms containing engineered gene drives was noted in the context of decision-making.

(a) They are identified by Parties as priorities, taking into account the challenges to risk assessment, particularly for developing country Parties and countries with economies in transition.

The AHTEG noted that the issue of living modified organisms containing engineered gene drives has been identified as a priority by Parties through various sources, including the submissions of information in response to decision CP-VIII/12, the "Study on risk assessment: application of annex I of decision CP-9/13 to living modified organisms containing engineered gene drives", and fourth national reports on the implementation of the Cartagena Protocol on Biosafety. The cross-cutting nature of the issue of organisms containing engineering gene drives with other areas or work under the Convention on Biological Diversity (for example, synthetic biology) was also noted. The AHTEG further noted that developing countries could be the first ones to be confronted with the need to perform a risk assessment for organisms containing engineered gene drives, for example living modified mosquitos containing engineered gene drives. The importance of proper assessment of potential risk from the release of organisms containing engineered gene drives for indigenous peoples and local communities was also noted to ensure free, prior informed consent and full and effective participation.

Further information regarding the challenges related to risk assessment of living modified organisms containing engineered gene drives are included in the analysis of the AHTEG under criteria (c) and (d) below.

(b) They fall within the scope and objective of the Cartagena Protocol on Biosafety.

The AHTEG considered that LMOs containing engineered gene drives fall within the scope and objective of the Cartagena Protocol on Biosafety.

(c) They pose challenges to existing risk assessment frameworks, guidance and methodologies, for example, if the issue at hand has been assessed with existing risk assessment frameworks but poses specific technical or methodological challenges that require further attention.

The AHTEG recognized that, while existing risk assessment methodology may still be applicable for LMOs containing engineered gene drives, there are specific technical or methodological challenges that require further attention. These include: a lack of data to inform the risk assessment process; the limited applicability of some aspects of risk assessment methodologies to living modified organisms containing engineered gene drives, such as challenges to the comparative risk assessment framework and monitoring methods, lack of guidance on how to assess uncertainty, lack of validated modelling tools; and lack of experience or capacity.

The AHTEG also recognized that solutions to the challenges posed by LMOs with engineered gene drives will entail reconsideration of risk assessment and monitoring methods, as well as making more widely available the necessary expertise, training and resources required and the participation of indigenous peoples and local communities.

The AHTEG also noted that LMOs containing engineered gene drives have the potential to result in an irreversible impact on biodiversity at various scales up to the global level, and international cooperation may be required for risk assessment.

The AHTEG pointed out that no actual release of an LMO with engineered gene drives has been assessed to date.

Recognizing the linkages between criteria (c) and (d), the AHTEG further described the challenges related to living modified organisms containing engineering gene drives as detailed in criterion (d) below.

(d) The challenges in addressing the specific issue are clearly described.

Regarding the specific challenges related to the risk assessment of living modified organisms containing engineered gene drives, the AHTEG described the following challenges, recognizing that some of these challenges may relate to more than one of the categories below and may not relate to all types of drives:

(a) Related to the engineered gene drive system:

(i) Super-Mendelian inheritance, genetic and phenotypic stability, and persistence and invasiveness;

(ii) Difficulty in predicting all relevant genomic effects that could emerge in the next and subsequent generations, and from interactions with the receiving environments;

(iii) Controllability of engineered gene drive systems after release;

(iv) Evaluation of off-target changes and their consequences over time in different genetic backgrounds and their potential accumulation in populations;

(v) The potential for the engineered gene drive to evolve after release, including through unexpected genetic drift;

(b) Related to the target organism/species:

(i) Need for information on the potential genetic diversity of the target species;

(ii) Need for information on the functional role of the targeted species and potential interfertile species in the various ecosystems that may be encountered;

(iii) Consideration of the reproductive strategies, population dynamics and life cycle of the target organism;

(iv) Consideration of possible development of resistance in pathogens regarding vector control;

(c) Related to the receiving environment:

(i) Limited information on the potential interactions with natural receiving environments;

(ii) Limited information on long-term evolutionary processes occurring in these ecosystems;

(iii) Need for information on potential for cross-hybridization with non-target species;

(iv) Diversity of potential receiving environments;

(d) Related to risk assessment methodologies:

(i) Difficulties of applying the stepwise approach of environmental release;

(ii) Challenges to the comparative risk assessment framework;

(iii) Assessing and taking into consideration uncertainty;

(iv) Need to address the broader temporal and spatial scale;

(v) Higher dependency on model-based predictions (for example, to address the long temporal and wide spatial scale of some engineered gene drive applications and

to anticipate the range of scenarios for the possible evolution of the engineered gene drive in the environment);

(vi) Difficulty to comprehensively assess risks prior to release;

(vii) Difficulties in assessing next generation effects of organisms containing engineered gene drives;

(viii) Potential adverse effects may differ depending on the type of gene drive mechanism (for example, population suppression drives versus modification drives);

(ix) The need to develop knowledge and procedures for assessing the engineered gene-drive's long-term effects on ecosystems;

(e) Related to data collection and analysis:

(i) Additional information needed on the molecular characterization of both the engineered gene drive mechanism and the engineered gene drive-bearing organism;

(ii) Information to predict off-target effects and potential consequences in the target organism;

(iii) Lack of environmental and ecological data;

(iv) Difficulties with obtaining data for relevant modelling;

(v) Difficulties with validation and calibration of modelling data before the occurrence of an environmental release;

(f) Related to risk management and monitoring:

(i) Post-release environmental monitoring is challenging;

(ii) Evaluation of impacts over long periods of time;

(iii) Need for monitoring plans at supranational level to follow the spread of the engineered gene drive;

(iv) Proven strategies for controlling the spread of an engineered gene drive, should monitoring data show that it has some negative impact on health or the environment;

(v) Unavailability of management plans for possible reversion.

(e) The specific issues concerning living modified organisms that:

(i) Have the potential to cause adverse effects on biodiversity, in particular those that are serious or irreversible, taking into account the urgent need to protect specific aspects of biodiversity, such as an endemic/rare species or a unique habitat or ecosystem, taking into account risks to human health and the value of biological diversity to indigenous peoples and local communities;

(ii) May be introduced into the environment either deliberately or accidentally;

(iii) Have the potential to disseminate across national borders;

(iv) Are already, or are likely to be, commercialized or in use somewhere in the world.

The AHTEG recognized the need for information on potential impacts of living modified organisms containing engineered gene drives on biodiversity and noted that the study's analysis of criterion (e)(i) contained relatively little such information. For example, the AHTEG suggested that effects on biodiversity and ecosystems should not be limited to keystone species, valued species or ecosystem services as currently reflected in the study but, rather, examined in a more comprehensive manner. Notwithstanding this, the experts acknowledged the potential for living modified organisms containing engineered

gene drives to cause adverse, and in some cases irreversible, effects on biodiversity. It was further suggested that the potentially global spread of living modified organisms containing engineered gene drives could then impact endemic/rare species or a unique habitat or ecosystems. It was also suggested that LMOs containing engineered gene drives could adversely affect disease transmission.

Experts noted the perspectives of indigenous peoples and local communities, and the particular importance of nature and biodiversity for them. It was recognized that more information was needed to better understand the potential implications of the release of organisms containing engineered gene drives for indigenous peoples and local communities. In particular, when the broad spread of an LMO with an engineered gene drive is likely, it would be challenging for instance, to obtain the free, prior and informed consent of indigenous peoples and local communities and their full and effective participation, although it was also noted that this was a necessary step.

Regarding criterion (e)(ii), the AHTEG noted that living modified organisms containing engineered gene drives could be introduced into the environment, either accidentally or deliberately.

Concerning criterion (e)(iii), the AHTEG agreed that living modified organisms containing engineered gene drives have the potential to disseminate across national borders.

Regarding criterion (e)(iv), the AHTEG noted that living modified organisms containing engineered gene drives were likely to be utilized and/or released in the near future.

B. Stocktaking of resources on similar issues

The AHTEG concluded that resources related to risk assessment of living modified organisms containing engineered gene drives do exist and could be useful for the purpose of undertaking risk assessments. However, it was acknowledged that the resources currently available are not applicable on a global level.

The AHTEG noted the compilation of bibliographic references that had been prepared by the Secretariat as an information document for the meeting (CBD/CP/RA/AHTEG/2020/1/INF/3) and that the compilation would be revised and updated with additional references, including those provided by AHTEG members, and made available for the twenty-fourth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice.

C. Need for guidance to be developed on risk assessment of living modified organisms containing engineered gene drives

Having undertaken the review of the study and performed an analysis of the topic of living modified organisms containing engineered gene drives against annex I of decision CP-9/13, the AHTEG recommended that guidance for the risk assessment on living modified organisms containing engineered gene drives should be developed, noting that all criteria have been fulfilled.

III. adjustments to annex I of decision CP-9/13

The AHTEG considered possible adjustments to annex I of decision CP-9/13, including taking into account its experience in applying it to the specific issues of living modified fish and living modified organisms containing engineered gene drives.

The AHTEG discussed the different elements in annex I. It noted that criteria (a) through (d) should be understood as mandatory criteria while criterion (e) was "for consideration".

The AHTEG discussed the relationship between criteria (c) and (d) and noted that criterion (d) was meant to gather information and further details to substantiate the challenges identified under criterion (c).

The AHTEG noted that criterion (e)(iv) was not limited to those living modified organisms that are already or are likely to be commercialized, as the criterion also referred to those that are already or are likely to be "in use".

It was recognized that the stock-taking exercise provided for in annex I would also include work undertaken by other international bodies.

The AHTEG did not recommend any adjustments to annex I.

IV. ANALYSIS ON NEEDS AND PRIORITIES FOR FURTHER GUIDANCE IDENTIFIED BY PARTIES IN RESPONSE TO DECISION CP-VIII/2

The AHTEG considered the various topics suggested by Parties in their submissions made in response to decision CP-VIII/12, summarized in document CBD/CP/RA/AHTEG/2020/1/2 and further elaborated in the SBSTTA/22/INF/11 and SBSTTA/22/INF/12 documents. In doing so, it was noted that the mandate of the AHTEG for this task had not been elaborated very clearly.

There were different views on whether some of the topics that were identified by Parties as priorities in response to decision CP-VIII/12 should be considered under the process for identification and prioritization of specific issues on risk assessment of living modified organisms.

The AHTEG also took note of the horizon scanning process proposed by the AHTEG on Synthetic Biology and additionally suggested that there could be potential synergies between the two AHTEGs.

Background

Guidance documents (Item 15)

The history of the development and use of guidance documents under the CP is fraught. An eight year process undertaken by an AHTEG established after COP-MOP4 (BS-IV/11) failed to produce a Guidance document that was considered acceptable by the Parties (BS-VIII/12). A major difficulty that many Parties identified with the voluntary guidance was that it identified a broad range of rather generic, and often highly improbable, risks in a way that did not allow the case-by-case risk assessment of LM trees or LM mosquitos on the merits of any specific characteristics of a given modification. The difficulty with the process led to the termination of the Risk Assessment AHTEG, and the removal of the guidance document it developed from the Secretariat's Biosafety Technical Series. The AHTEG's guidance document (generally referred to as "the voluntary guidance") is available to download from the BCH website, but in draft form only.

17 months later at SBSTTA-22, there was clear consensus amongst Parties that evaluation of the need for additional guidance materials would be done through an AHTEG process, supplemented with an online forum, rather than the online forum alone, as was favoured by New Zealand. Thus, at SBSTTA-22, Parties agreed on the process that was ratified at COP-MOP10 that provided criteria for the AHTEG to evaluate a stated

need for guidance. These criteria constitute Annex I of CP-9/13, and they must be fulfilled before the development of new guidance can be recommended.

It was also clear at SBSTTA-22 that little enough was known about gene drives and gene drive organisms that it would be impossible to prevent the inclusion of the development of guidance for such organisms in CP-9/13, despite the fact that any such guidance would likely be very high level, and probably not case-by-case, since gene drive organisms are still under development, and still years away from any potential release. It was clear even at SBSTTA that the outcome of any AHTEG evaluation would be to recommend the development of guidance.

This concern was accounted for in part by Parties in parallel statements regarding risk assessment of organisms resulting from Synthetic Biology in decision 14/19 as well as other LMOs in decision CP-9/13. This statement can be found in the Talking Points above, but essentially, the decisions note that any guidance developed under the auspices of the CBD should be "specific" and should also "support case-by-case risk assessment". This is to ensure that the fundamental principles of risk assessment can be taught to enable their application to specific LMOs, thereby strengthening capability amongst Parties who have identified a need for guidance.

The AHTEG that met earlier this year was the first to be convened since CP-9/13 was ratified. From a New Zealand perspective it was successful, in that the AHTEG evaluated LM fish against the criteria and decided that the development of further guidance was not warranted. As expected, the AHTEG recommended that guidance be developed for gene drive organisms. Our suggested changes to the draft decision are meant to ensure that the guidance developed remains aligned with the intent of decisions 14/19 and CP-9/13.

We note that there is a wide range of guidance for risk assessment of LMOs, and we consider the available guidance to be adequate to meet the needs of Parties that have expressed a need for guidance. However, the Secretariat has historically taken the view that the only guidance documents that are acceptable for use in maintaining compliance with the CP are those that only apply the criteria in Annex III of the CP. Annex III only allows for the assessment of risk, and not the benefit of the release of an LMO. This is inconsistent with New Zealand's national legislation (the HSNO Act) which allows for the assessment of the potential benefits of a GMO in decision making, in addition to its risks.

Thus, while New Zealand supports capability building for risk assessors, our view on guidance documents that are consistent with only Annex III of the CP and/or do not take into account case-by-case risk assessment can be described as guarded at best. While there is very little we can do about this, we can work to ensure that risk assessments are conducted in a scientifically rigorous way, on the merits of the specific LMO under assessment.

EPA/MfE, December 2020

The remainder of this document is removed as out of scope

SBSTTA Informal meeting – 18-19 February 2021

Agenda item: 4. Synthetic biology

New Zealand objectives:

- To support a reasonable and science-based approach to synthetic biology that is consistent with our existing domestic framework. To only support mechanisms, such as horizon scanning, "technology assessments" and reporting, that are non-duplicative and add value.
- To ensure a mechanism by which the horizon scanning and reporting function is subject to periodic review as to its relevance and usefulness, and thus to limit the duration of existence of the proposed new Multidisciplinary Technical Expert Group (MTEG), as is required of an AHTEG in section H of the consolidated modus operandi of the SBSTTA.
- To resist calls for certain activities as described in the AHTEG report (Annex I) to be considered as aspects of synthetic biology, particularly as new and emerging issues.
- To resist calls to have synthetic biology or open-air use of nucleic acids to be considered a 'new and emerging issue' under the Convention, consistent with CBD/SBSTTA/REC/23/7 to add no additional new and emerging issues for consideration by the COP.
- To encourage the consideration of some issues identified in the AHTEG's horizon scanning exercise to be more appropriately considered to be part of the definition of 'biotechnology' under the Convention, and therefore subject to its provisions of "aiding the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.", and concomitant considerations of its potential benefit to the environment, in addition to any risks.

Main points of discussion

- A number of delegations asked for clarification on the definition of SynBio.
- A number of delegations expressed that Synthetic Biology is not a 'New & Emerging' issue' including: s6(a) I agreed with the AHTEG's work and did not see necessity to reopen the issue after SBSTTA-23. s6(a) stated the "AHTEG conclusion, contained in the report CBD/SYNBIO/AHTEG/2019/1/3, that states "most living organisms already developed or currently under research and development through techniques of synthetic biology, including organisms containing engineered gene drives", fall under the definition of LMOs as per the Cartagena Protocol". s6(a) also indicated that indirectly.
- Some parties and NGOs expressed the view that SynBio is a 'New & Emerging' issue including s6(a)
- Some other parties requested for clarification on whether or not SynBio is a 'New & Emerging' issue.
- Some parties and NGOs supported a precautionary approach for SynBio including s6(a)
- Some parties and NGOs supported a precautionary approach for gene drive organisms including s6(a)
- Many parties supported a formal 'horizon scanning' process.
- Some parties and NGOs supported the establishment of an MTEG on Synthetic Biology with the aim to support the process for a broad and regular horizon scanning.
- s6(a) expressed the view that gene drive organisms (GDOs) are LMOs.
- Some NGOs asked the CBD to declare a moratorium on any release of GDOs, including s6(a)

Table 1. Summaries of main points of discussions by the countries and NGOs

SynBio is a 'New & Emerging' issue
SynBio is not a 'New & Emerging' issue
GDOs are LMOs
Precautionary approach for GDOs
Precautionary approach for SynBio
Supporting establishing an MTEG
Clarification on MTEG's mandate
Supporting formal process for 'horizon scanning'
Moratorium on release of GDOs
Revisiting SynBio definition (more clarity on the definition)
Focusing on SynBio products, rather than techniques
Separating genetic engineering and SynBio
Concerns regarding 'Transient Modifications' eg RNAi sprays
Not supporting recommendations to not to release GDOs until further guidance is developed, or all questions are answered

s6(a)

Positions taken by other countries

- s6(a) appreciated the need to have robust processes in place for assessing new developments in modern biotechnology, including horizon scanning, monitoring and assessment of developments in Synthetic Biology. s6(a) notes the positive contribution that can be made by voluntary guidance in supporting Parties to establish robust and effective frameworks to manage the risks associated with modern biotechnology, including synthetic biology. s6(a) assessment remains that synthetic biology does not meet the seven new and emerging criteria.
    - *NZ agrees with* s6(a)
    - *NZ agrees that evaluating whether or not something is 'new and emerging', the seven criteria in paragraph 12 of Decision IX/29 (footnote one below) should be met. NZ agrees that SynBio does not meet those criteria*
- s6(a) strongly recommended that future discussions on new and emerging issues must be based on a strict and robust evaluation of the wording and suitability of the criteria set out in Decision IX/29, paragraph[1] 12 to refrain from setting precedents that could lead to uncertainty about the applicability of existing rules of procedures and that could require additional efforts and resources. Regarding the potential adverse effects of synthetic biology on the conservation of biodiversity, s6(a) views that risk assessment and risk monitoring for Living Modified Organisms (LMOs) provide a solid basis to face the challenges that may emerge in the future. s6(a) believes we should build on pre-existing efforts and take into account science-based evidence to improve existing frameworks. s6(a) expressed we would need to make sure that the best available methods and expertise are easily accessible for all Parties of the Convention to address the capacity gaps of developing countries.
    - *NZ agrees with* s6(a)

[1] Further decides that the following criteria should be used for identifying new and emerging issues related to the conservation and sustainable use of biodiversity:
(a) Relevance of the issue to the implementation of the objectives of the Convention and its existing programmes of work;
(b) New evidence of unexpected and significant impacts on biodiversity;
(c) Urgency of addressing the issue/imminence of the risk caused by the issue to the effective implementation of the Convention as well as the magnitude of actual and potential impact on biodiversity;
(d) Actual geographic coverage and potential spread, including rate of spread, of the identified issue relating to the conservation and sustainable use of biodiversity;
(e) Evidence of the absence or limited availability of tools to limit or mitigate the negative impacts of the identified issue on the conservation and sustainable use of biodiversity;
(f) Magnitude of actual and potential impact of the identified issue on human well-being;
(g) Magnitude of actual and potential impact of the identified issue on productive sectors and economic well-being as related to the conservation and sustainable use of biodiversity

- s6(a) agrees with the proposal to develop a primarily science-based process for horizon scanning, monitoring, and assessment to determine any impacts of organisms, components and products resulting from synthetic biology relevant to the objectives of the Convention and its Protocols. s6(a) believes a complete list of trends that will inform the horizon scanning, monitoring, and assessment process should be made available before resources are committed. s6(a) is generally supportive of the AHTEG's recommendation to establish an MTEG, however, seeks clarification on the scope, purpose, pros and cons, and timing of the MTEG as well as its outcomes review. s6(a) strongly supports the request to continue cooperating with others, including indigenous peoples. s6(a) view is that if the analysis against the new and emerging issue criteria is not concluded, it should be clearly indicated in subsequent CBD documents on synthetic biology that the process was not concluded and agreement has not been reached on whether or not synthetic biology is a new and emerging issue.
    - *NZ agrees with* s6(a) *that clarification on MTEG's mandate is needed*
- s6(a) supports a process for broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology. s6(a) believes that multidisciplinary expertise is needed for this process and is flexible with respect to the implementation of the steps in the horizon scanning process (i.e. information gathering, compilation, organisation and synthesis of the information, assessment of the information, reporting on the outcomes). s6(a) agrees to start with two rounds of horizon scanning during two consecutive intersessional periods.
    - s6(a) *regarding the need for a multidisciplinary expertise aligns with NZ's view on the need to review the ongoing need for the MAHTEG at COP17.*
- s6(a) Supports EU regarding a process for horizon scanning. s6(a) proposes to recall paragraphs 9 to 11 of Decision 14/9 and reinforce the precautionary approach with respect to engineered gene drives. With respect to evaluating synthetic biology against the criteria of new and emerging issues, s6(a) does not see the necessity to do further work beyond the Ad Hoc Technical Expert Group and SBSTTA-22 and is not in favour of reopening the discussion.
    - *NZ should watch taking the precautionary approach regarding gene drive organisms, as it should be consistent with that promulgated in the Rio Declaration of 1992.*
    - *NZ agrees with* s6(a) *that does not want the discussion regarding whether or not SynBio is a 'New & Emerging' issue to get re-opened. NZ agrees with SBSTTA23 and AHTEG work which said SynBio is not a new and emerging issue, and does not want the discussion re-open in SBSTTA24*

- s6(a) supported s6(a) statement, and had similar views on a process for horizon scanning, being flexible regarding the implementation of the steps in the horizon scanning process, and the need for a Multidisciplinary Ad Hoc Technical Group to contribute to the horizon scanning process.

- s6(a) supported the AHTEG conclusion, contained in the report CBD/SYNBIO/AHTEG/2019/1/3, that states "most living organisms already developed or currently under research and development through techniques of synthetic biology, including organisms containing engineered gene drives, fall under the definition of LMOs as per the Cartagena Protocol." s6(a) supported establishing a process for a broad and regular horizon scanning. In this regard, taking into account that synthetic biology is a tricky topic as it covers a wide range of techniques, scientific disciplines and fields of application, and evolves at a rapid pace, s6(a) considers useful a periodic evaluation on the effectiveness of the proposed process. s6(a) agrees to establish an MTEG on Synthetic Biology with the aim to support the process for a broad and regular horizon scanning, and suggests that it should be clarified that the modus operandi and the selection of the expert group should mirror the one of the AHTEG.

    - *NZ agrees that "most living organisms already developed or currently under research and development through techniques of synthetic biology, including organisms containing engineered gene drives, fall under the definition of LMOs as per the Cartagena Protocol." Which means SynBio is not a New & Emerging issue.*

    - *NZ agrees that MTEG should reflect AHTEG*

    - *NZ agrees if horizontal scanning processes are established, they need to be reviewed regularly to stay fit for purpose.*

- s6(a) had separate interventions but all very similar with these key points: emphasising to apply a precautionary approach with respect to organisms containing engineered gene drives. Supporting the establishment of an efficient horizon scanning process of the most recent technological developments in synthetic biology. Emphasizing themes for MTEG to establish the horizon scanning process. Expressing that the horizon scanning process needs to be clearly described and suitable to assess and identify the potential positive and potential negative impacts of synthetic biology vis-à-vis the three objectives of the Convention and those of its Protocols. Believing that two rounds of horizon scanning during two consecutive intersessional periods where the expert group meets once per intersessional period would be a good start.

    - *NZ should watch taking the precautionary approach regarding gene drive organisms, as it should be consistent with that promulgated in the Rio Declaration of 1992.*

- *NZ supports horizon scanning process (in the context of continuing capacity building) for the next 4 years, and would like to be reviewed in COP17.*

- s6(a) supported a formal process for 'horizon scanning'.s6(a) raised the issue of synthetic biology being classified as a "new and emerging issue", and does not see the need to maintain this position at this stage. s6(a) also does not support a process to review the criteria for new and emerging issues, as this will be a large process that requires a lot of work and would not necessarily be helpful at this point. s6(a) strongly emphasized the importance of thorough risk assessments and the importance of a precautionary approach with regards to Living Modified Organisms with gene drives. They believed that adapted guidance must be developed under the Cartagena Protocol.
  - *NZ agrees with* s6(a) *that SynBio should not be classified and 'New & Emerging' issue.* s6(a)
  - *NZ should watch* s6(a) *position regarding 'precautionary approach' for gene drive, organisms, as it should be consistent with that promulgated in the Rio Declaration of 1992.*
  - *NZ supports horizon scanning process (in the context of continuing capacity building) for the next 4 years, and would like to be reviewed in COP17.*

- s6(a) pleaded for the precautionary approach at any stages of use of products and components engineered through synthetic biology (research, development and release of organisms). In particular they strongly pleaded for precautionary approach for the development and release of organisms which contain engineered gene drives. They also expressed the view that when necessary, and on a case by case basis, releasing organisms containing engineered gene drive to the environment should be refrained from as long as risks and benefits cannot be correctly assessed.

  s6(a) stated that the organisms engineered through synthetic biology, and/or those that contain engineered gene drive, which are considered as LMO, shall fall under the Cartagena Protocol.

  s6(a) supported the establishment of a horizon scanning process as well as a MTEG and the proposed activities and processes to follow this issue over the long term.

  - *NZ does not agree with the precautionary approach either for SynBio or gene drive that is not consistent with the Rio Declaration definition*
  - *NZ agrees that any organism falls within LMO definition, shall fall under the Cartagena protocol (including gene drive organisms or the products of SynBio) but we support the horizon scanning on that process*

- s6(a) emphasized the importance of applying a precautionary approach when considering applications of synthetic biology. s6(a) supported the horizon scanning process. s6(a) expressed that the MTEG recommended by the AHTEG is the only possible option, and they would need clarification on its mandate, structure, and compositions as establishing it as proposed would set a precedent in the Convention. s6(a) prefers a well-circumscribed, light-touch and adaptable system and is ready to constructively consider alternatives.

  - *NZ does not agree with a precautionary approach for SynBio that is not consistent with the Rio Declaration definition*

- s6(a) emphasised applying a precautionary approach to the organisms developed by gene drive technology and intended for release into the environment, or which may be a subject of unintentional release have the potential to result in an irreversible impact on biodiversity.

  s6(a) welcomed the process for broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology, and the establishment of an MTEG.

  s6(a) urged cooperative work in the area of detection, identification and monitoring of organisms, components and products of synthetic, in particular, to identify potential organisms of synthetic biology for which current detection tools are not sufficient and to develop additional detection, identification and monitoring tools. s6(a) also reiterates a need for capacity building in the field of synthetic biology, including risk assessment, monitoring, control, detection and identification of such organisms.

  - *NZ should watch* s6(a) *position on the precautionary approach on gene drive organisms, as it should be consistent with that promulgated in the Rio Declaration of 1992.*
  - *NZ agrees with* s6(a) *in cooperative work in the area of detection and identification of LMOs, and capacity building*

- s6(a) expressed that GDOs are LMOs and as such are subject to case by case risk assessments under the Cartagena Protocol and other national and international regulatory frameworks.

  s6(a) that although an analysis of the criteria for identifying New and Emerging Issues was done by the AHTEG, SBSTTA has yet to make a decision on this issue.

  s6(a) last meeting the COP called upon Parties and other Governments to apply a precautionary approach, and to only consider introducing organisms containing engineered gene drives into the environment, including for experimental releases and research and development purposes, when: (a) Scientifically sound case-by-case risk assessments have been carried out; (b) Risk management measures are in place to avoid or minimize potential adverse effects, as appropriate;

  s6(a) they will not support a recommendation which contradicts the above, such as a recommendation that introducing organisms containing engineered gene drives into the environment must not take place until further guidance is developed or until all open questions, challenges and data requirements have been fulfilled.

  s6(a) case-by-case Risk Assessment

  s6(a) supported the establishment of an MTEG.

  - *NZ agrees with* s6(a) *how to use the precautionary approach*
  - *NZ supports* s6(a) *case-by-case Risk Assessment*
  - *NZ agrees with* s6(a) *GDOs are LMOs*
  - s6(a), s9(2)(g)(i)

- s6(a) supported the statement of s6(a) noted that in their legislation synthetic biology and genetic engineering are divided: genetic engineering produces LMOs, and implies nature-like technologies, whereas, synthetic biology provides for the design and creation of biological systems and objects with specified properties and functions that have no analogues in nature. Therefore, the main difference between synthetic biology and genetic engineering is that synthetic biology does not imply nature-like technologies.

- *NZ does not agree with the separation of genetic engineering and SynBio. NZ does not agree that SynBio has no analogue in nature. NZ does not agree that LMOs are only the products of genetic engineering since products of synthetic biology can fall within or outside the scope of LMOs. As the AHTEG noted "given the rapid developments in the field, it may be possible that synthetic biology organisms developed in the future could fall outside the definition of "living modified organism" in the Protocol. Were such a situation to arise, it was recognized that the relevant obligations in the Convention would continue to apply".*

s6(a) suggested to minimize environmental risks, synthetic biology products should be used only in containment, and not for release into the environment. s6(a) expressed that the development of synthetic biology can have threats to biodiversity, but also significant economic and geopolitical gains. s6(a) expressed that an important area of interaction with the AHTEG is to establish criteria to assess the risk of synthetic biological products leaving the containment.

- *NZ does not agree that to minimise environmental risks, synthetic biology products should be used only in containment, but calls for effective case-by-case risk assessment and risk management for any potential release. NZ does not support the AHTEG guidance on risk assessment as it is a voluntary guidance, and is not guidance for case-by-case risk assessment. NZ agrees that use of any technology (including SynBio) can pose risks as well as benefits, but the Cartagena protocol manages the risk of transferring of LMOs, and national legislations should manage the risk of development of LMOs, and any potential adverse effects of biodiversity*

s6(a) claimed that there is an increased invasive potential of biological agents and LMOs (living modified organisms) which is the consequence of using synthetic biology tools and methods, and this elevated invasive potential is a source of possible risks at the individual, local, regional and ecosystem level. Therefore, it is necessary to improve technologies and methods in synthetic biology area.

- *NZ does not agree that SynBio uniformly increases the invasive potential of LMOs (or any SynBio products) if is regulated. NZ evaluates the risk of LMOs on a case-by case basis and if the risk outweighs the benefit, would not approve it*

s6(a) stated that those countries which use synthetic biology tools and technologies, should ensure the maximum level of physical protection, and to introduce and maintain a unified national register of such activities.

- *NZ agrees that countries which develop LMOs need to have controls in place, but maximising the physical protection can be unnecessary and not-cost effective. Countries should try to follow the best practice, rather than maximising the physical protection.*

- s6(a) recognized beneficial potentials of synthetic biology but said that any utilization of synthetic biology should be in accordance with a precautionary approach, and the monitoring, assessment, and risk management should be based on particular species of concern, to minimize the impacts with related ecosystems and the environment. s6(a) expressed additional channels for information exchange for all matters related to LMOs between parties should be developed.
    - *NZ does not agree with taking the precautionary approach regarding SynBio organisms, as it should be consistent with that promulgated in the Rio Declaration of 1992.*
- s6(a) supported the horizon scanning and emphasized the need for adequate management of SynBio. s6(a expressed the need to improve the criteria on GDOs as a new and emerging issue.
- s6(a) highlighted the importance of a science-based discussions around synthetic biology, and expressed that the definition of SynBio is yet to be agreed by the parties. s6(a) considers that the determination of whether synthetic biology is or is not a "new & emerging issue" is carried out according to the analysis criteria established in decision COP IX 29[2]. s6(a) noted with concern that the discussion of this matter did not resolve in the AHTEG report. They said that no more expert groups should be formed, and the agreement on new and emerging should be made before further assessments.

  s6(a) expressed it is not clear what distinguishes MTEG from AHTEG except that the MTEG appears not to be time-bound, which is not ideal. They suggested that reviewing technologies in development should be done in SBSTTA, rather than a new AHTEG group.

  s6(a) touched on "the objective of distributing fairly and equitably the benefits derived from the utilization of genetic resources with countries of origin", "carrying out risk assessments of new biotechnological developments", and "the transfer of technology to developing countries so that they can conserve biodiversity and use the benefits of modern biotechnology[3]".

  s6(a) seeks further clarifications regarding the request that the Secretariat made on "technology assessments". Since there is a long history between the Parties in carrying out risk assessments on modern biotechnology. Such is the case in s6(a) where regulations are frequently updated based on the latest developments scientists, being appropriate to face these types of novel technologies.

  s6(a) supported the four steps.

- s6(a) expressed that much more clarity about the definition of SynBio is required. For example:
  - Sometimes synthetic biology is understood as a process and other times as a product
  - There is a lack of clarity regarding how much of the specimen's genome should be
  - artificially created to be considered Synthetic Biology
  - it must be clarified whether a synthetic organism, in order to be considered
  - as such, must be able to reproduce or not
  - would gene editing techniques be considered part of synthetic biology or not

  s6(a) supported the establishment of an MTEG on synthetic biology, but required clarity on its mandate. MTEG should develop a robust conceptual framework to be later adopted by the COP. MTEG must focus on the most recent advances in technology. Clarification is also needed on what constitutes a technical/technological advance.
  - *NZ agree with* s6(a *regarding the questions asked for clarity on SynBio. This is another call to revisit the definition. We should support it, but might be hard to get traction in this round.*
- s6(a) recommended a more coordinated approach between SynBio and RARM of LMOs.
  - *NZ supports this approach to the extent that it keeps the decision making between SynBio and RARM from going off in wildly different directions, and that RA should be science-based, and case-by-case.*
- s6(a) believes SynBio should not be a new and emerging issue. s6(a) requests the deletion of paragraphs one through six of the draft Recommendation, which recommends specific consideration of the treatment of synthetic biology. s6(a) would like to propose changing the "four years" in paragraph 4 of Annex II to "two years".
  - *NZ agrees with* s6(a) *that SynBio is not a new and emerging issue*

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[2] *The COP-13 decision refers to this, stating that the definition in the decision is "a good starting point".*

[3] *This refers to a sticking point between the Articles of the Convention (minimise risk of biotech to maximise its benefit) benefit vs those of the Cartagena Protocol (completely about RA, no mention of risk/benefit analysis in its operational articles). There is discussion of benefit in the prefatory paragraphs of the CP however. Because the SynBio decisions are being covered under the Convention, and not the CP, they are reminding us that the Convention allows benefit to be taken into account.*

- s6(a) expressed no new expert group is needed. They expressed with the lack of a time limit on the MTEG in the current draft. They expressed process should involve collecting, organising, & synthesising information for consideration directly by the SBSTTA. They said that currently there is no agreed definition on SynBio and expressed a waste of resources dedicated to this issue when we're already dealing with it in the LMO RARM space. s6(a) said the process should not continue until the new and emerging issue decision is resolved.[5]

- s6(a) welcomed the Expert group's reports, including the list of synthetic biology applications in the research and development stage. s6(a) said SynBio is a New & Emerging issue: s6(a) follows closely the development of new and emerging biotechnologies including synthetic biology as well as their risk management and control". s6(a) encourages multi-disciplinary discussions and exchanges to proactively identify and manage potential risks posed by synthetic biology to biodiversity conservation, while caring about the impact on human health.
    - *NZ does not agree with* s6(a) *regarding SynBio being classified as new and emerging*

[4] s6(a) appear to be well-aligned in their views that SynBio is not N&E, that they don't want to see the MTEG, and are wanting time limits on the MTEG if there is going to be one.
[5] There is no stopping moving ahead on the development of guidance for GDOs, but agree otherwise, and we must ensure we apply the RARM criteria to anything beyond this.

- s6(a) follows SynBio developments closely and supports the Convention decision. s6(a) expressed new expert groups are required to cover all aspects of SynBio, and need adequate time to conduct their research.

- s6(a) welcomed the draft recommendation presented, the solid scientific foundation of Technical Group work, case by case assessment, and the focus of the products of synthetic biology rather than the technique. s6(a) asked for clarity on 'trends in new technological advances in synthetic biology' in the draft recommendation to clarify what it is pursuing and what it will monitor and evaluate in the coming years.

  s6(a) suggested establishing technological surveillance methodologies to be considered as an option to be taken into account by the parties to evaluate the impacts of the use of synthetic biology. s6(a) suggested taking into account the inclusion in other applications of synthetic biology the environment (other than research and development), in particular the management and effective management of invasive alien species.

  s6(a) expressed that the group of experts must go beyond gathering information and opinions. They suggested requesting broader analyses based on scientific evidence and multidisciplinary work, made up of representatives from all regions.

  Regarding the precautionary principle, s6(a) recognized that synthetic biology could bring benefits for biodiversity, however, they said we must also make informed decisions based on the precautionary principle, in order to avoid negative impacts on biodiversity.

  They asked for clarity on whether or not SynBio should be a New & Emerging issue.

  - *By focusing on the product, rather than the technique, they presumably mean SynBio organisms, and not the products that they may make. This is an important distinction, because the current definition talks about non-living products of organisms, which is a clear overreach, as we have multiple conventions on hazardous substances.*

- s6(a) No notes and no intervention uploaded

- s6(a) emphasised the consideration of the precautionary principle to avoid the adverse effects that the possible releases of new developments derived from synthetic biology could have and incur irreversible damage to the environment and biodiversity. s6(a) suggested a joint mandate to the RARM AHTEG and the multidisciplinary group in Synthetic Biology to coordinate directly, including within the framework of the development of the guide for the evaluation of organisms with modifications corresponding to the gene drive technology. s6(a) emphasised on the communication and effective participation of indigenous peoples and local communities in decision-making processes related to developments derived from synthetic biology.

    - *NZ does not agree with* s6(a) *position on the precautionary principle for SynBio. While our legislation calls for a precautionary approach,* s6(a) *current position is more in line with a so-called "strong" precautionary approach, meaning that if there is any uncertainty whatsoever, then one should not proceed with the use of a technology. This is essentially the opposite of the precautionary approach as stated in the 1992 Rio Declaration, which says that the need for precaution regarding scientific uncertainty should not preclude the use of a technology for environmental benefit. It's also not consistent with the precautionary approach as laid out in s7 of the HSNO Act.*

    - *NZ should watch* s6(a) *suggestion regarding a joint RARM and AHTEG. It is in some ways similar to the identical on gene drives in the COP14 decisions on SynBio and RARM. It should be carefully watched to resist a consensus for a moratorium.*

    - *NZ should carefully watch* s6(a) *emphasis regarding IPLCs in decision-making and synergies with WHO and FAO as they might be relevant to the IPBES report on deforestation & bushmeat consumption being drivers for pandemics.*

- s6(a) called for the substantive matters related to digital sequence information (DSI) on genetic resources and fair and equitable benefit-sharing to be fully addressed through the process set out in decision 14/20. s6(a) supported the approach of grouping new technological developments into thematic trends that could inform a process for horizon scanning and assessment, while acknowledging that some identified technological trends may in themselves not be synthetic biology. s6(a) said that the proposed establishment of an MTEG on synthetic biology requires further reflection to avoid creating a process that would fail to deliver on its mandate. It is also equally important to reflect on whether the proposed mode of constituting the MTEG would deliver a result that ensures the right composition. s6(a) recognised the need to go beyond the current operational definition of synthetic biology and called for a mutually agreed and accepted definition for synthetic biology.s6(a) supported the call of the AHTEG for SBSTTA and COP to take into consideration its advice on whether synthetic biology should be classified as a new and emerging issue.
    - *NZ agrees with* s6(a) *on clarification on the proposed MTEG*
    - *NZ views revisiting the definition of synthetic biology as a positive development, although it is unlikely to gain any traction, at least in the COP15 cycle.*
    - *NZ does not support calling synthetic biology new and emerging*
    - s6(a), s9(2)(g)(i)

- s6(a) supported the s6(a) statement given by s6(a) supported decision XIII/17 on the need for experience sharing and capacity building in detection, identification, horizon scanning and monitoring of living modified organisms and products developed through synthetic biology including the need for development of guidance with clear methodologies for risk assessment of LMOs resulting from synthetic biology. s6(a) supported the need to look beyond the operational definition of Synthetic biology and call for clarify on what products of synthetic biology need to be regulated and those to be exempted if any, under the Cartagena Protocol on Biosafety.
    - *NZ thinks* s6(a) *may want to have guidance developed referring to GDOs*

Statements by non-Parties

None.

Positions taken by s9(2)(ba)(i)

- s9(2)(ba)(i) MTEG must include all 7 regions of IPLCs, indigenous women and youth. They appealed to the Secretariat to support the financial mechanisms/processes for that.

- s9(2)(ba)(i) SynBio is a New & Emerging issue for CBD. s9(2)(ba)(i) called for strong precautionary regulations regarding SynBio. They asked to declare an immediate global moratorium on any release of gene drive organisms into the environment. They also called on parties to insist that free and prior informed consent be obtained before any release of synthetic biology organisms, components or products that may impact traditional knowledge, practices, livelihoods and use of land, resources and water.

  s9(2)(ba)(i) strongly supported the establishment of an MTEG and stated that the MTEG should include expertise from women, indigenous people and local communities. They expressed the view that the MTEG should include precautionary technology assessments. They said the most recent AHTEG on Synthetic Biology flagged concerns about new transient modification biotechnologies, such as gene silencing RNAi sprays, and how they should be governed given their novel risks. s9(2)(ba)(i) urge parties to request work exploring both the risks and governance of transient modification and other emerging new biotechnologies.

  They expressed before any organisms, components and products of synthetic biology are approved for release into the environment or market, developers should be required to develop additional detection, identification and monitoring tools. Currently, these tools are inadequate and insufficient.

- s9(2)(ba)(i) SynBio is a new and emerging issue. A precautionary regulation regarding SynBio should be developed. A moratorium on the release of any gene drive organisms should be declared. The topic of 'transient modifications' need to be classified as new and emerging too.

- s9(2)(ba)(i) expressed the opinion that synthetic biology is clearly a new and emerging Issue for the CBD. Participatory technology assessment methodologies are key for the MTEG to adequately assess health, socioeconomic, cultural and ethical impacts. They said that the most recent AHTEG on Synthetic Biology flagged concerns that these new transient modification[6] biotechnologies may fall outside of the Cartagena Protocol. urged parties to request work by the CBD to explore both the risks and governance of these transient expression technologies. reiterated the need to apply extreme precaution on gene drive organisms and to re-emphasize the importance of free prior informed consent of potentially affected peoples. They called for an immediate global moratorium on the release of gene drive organisms into the environment, including experimental release. expressed FPIC must be obtained before releasing any synthetic biology organisms, components or products that may impact traditional knowledge, innovation, practices, livelihoods and use of natural resources. They said further work is needed on detection, identification and monitoring of organisms, components and products of synthetic biology, as current detection tools are not sufficient to identify those.

Information in above paragrapah withheld under S9(2)(ba)(i)

[6] This is primarily about RNA-based pesticides and the attempt to classify transient gene expression/suppression & epigenetic changes to be considered as genetic modification resulting in the creation of LMOs.

Positions taken by NZ

New Zealand: Spoken intervention for informal SBSTTA: Agenda item 4

Although it has a new name, the proposed Multidisciplinary Technical Expert Group is simply an AHTEG. This is alluded to in paragraph 2 of the draft decision, in that the membership of the proposed multidisciplinary group is to be selected in accordance with section H of the consolidated modus operandi of the SBSTTA. Section H describes the establishment of Ad Hoc Technical Expert Groups. Indeed, the consolidated modus operandi of the SBSTTA only allows for the creation of AHTEGs. To ensure future clarity that the SBSTTA is recommending the creation of a new AHTEG, we suggest that the proposed multidisciplinary expert group be identified as a multidisciplinary AHTEG, if the multidisciplinary nature of the group must be emphasised. To accomplish this, we propose the insertion of the words "Ad Hoc" after "multidisciplinary" at all points in the draft decision, Annex II, and Table 1 of Annex II.

Further to this point, Section H also states that ad hoc technical expert groups must be of limited duration. Thus, we suggest the addition of a new paragraph 5 to the draft Annex II, Part B, requiring the periodic review of the continuing need for the existence of the group.

We disagree with the proposed move of commissioning technology assessments exercises and/or collaborative activities from step "c" to step "a", in Table 1 of Annex II, as explained in footnote 21 of CBD/SBSTTA/24/4/Rev.1. The initial commissioned technology assessment reports called for in the assessment step of the Multidisciplinary AHTEG's Terms of Reference appears to be unnecessarily duplicative to the responsibilities of the multidisciplinary AHTEG for technology assessment. If a commissioned technology report is required, it should only be authorised if the multidisciplinary AHTEG decides it lacks sufficient capacity and/or expertise to carry out the assessment itself, and requests such reports to be commissioned by the Secretariat. Therefore, we suggest the commissioning of technology assessments be moved to the "Assessment" section of Table 1 in Annex II, as was recommended by the AHTEG in the report of its outcomes.

New Zealand: Written annex to intervention at informal SBSTTA: Agenda item 4

We agree with our earlier statement and do not propose any changes to the briefing

Next steps
N/A
Anything else of relevance
The operational definition of synthetic biology that was agreed in decision XIII/17 covers a very broad range of current and future trends and applications. As can be seen in the comments on the report of the AHTEG, there are many "trends" identified that are not new at all, and represent lines of research that have roots dating back to the 1980s, if not earlier. This was an issue that was identified as a difficulty with the definition at COP13. However, given the many other issues with Risk Assessment and Risk Management at that Conference, Parties agreed that the definition was "a useful starting point". However, there has been no effort made to revise it since COP13.
While New Zealand will not raise these issues in the informal SBSTTA sessions in relation to the proposal that Synthetic Biology should be considered as a "new and emerging" issue by Parties. However, this may be raised in formal sessions, so the following talking point is placed here, in case of need.

- The operational definition of synthetic biology that was agreed in decision XIII/17 covers a very broad range of current and future trends and applications, including the use of organisms with engineered gene drives. As noted in decision 14/19, such organisms require case-by-case risk assessment. The same is true of the seven trends and 17 applications of synthetic biology identified by the AHTEG in its horizon-scanning exercise[7], with the note that the lists are not exhaustive. We note that many of the applications identified by the AHTEG have research histories dating back as far as the 1970s and 1980s[8]. This demonstrates that "synthetic biology" as we have defined it is neither new, nor emerging, but simply a name given to cover long-standing activities that often now have engineering principles applied to them. Thus, we endorse SBSTTA23's recommendation "not to add to the agenda of the Subsidiary Body in the coming biennium a new and emerging issue".[9]

[7] Annex I, paragraphs 5 and 12, respectively
[8] Annex I, paragraphs 12(a)(ix); 12(b)(i, ii, iii), 12(c)(iii)
[9] CBD/SBSTTA/REC/23/7, paragraph 3.

SBSTTA Informal meeting – 20 and 25 February 2021

Agenda item: 5. Risk Assessment and Risk Management

New Zealand objectives:

- To avoid a repetition of the eight-year process undertaken by the AHTEG established after COP-MOP4 (BS-IV/11) which failed to produce a Guidance document on LM mosquitos and LM trees that was considered acceptable by the Parties (BS VIII/12). We consider that the development of risk assessment guidance on "gene drive organisms" has great potential to follow the same path, given the range of gene drive technologies, organisms that may be modified, and scenarios under which such organisms may be released.
- To support the conclusion of the AHTEG that additional guidance for the risk assessment of living modified fish is not required.
- To support the conclusion of the AHTEG for the development of guidance for the risk assessment of living modified gene drive organisms, provided that the guidance is pertinent to organisms currently under development, scientifically- and evidence-based, and supports case-by-case risk assessments.

Main points of discussion

- Interventions were mainly focused on whether or not there is a need to develop an additional RARM guidance on LM fish. Only a few delegations and NGOs believed there is a need to develop an additional RARM guidance on LM fish.
- Most delegations supported developing RARM guidance on GDOs except for s6(a) Also s6(a) did not support establishing an AHTEG to develop the RARM guidance and suggested to look at AHTEG as only one possible option. Their reason was that last time it took AHTEG seven years to develop a guidance and in the end it was not welcomed by all the parties.
- Some delegation and NGOs asked for a precautionary approach on the release (including experimental release) of GDOs.

Table 1. Summaries of main points of discussions by the countries and NGOs

Not supporting an additional guidance on LM fish
Supporting an additional guidance on LM fish
Supporting developing a guidance on GDOs
Not supporting developing a guidance on GDOs
The GDOs guidance is NOT a pre-requisite for GDO release
Concerned about the establishment of an AHTEG on Risk Assessment
Precautionary approach on Cartagena Protocol
Precautionary approach on GDOs
Both benefit and Risk of GDOs to be considered
Supporting a division between the work done under the Protocol and the Convention since GDOs are a topic of SynBio under the convention (to avoid duplication)
Developing a guidance on LMOs produced through genome editing
Moratorium on GDOs

s6(a), s9(2)(ba)(i)

Positions taken by other countries

- s6(a) believes that there is no need to develop further RARM guidance for living modified fish (LM fish). Regarding gene drive organisms (GDOs), s6(a) expressed that we need to approach them in a balanced manner, equally presenting the potential benefits and negative impacts. They said a growing body of scientific evidence has demonstrated the promising applications of gene drives, especially for the control and reduction of disease vectors that affect developing countries, or to address sustainable agriculture and foster the conservation and sustainable use of biodiversity. With reference to GDOs, s6(a) believes we need to continue scientific-based discussions to achieve a comprehensive understanding of gene drives' specificities, and avoid developing a "one size fits all" approach to GDOs. They suggested engaging in improving existing risk assessment frameworks, by building on available scientific evidence and considering the many types of existing gene drives to support case-by-case analysis.
    - *NZ agrees with* s6(a) *view on assessing both benefits and risks of GDOs (which is the approach of the HSNO Act), and also avoiding developing a 'one size fit all' guidance which can be a barrier to biotechnology.*
- s6(a) reconfirmed the importance of the precautionary approach in regards with Cartagena Protocol. s6(a) supported developing RA guidance of GDOs to be both general, and focus on upcoming applications in the near future, like mosquitoes containing engineered gene drives. To ensure an efficient process, they recommended making use of existing guidance materials in order not to duplicate work, and suggested a smaller expert group for the initial drafting of the additional guidance materials on engineered gene drives. They emphasised the need for the process to be transparent and Party driven and involve all stakeholders.
    - *NZ should watch taking the precautionary approach regarding gene drive organisms, as it should be consistent with that promulgated in the Rio Declaration of 1992.*
- s6(a) said it is of crucial importance to develop guidance for robust and scientifically sound risk assessments of engineered gene drives and their potential effects on biodiversity and human health, especially for the use of engineered gene drives for the control of mosquito borne diseases and eradication of IAS. s6(a) supported the establishment of an AHTEG to develop a RARM guidance for GDOs.

- s6(a) supported developing RARM guidance for GDOs. They expressed these guidance materials should address general issues of GDOs and focus on upcoming applications in the near future, like mosquitoes containing engineered gene drives. They said the development process must be Party driven, transparent, and includes representatives from international organizations. s6(a) emphasized a precautionary approach with respect to engineered gene drives. They suggested that Parties submit to the Executive Secretary information on their needs and priorities for further guidance materials on specific topics of risk assessment of LMOs including a rationale reflecting the criteria set out in annex I of decision CP-9/13, and that the AHTEG prepares a prioritized list of topics on which further guidance materials on risk assessment may be needed, based on the submissions of the Parties and their national reports.
    - *NZ should watch taking the precautionary approach regarding gene drive organisms, as it should be consistent with that promulgated in the Rio Declaration of 1992.*
- s6(a) had separate, but similar, statements in line with s6(a) They agreed not to develop guidance materials on living modified fish at this stage. They welcomed the development of a guidance material for the risk assessment of GDOs. They emphasised that this guidance material should be dedicated to general issues for conducting risk assessment of GDOs and on imminent applications, such as mosquitoes containing engineered gene drives. s6(a) recommended the use of existing guidance materials to avoid work duplication, and to have a close collaboration between all parties and the inclusion of specific expertise and representatives from international organizations to ensure a successful output. They emphasised on the transparency of the process.
- s6(a) welcomed the analysis performed by the AHTEG on the topics of living modified organisms containing engineered gene drives and of living modified fish in this intersessional period and agrees on the need to develop additional guidance materials.
    - *NZ does not agree with* s6(a) *to develop RARM guidance for LM fish (although we struggled to understand due to connectivity/translation issues, so we are not sure this is what* s6(a) *suggested.)*
- s6(a) agreed to focus the efforts on the development of additional guidance materials for the risk assessment of GDOs. They emphasised that the additional guidance materials should address general issues for conducting risk assessment of LMOs containing engineered gene drives and focus on upcoming applications in the near future, like mosquitoes containing engineered gene drives. They recommend making use of existing guidance materials and not to duplicate work. s6(a) expressed the development process should be transparent and include all the parties.

s6(a) said it is highly important to develop guidance materials for risk assessment of GDOs under the Cartagena Protocol, in order to support a robust and scientific approach to these. s6(a) recommended applying a precautionary approach, in combination with the assessment of other criteria such as ethical considerations regarding GDOs before they are introduced into the environment. According to s6(a) GDOs are included as one of the topics of synthetic biology being considered under the Convention, and that there will be overlap and the potential for synergies between the knowledge base for synthetic biology and the knowledge base for risk assessments of GDOs. s6(a) supports an appropriate division of labour and good coordination between work under the Protocol and the Convention in order to avoid unclear boundaries and possible duplication.

- *NZ should watch taking the precautionary approach regarding gene drive organisms, as it should be consistent with that promulgated in the Rio Declaration of 1992.*
- *NZ agrees with* s6(a) *point regarding non-duplicative work, and decisions on GDOs under the Convention must not get ahead of the process for the development of RARM guidance on GDOs.*

- s6(a) reiterated the importance of the precautionary approach in accordance with the Cartagena Protocol and agrees to focus the immediate efforts on the development of additional guidance materials for the risk assessment of GDOs. They expressed the GDO guidance material should focus on upcoming applications in the near future, like mosquitoes containing engineered gene drives. They recommended making use of existing guidance materials in order not to duplicate work. To ensure efficient progress, they suggest performing the initial drafting in a smaller group of experts. They emphasised the process must be transparent, and Party driven.
  - *NZ agrees with* s6(a) *that the development of RARM guidance on GDOs should focus on organisms most likely to be released in the near future, and regarding a transparent, Party-driven approach.*
  - *NZ is cautious regarding the comment referring to the use of existing guidance, as the speaker was the chair of the previous RARM AHTEG that developed the guidance rejected by Parties at COPMOP8, which included guidance on LM mosquitos. We note the recent publication on RARM principles for gene drive mosquitos published in the Malaria Journal, which should be taken into consideration.*

- s6(a) supported the development of RARM guidance on both LM fish and GDOs. They expressed taking into account the nature and type of use of LM fish and GDOs, considering their higher risk when released, they will spread across borders and affect biodiversity on a wider scale.

According to s6(a) as long as risks and benefits of GDOs cannot be correctly assessed, and risk management measures cannot be correctly set into force, it is necessary to refrain releasing GDOs to avoid irreversible effects to the biodiversity and unintended transboundary movements.

- *NZ does not agree with* s6(a) *to develop additional guidance on LM fish*
- *NZ does not agree with* s6(a) *statement to refrain releasing GDOs as the term "correctly assessed" is subjective, and the proposal is one of a* de facto *moratorium. Parties must be free to assess GDOs on a case-by-case scientifically sound basis.*

- s6(a) agreed not to develop guidance materials on living modified fish at this stage and encourage Parties to promote international cooperation, knowledge sharing and capacity-building and to make use of existing guidance materials. s6(a) attaches great importance to the precautionary principle as described in principle 15 of the Rio Declaration on Environment and Development. They suggested that a small panel of experts with specific expertise in drafting guidance materials on risk assessment of living modified organisms containing engineered gene drives such as mosquitoes, is tasked with the development of the future guidance for this issue, and cooperate with other international organizations to avoid duplications.

- s6(a) supported the decision to postpone for now the development of additional guidance for LM Fish. However, based on their previous recommendations for the development of guidance on Genetically Engineered Fish, they expressed these concerns:

  Despite the fact that there are Risk Assessment guidance documents, including those prepared by the European Food Safety Authority and the Organization for Economic Co-operation and Development, and Cartagena Protocol on Biosafety * Guidance on Risk Assessment of Living Modified Organisms and Monitoring in the Context of Risk Assessment, these documents contain no specific considerations related, for example, to the long-term exposure or next-generation effects, and there is great uncertainty in assessing the spread of such organisms in marine ecosystems, movement them between countries' borders, and special attention should be given to the control and monitoring of such organisms. In general, taking into consideration the fact that laboratories are developing not only genetically engineered fish, but also crustaceans, as well as other marine organisms (e.g. algae), s6(a) suggested to develop guidance on Marine Organisms in general. s6(a) proposed to collect information on scientific developments in this area and consider in the next intersessional period the need to develop guidance on Risk Assessment not only of genetically engineered fish, but also genetically engineered marine organisms in general.

  They supported the development of guidance on Risk Assessment of GDOs. They said such guidance should apply a precautionary approach, obtaining the free, prior and informed consent of potentially affected indigenous peoples and local communities, and assessing socioeconomic, cultural and ethical dimensions.

  - *NZ should watch taking the precautionary approach regarding gene drive organisms, as it should be consistent with that promulgated in the Rio Declaration of 1992.*
  - *NZ does not support the development of RA guidance for LM marine organisms, as our view is that capacity building is better directed at training staff in the processes and principles of scientifically based, specific, case-by-case RARM of LMOs.*

- s6(a) supported the decision not to develop an additional guidance materials for the risk assessment of LM fish, and to establish an AHTEG to develop guidance materials on GDOs.

  In relation to the latter, s6(a) noted that gene drive organisms are LMOs, and as such will be subject to a case by case risk assessment under the provisions of the Cartagena Protocol on Biosafety and other national and international regulatory frameworks controlling the use of LMOs. They expressed that the development of additional guidance materials is not a pre-requisite for the introduction of engineered gene drives into the environment.

They said "In accordance with outcome of the previous CBD COP the introduction of organisms containing engineered gene drives into the environment, including for experimental releases and research and development purposes, may be carried out when: (a) Scientifically sound case-by-case risk assessments have been carried out; (b) Risk management measures are in place to avoid or minimize potential adverse effects, as appropriate".

- *NZ agrees with* s6(a) *that GDOs are LMOs, and the development of RA guidance on GDOs is not a pre-requisite of releasing GDOs into the environment*

- s6(a) expressed the view that the introduction of GMOs (LMOs) threatens sustainable ecosystem development and biodiversity, similar to the introduction of alien species. s6(a) believes that GMOs are genetically engineered products that could be obtained in a natural way, so we can gradually come to release them into the environment after having a comprehensive risk analysis done. s6(a) noted the solutions below for release of GMOs in a closed environment (rather than full release of them) to minimize their risks to the environment and biodiversity:

  - releasing aquaculture animals (fish, crustaceans, etc.) into semi-closed isolated systems, that is, cage production, in which there is no further interaction with environmental objects
  - cultivating of GM algae in artificially created reservoirs with bioreactors installed there (closed system)
  - sterilizing microorganisms to use them in open or semi-open systems
  - regarding agricultural plants, their risks to be assessed on a case-by-case basis while taking into account the receiving environment. s6(a) expressed it is assumed that cultivated and wild plants practically do not interact, and the influence of GM varieties on wild species outside the target agroecosystem is less significant than the potential influence of traditional agricultural crops due to the lack of competitive advantages and less resistance to other environmental factors in GM crops in wild nature. s6(a) said assessing risk on a case-by-case basis, takes years of testing, taking into account the risks of gene drive, vertical and horizontal transfer

  s6(a) stated that the release of products of genetic engineering should not occur in specially protected natural areas in accordance with this principle: to preserve the environment with minimal interference.

  s6(a) believed that gene drive technologies are not intended to be used in open systems.

  s6(a) expressed the position that it is important to preserve endangered species using genetic engineering methods in closed systems without reintroduction, while the primary task at this stage for science is full-genome sequencing of rare species, genome analysis and preservation of the genome as a source of information about the unique properties of biodiversity objects.

- *NZ agrees with* s6(a) *on classifying GMOs (LMOs) as the products of genetic engineering that could have been could potentially occur in nature in some cases (but we do not agree with the* s6(a) *statement in agenda item 4 (SynBio) that GMOs and SynBio products are different and SynBio products are those that cannot be made by nature)*
- *NZ does not necessarily agree with* s6(a) *views on release in a closed environment (rather than full release) for all GMOs, as a comprehensive doctrine, as all such decisions should be undertaken on a case-by-case basis whether deciding on conditional or unconditional release*
- *NZ does not agree with* s6(a) *that all GDOs are not intended to be used in open systems. We support a case-by-case risk assessment rather than a blanket statement*

- s6(a) suggested the need to develop guidelines for marine organisms in general, and also supported the development of the guidance for risk assessment of LMOs containing engineered gene drives. They believe that such guidance should take into account the precautionary approach.
    - *NZ should watch taking the precautionary approach regarding gene drive organisms, as it should be consistent with that promulgated in the Rio Declaration of 1992.*

- s6(a) agreed with the decision of the AHTEG to not to develop an additional guidance on the risk assessment of LM fish. s6(a) has an opinion that the guidance on risk assessment of living modified organisms and monitoring in the context of risk assessment developed by AHTEG can be applied to the risk assessment of living modified fish, and invited countries with experiences and practices regarding living modified fish to adopt the said guidance and sharing relevant information and recommendation. s6(a) also agree with AHTEG's decision to develop the guidance on risk assessment of GDOs, and the designation of new AHTEG to develop the above-mentioned guidance.

- s6(a) supported case-by-case RARM of LMOs.s6(a) supported the proposal not to develop guidance materials for LM fish; instead, it considered that a greater understanding of the subject should be prioritized, as well as the creation of capacities, the exchange of experiences and study of the existing materials in this regard. s6(a) supported the creation of an AHTEG for the preparation of guidance materials on risk assessment for GDOs, since these organisms involve high uncertainty both when carrying out the corresponding evaluation and when establishing monitoring and surveillance actions.

- s6(a) noted with concern that AHTEGs and other Special Groups held to date have taken many years to produce guidance for risk assessment and that, when these were finalized, were not supported by all the Parties. Therefore, s6(a) recommended taking into account this experience and considering other mechanisms to respond to the need to facilitate evaluations science-based risk management. However, if the parties decided to establish a new AHTEG, s6(a) would like it to be time-bound (until COP-MOP11), includes experts who work directly with gene drive technologies, and the AHTEG work on GDOs that are in development now.
    - *NZ agrees with* s6(a) *view that the AHTEG's work may have the same problems as the previous one. It is our view that capacity development would be best supported by the training of risk assessors rather than the development of new guidance documents. However, it is also our view that Parties expect the development of some form of guidance on GDOs, and they will not accept a non-AHTEG process.*
    - *Therefore, NZ supports* s6(a) *view that there needs to be tight control on how long the AHTEG is allowed to carry on with its work, and that two years should be sufficient for the process to achieve an outcome.*
- s6(a) said it is not necessary to establish another AHTEG to develop RARM guidance on GDOs, since last time it took them more than 7 years to produce risk assessment guidance and in the end, the guidance was not agreed upon by the Parties. s6(a) recommended considering this experience and seeking other mechanisms to respond to the needs of the Parties on this issue. s6(a) said if despite their wish, Parties agreed to establish a new AHTEG to develop RARM on GDOs, it should include sectors directly involved in working with gene drive technologies, have a limited duration (till COP-MOP11), and its work should be limited to developing an environmental risk assessment guide for LMOs containing gene drives, and not to be expanded to all gene drives.
    - s6(a) *position is essentially equivalent to* s6(a) *NZ agrees with* s6(a) *that if an AHTEG is established it should be bound to the three criteria that* s6(a) *mentioned.*

- s6(a) reiterated the importance of applying the precautionary principle in the absence of information on the effects on biological diversity of GDOs. Regarding LM fish, s6(a) raised concern that accidental releases or escapes of LM fish that are dispersed to the environment has already occurred, and they called for continued work on the effects on biological diversity of genetically modified fish. s6(a) supported developing new guidance on both LM fish and GDOs.
    - *NZ does not agree with* s6(a) *on the development of new guidance on LM fish*
    - *NZ should watch taking the precautionary approach regarding gene drive organisms, as it should be consistent with that promulgated in the Rio Declaration of 1992.*

- s6(a) expressed there is no need to develop a further RA guidance for LM fish. They emphasised that a case-by-case RA on fish is required since life history varies depending on the fish species and breeding method. Regarding GDOs, s6(a) has doubts whether additional guidance is required.
    - *NZ agrees with* s6(a) *insofar as that RA on GDOs should be carried out on a specific, scientific, case-by case basis, supported by the training of personnel in the principles and practices of RARM.*

- s6(a) supports an AHTEG to develop RARM guidance on GDOs. They recommended to invite experienced parties to continue providing knowledge and information on RARM of new types of living modified organisms containing engineered gene drives, living modified fish, and etc. s6(a) expressed that the Secretariat is recommended to strengthen communication with relevant international organizations and carry out extensive international cooperation, knowledge sharing and capacity building to support Parties to improve their risk assessment and risk management capabilities.
    - *NZ does not agree with* s6(a) *regarding the need for development of LM fish guidance*

- s6(a) noted the existence of various documents and resources for living modified fish and living modified animals, and supported the decision that the development of guidance on risk assessment of living modified fish should not be prioritized at this stage. s6(a) noted the AHTEG's conclusion that resources related to risk assessment of living modified organisms containing engineered gene drives do exist and that these could be useful resources when undertaking risk assessments, but that these are not always globally applicable. s6(a) is of the view that existing risk assessment resources for GDOs should be revised or adapted to align with the locally relevant objective of the Cartagena Protocol. s6(a) supports scientifically sound, case-by-case risk assessments and a decision-making process that weighs risks against benefits including the perspectives of indigenous peoples and local communities (IPLCs), as appropriate. s6(a) is concerned about the proposed establishment of an AHTEG on Risk Assessment due to the lack of a clear mandate, structure and process.

  s6(a) expressed its concerns regarding the low visibility of the Cartagena Protocol on Biosafety in intersessional work, and stressed the importance of including biosafety in the post-2020 Global Biodiversity Framework, as well as the necessity of developing a specific Implementation Plan for the Cartagena Protocol as a follow-up to the 2011-2020 Strategic Plan for the Protocol.

  - *NZ agrees with* s6(a) *that a guidance for LM fish is not required*
  - *NZ agrees with* s6(a) *regarding their statement on scientifically sound case-by-case Risk Assessment, as well as risk/benefit assessment*

- s6(a) supported the statement presented by s6(a) does not prioritize developing new guidance for Living Modified fish at this stage. However, they expressed the view that there is need for capacity building on existing risk assessment guidance for living modified animals. s6(a) supported the need for the development of guidance on GDOs by an AHTEG. They said that, considering the advanced research already done on gene drive mosquitoes and the challenges related to the non-restricted movement of gene drive organisms after release, the development of guidance for such organisms is required.

  s6(a) supported concerns in the statement by s6(a) on the low visibility of the Cartagena Protocol on Biosafety in the post 2020 GBF. The fact that there is no goal on biosafety in the post 2020 GBF, (yet it also contributes to conservation and sustainable use of biological diversity), makes the protocol less visible than the Nagoya Protocol on access and benefit sharing.

Statements by non-Parties

None

Statements by IPLC, NGOs, others

- s9(2)(ba)(i) raised concerns regarding the known and unknown risks posed by unregulated scientific and technological development, specifically with regard to the release of GDOs. They noted that, as pointed out by the AHTEG, it is difficult to predict the behaviour of gene drive organisms prior to their release into the environment, and therefore, they strongly supported a precautionary approach to LMOs containing engineered gene drives. They emphasised that GDOs should be released only if scientifically sound case-by-case risk assessments have been carried out on them, and risk management measures are in place to avoid or minimize potential adverse effects, and free, prior and informed consent of potentially affected Indigenous Peoples is obtained for any introduction anywhere and in all situations that may impinge on Indigenous Peoples' resources or heritage.

s9(2)(ba)(i) said that a robust regulatory mechanism must be developed that allows scientific collaboration, taking Indigenous science into account, technological co-operation, and long-term capacity building that is inclusive and participatory.

s9(2)(ba)(i) supported the establishment of an AHTEG to develop additional guidance for risk assessment on LMOs containing engineered gene drives.

- s9(2)(ba)(i) supported the development of a new RARM guidance on LM fish since next-generation effects need to be taken into account. They supported s9(2)(b)(i) intervention in this regard. They called for an immediate global moratorium on the release, including experimental release, into the environment of GDOs. Regarding GDOs, they support the precautionary principle. Also, they believe new RARM guidance should be developed for LMOs produced through genome editing techniques.

- s6 represented millions of small-scale farmers across s9(2)(ba)(i). They supported s6(a) position, calling for further risk assessment guidance on LM fish. They called for a global moratorium on the release of GDOs. They said targeting Malaria using GDOs was a failure in the first phase of the project. They expressed that they have witnessed human strained capacity on the part of regulatory authorities, lack of experience, transparency, and compliance with the CBD and Cartagena Protocol and most disturbing, the alleged human rights violations. While they did not support the release of GDOs, they supported more scientific and socio-economic discussions on the issue. They called for the precautionary principle regarding GDOs, and said the risk assessment must go beyond pure science-based risk assessment, as people have diverse relationships with their environment. They supported the continuity of the AHTEG to develop this guidance, seeking a well-balanced representation of IPLC and small-scale food producers and especially those parties in developing countries that will be affected by the releases. s6(b)(i)

- s9(2)(ba)(i) spoke on behalf of the s9(2)(ba)(i) that aims to raise awareness of the value of gene drive research for public good such as fighting invasive species or providing a complementary tool to fight vector borne epidemics. They recognise and value the knowledge of IPLCs and the information shared with them, and emphasised that consultation with IPLCs should be happening early on.

  They reiterated that GDOs are LMOs, and therefore, the provisions of the Cartagena Protocol apply to them. They expressed all gene drive organisms should be subject to a risk assessment on a case-by-case basis before any release in the environment, as are all LMOs. They said this was clearly stated and agreed at COP 14 and we hope that the discussions relative to gene drive can now progress under the umbrella of the Cartagena Protocol and remain under a single track.

  They said "It is also important to note that work on guidance for responsible gene drive research has progressed since COP 14 and since the AHTEG met and these elements should be taken into consideration. For example, the WHO is preparing to release an update to its guidance on genetically modified mosquitoes that will address gene drive. Regulatory experts in the West Africa region are also in the final phase of developing a regional mechanism for assessing new vector control tools that would also include gene drive organisms. Finally, while these discussions on risk assessment are timely and important to the establishment of a clear framework in which research can take place, we want to emphasise the fact that releases of engineered gene drive organisms, including for experimental purposes, are still years away".

  - *NZ agrees with their position that GDOs are LMOs and the provisions of Cartagena Protocol need to apply to them, and all LMOs (including GDOs) need to be risk assessed on a case-by-case basis*

- s9(2)(ba)(i) supported developing an additional RARM guidance on LM fish which takes into consideration the effect on IPLCs. They supported a precautionary approach on GDOs, and developing appropriate guidance on risk assessments. Regarding GDOs they expressed concern that they have the potential to impact indigenous territories and significant places, biocultural and subsistence resources, and traditional and customary practices, potential cascading effects on ecosystem flora and fauna on which IPLCs depend for subsistence and cultural identity, including women and youth. s9(2)(b) expressed that support including financial resources should be mobilised for capacity building and knowledge management tools on RARM of GDOs to ensure for the full, meaningful and effective participation of IPLCs, women and youth- and make space at the table - at all levels of planning and decision making.

- s9(2)(ba)(i) supported developing a guidance for LM fish that takes into consideration next-generation effects and socio-economic effects. They support developing RARM guidance on GDOs, and emphasises taking precautionary approach. They think that the work of the Convention and the Cartagena Protocol has to be coordinated and complementary regarding gene drive organisms, addressing these from a broader perspective and not just from the perspective of the risk assessment. In this regard, they strongly suggested that the work of the AHTEG builds on and complements CBD decisions, including the precautionary approach, ensuring free, prior, informed consent of potentially affected indigenous peoples, and assessing cultural, environmental, ethical and socioeconomic impacts of any kind of release of gene drive organisms into the environment.

Positions taken by NZ

New Zealand: Spoken intervention for informal SBSTTA: Agenda item 5

New Zealand commends the substantial effort undertaken by the Risk Assessment AHTEG, notes its report and endorses its conclusion that the development of further guidance for living modified fish is not required at this time. Further, New Zealand supports the AHTEG's conclusion that the development of guidance regarding living modified gene drive organisms is warranted, with certain reservations.

Recalling that both decisions 14/19 on synthetic biology and CP 9/13 on risk assessment of LMOs contain the statement "...as there could be potential adverse effects arising from organisms containing engineered gene drives, before these organisms are considered for release into the environment, research and analysis are needed, and specific guidance may be useful, to support case-by-case risk assessment." We are particularly concerned that the draft decision and Terms of Reference for the AHTEG, as written, do not account for the development of "specific guidance" to support "case by case" risk assessments of living modified gene drive organisms. It is New Zealand's view that the purpose of the new AHTEG described in paragraph 6 must be clarified to align it with the original intention of decisions 14/19 and CP 9/13 in this draft decision and its supporting annex.

To this end, we propose textual changes to paragraphs 6 and 9 of the draft decision, as well as paragraph 1(c) of the annex to the decision, which we will submit in writing to the Secretariat, to account clearly for the intent of decisions 14/19 and CP-9/13 for guidance that supports case-by-case risk assessment.

In addition to these changes, New Zealand suggests two minor changes to the text to correct a grammatical error and a possibly erroneous internal reference. Specifically:

In paragraph 1, the phrase 'Recalling of' should simply be 'Recalling'.

In paragraph 8(c), we note a reference to paragraph 5, which we believe should be a reference to paragraph 7.

Finally, we note that the draft decision does not provide a mechanism by which Parties may submit information regarding their needs on issues of risk assessment. We propose changes to the text of paragraph 10 to enable the submission of identified needs to the Secretariat. We will submit this suggested change to the text to the Secretariat in writing.

New Zealand: Written annex to intervention at informal SBSTTA: Agenda item 5

We agree with our earlier statement and do not propose any changes to the briefing

Next steps
N/A

Anything else of relevance
Guidance documents (Item 15)
The history of the development and use of guidance documents under the CP is fraught. An eight year process undertaken by an AHTEG established after COP-MOP4 (BS-IV/11) failed to produce a Guidance document that was considered acceptable by the Parties (BS-VIII/12). A major difficulty that many Parties identified with the voluntary guidance was that it identified a broad range of rather generic, and often highly improbable, risks in a way that did not allow the case-by-case risk assessment of LM trees or LM mosquitos on the merits of any specific characteristics of a given modification. The difficulty with the process led to the termination of the Risk Assessment AHTEG, and the removal of the guidance document it developed from the Secretariat's Biosafety Technical Series. The AHTEG's guidance document (generally referred to as "the voluntary guidance") is available to download from the BCH website, but in draft form only.

17 months later at SBSTTA-22, there was clear consensus amongst Parties that evaluation of the need for additional guidance materials would be done through an AHTEG process, supplemented with an online forum, rather than the online forum alone, as was favoured by New Zealand. Thus, at SBSTTA-22, Parties agreed on the process that was ratified at COP-MOP10 that provided criteria for the AHTEG to evaluate a stated need for guidance. These criteria constitute Annex I of CP-9/13, and they must be fulfilled before the development of new guidance can be recommended.

It was also clear at SBSTTA-22 that little enough was known about gene drives and gene drive organisms that it would be impossible to prevent the inclusion of the development of guidance for such organisms in CP-9/13, despite the fact that any such guidance would likely be very high level, and probably not case-by-case, since gene drive organisms are still under development, and still years away from any potential release. It was clear even at SBSTTA that the outcome of any AHTEG evaluation would be to recommend the development of guidance.

This concern was accounted for in part by Parties in parallel statements regarding risk assessment of organisms resulting from Synthetic Biology in decision 14/19 as well as other LMOs in decision CP-9/13. This statement can be found in the Talking Points above, but essentially, the decisions note that any guidance developed under the auspices of the CBD should be "specific" and should also "support case-by-case risk assessment". This is to ensure that the fundamental principles of risk assessment can be taught to enable their application to specific LMOs, thereby strengthening capability amongst Parties who have identified a need for guidance.

The AHTEG that met earlier this year was the first to be convened since CP-9/13 was ratified. From a New Zealand perspective it was successful, in that the AHTEG evaluated LM fish against the criteria and decided that the development of further guidance was not warranted. As expected, the AHTEG recommended that guidance be developed for gene drive organisms. Our suggested changes to the draft decision are meant to ensure that the guidance developed remains aligned with the intent of decisions 14/19 and CP-9/13.

We note that there is a wide range of guidance for risk assessment of LMOs, and we consider the available guidance to be adequate to meet the needs of Parties that have expressed a need for guidance. However, the Secretariat has historically taken the view that the only guidance documents that are acceptable for use in maintaining compliance

with the CP are those that only apply the criteria in Annex III of the CP. Annex III only allows for the assessment of risk, and not the benefit of the release of an LMO. This is inconsistent with New Zealand's national legislation (the HSNO Act) which allows for the assessment of the potential benefits of a GMO in decision making, in addition to its risks.

Thus, while New Zealand supports capability building for risk assessors, our view on guidance documents that are consistent with only Annex III of the CP and/or do not take into account case-by-case risk assessment can be described as guarded at best. While there is very little we can do about this, we can work to ensure that risk assessments are conducted in a scientifically rigorous way, on the merits of the specific LMO under assessment.

CONVENTION ON BIOLOGICAL DIVERSITY

Formal 24th Meeting of the Subsidiary Body on Scientific, Technical, and Technological Advice (SBSTTA-24) and 3rd Meeting of the Subsidiary Body on Implementation (SBI-3)

3 May-13 June 2021

New Zealand Delegation Brief

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XII/24
14/19
CBD/SBSTTA/REC/23/7
VIII/10, Annex III, section H29
CBD/SYNBIO/AHTEG/2019/1/2
CBD/SYNBIO/AHTEG/2019/1/3
XIII/17
CBD/SBSTTA/22/INF/17
IX/29 (new and emerging issue criteria)
14/33 (conflicts of interest annex)

Issue

In decision 14/19, Parties agreed that "broad and regular horizon scanning, monitoring and assessing of the most recent technological developments is needed for reviewing new information regarding the potential positive and potential negative impacts of synthetic biology vis-à-vis the three objectives of the Convention and those of the Cartagena Protocol and Nagoya Protocol." To enable this, they authorised a continuation of the AHTEG on Synthetic Biology, under its existing terms of reference albeit with new membership. Parties also decided to continue the open-ended online forum on synthetic biology, to allow the submission of information from various sources to support the AHTEG.

The AHTEG's mandate included:

a) the completion of the analysis requested in decision XII/24, paragraph 2 (synthetic biology as a new and emerging issue as assessed against the criteria laid out in decision IX/29, paragraph 12), and reiterated in decision XIII/17, paragraph 13;

b) taking stock on new technological developments in synthetic biology since its last meeting, including genome editing as it pertains to synthetic biology;

c) undertaking a review of the current state of knowledge on the potential positive and negative impacts of synthetic biology (including organisms with engineered gene drives) on the environment;

d) consideration of whether any living organism developed through synthetic biology falls outside the definition of "Living Modified Organism" in the Cartagena Protocol;

e) compilation and analysis of information including peer-reviewed published literature to prepare a "forward looking report" on synthetic biology applications in the early stages of research and development;

f) recommendation of options for regular horizon scanning and assessment of developments as described in decision 14/19 paragraph 3;

29 AHTEG meetings under the Modus operandi of operations of the SBSTTA

g) preparation of a report on the outcomes of its work for consideration by the SBSTTA prior to COP15.

The Secretariat was also requested to carry out a range of activities in support of the AHTEG, including the convening of the Open-Ended Online Forum on Synthetic Biology, and the generation of a report (CBD/SYNBIO/AHTEG/2019/1/INF/2) for consideration by the AHTEG.

The AHTEG produced a report (task g)), covering tasks a) through f) and made a number of recommendations, based on its findings. The SBSTTA is now being asked to consider the AHTEG's report, in addition to the Secretariat's Terms of Reference for the activities of a proposed "Multidisciplinary Technical Expert Group" and make a recommendation for a draft decision to be considered by Parties at COP15.

New Zealand objectives

- To support a reasonable and science-based approach to synthetic biology that is consistent with our existing domestic framework. To only support mechanisms, such as horizon scanning, "technology assessments" and reporting, that are non-duplicative and add value.
- To ensure a mechanism by which the horizon scanning and reporting function is subject to periodic review as to its relevance and usefulness, and thus to limit the duration of existence of the proposed new Multidisciplinary Technical Expert Group (MTEG), as is required of an AHTEG in section H of the consolidated modus operandi of the SBSTTA.
- To resist calls for certain activities as described in the AHTEG report (Annex I) to be considered as aspects of synthetic biology, particularly as new and emerging issues.
- To resist calls to have synthetic biology or open-air use of nucleic acids to be considered a 'new and emerging issue' under the Convention, consistent with CBD/SBSTTA/REC/23/7 to add no additional new and emerging issues for consideration by the COP.
- To encourage the consideration of some issues identified in the AHTEG's horizon scanning exercise to be more appropriately considered to be part of the definition of 'biotechnology' under the Convention, and therefore subject to its provisions of "aiding the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.", and concomitant considerations of its potential benefit to the environment, in addition to any risks.

Talking points

- Although it has a new name, the proposed Multidisciplinary Technical Expert Group is simply an AHTEG. This is alluded to in paragraph 2 of the draft decision, in that the membership of the proposed multidisciplinary group is to be selected in accordance with section H of the consolidated modus operandi of the SBSTTA. Section H describes the establishment of Ad Hoc Technical Expert Groups. Indeed, the consolidated modus operandi of the SBSTTA only allows for the creation of AHTEGs. To ensure future clarity that the SBSTTA is recommending the creation of a new AHTEG, we suggest that the proposed multidisciplinary expert group be identified as a multidisciplinary AHTEG, if the multidisciplinary nature of the group must be emphasised. To accomplish this, we propose the insertion of the words "Ad Hoc" after "multidisciplinary" at all points in the draft decision, Annex II, and Table 1 of Annex II.
- Further to this point, Section H also states that ad hoc technical expert groups must be of limited duration. Thus, we suggest the addition of a new paragraph 5 to the draft Annex II, Part B, requiring the periodic review of the continuing need for the existence of the group.
- We disagree with the proposed move of commissioning technology assessments exercises and/or collaborative activities from step "c" to step "a", in Table 1 of Annex II, as explained in footnote 21 of CBD/SBSTTA/24/4/Rev.1. The initial commissioned technology assessment reports called for in the assessment step of the Multidisciplinary AHTEG's Terms of Reference appears to be unnecessarily duplicative to the responsibilities of the multidisciplinary AHTEG for technology assessment. If a commissioned technology report is required, it should only be authorised if the multidisciplinary AHTEG decides it lacks sufficient capacity and/or expertise to carry out the assessment itself, and requests such reports to be commissioned by the Secretariat. Therefore, we suggest the commissioning of technology assessments be moved to the "Assessment" section of Table 1 in Annex II, as was recommended by the AHTEG in the report of its outcomes[30].

Text changes proposed (for the Secretariat)

Uniformly replace the term "Multidisciplinary Technical Expert Group" with "Multidisciplinary *Ad Hoc* Technical Expert Group" in the draft decision, as well as in the Terms of Reference for the Group, and the table therein (Annex II). This text is found in the draft decision paragraphs 2, 5b, 5d, and 6, Annex II, Part B Header, and paragraphs 1, 2, 3, and 4. The text is also found at several points in Table 1 of Annex II, which I will list by column. In the "Coordinating actors" column, it is found in the first bullet point of row (c) Assessment, and in row (d) reporting outcomes in the first bullet point. In the "Other actors and considerations" column, it is found in the fourth and sixth bullet points of row (c) assessment.

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30 Annex I, paragraph 41(i)

Draft recommendation

The Subsidiary Body on Scientific, Technical and Technological Advice may wish to recommend that the Conference of the Parties at its fifteenth meeting adopt a decision along the following lines: *The Conference of the Parties,* *Recalling* decision 14/19, in which it agreed that broad and regular horizon scanning, monitoring and assessing of the most recent technological developments is needed for reviewing new information regarding the potential positive and potential negative impacts of synthetic biology vis-à-vis the three objectives of the Convention and those of the Cartagena Protocol on Biosafety and the Nagoya Protocol on Access and Benefit-sharing, *Welcoming* the outcomes of the meeting of the Ad Hoc Technical Expert Group on Synthetic Biology held in Montreal, Canada, from 4 to 7 June 2019,31	No comment
1. *Establishes* a process for broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology as set out in annex II, section A;	no comment.
2. *Establishes* the Multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology to support the process for broad and regular horizon scanning, monitoring and assessment in accordance with the terms of reference contained in annex II, section B;	no comment.
3. *Decides* that the trends in new technological developments in	Agree.

31 See annex I

synthetic biology identified by the Ad Hoc Technical Expert Group on Synthetic Biology32 will inform the horizon scanning, monitoring and assessment for the next biennium;	
4. *Invites* Parties, other Governments, indigenous peoples and local communities, and relevant organizations to submit to the Executive Secretary information relevant to the trends to inform the horizon scanning, monitoring and assessment;	agree.
5. *Requests* the Executive Secretary, subject to the availability of resources:	
(a) To commission technology assessments on the trends identified and requested by the Ad Hoc Technical Expert Group on Synthetic Biology;	(a) to bring this work in line with the recommendation of the AHTEG report.
(b) To convene online discussions to support the work of the Multidisciplinary Ad Hoc Technical Expert Group as needed;	(b) agree.
(c) To synthesize the information submitted in response to paragraph 4 above as well as the information provided through the online discussions;	(c) no comment
(d) To convene at least one meeting of the Multidisciplinary Ad Hoc Technical Expert Group to consider the technology assessments and the synthesis of information referred to in subparagraphs (a) and (c) above, and to review the components, products and organisms being developed through the trends referred to in paragraph 3 above and consider their possible impacts on the objectives of the Convention;	(d) agree.

32 See annex I

6. *Requests* the Subsidiary Body on Scientific, Technical and Technological Advice to consider the outcomes of the work of the Multidisciplinary Ad Hoc Technical Expert Group and make recommendations for the consideration of the Conference of the Parties at its sixteenth meeting and, as appropriate, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its eleventh meeting and the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol at its fifth meeting;	agree.
7. *Also requests* the Executive Secretary to continue pursuing cooperation with other organizations, conventions and initiatives, including academic and research institutions, on issues related to synthetic biology.	No comment.
8. The Subsidiary Body on Scientific, Technical and Technological Advice may also wish to recommend that the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol and the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol each take note of the decision of the Conference of the Parties on this matter.	agree.

Annex I

Outcomes of the meeting of the Ad Hoc Technical Expert Group on Synthetic Biology (Montreal, Canada, 4-7 June, 2019)

1. The AHTEG recognized that the different elements of its mandate were interrelated and that there may be some overlap in the discussions on these elements. It considered that new technological developments (addressed under its agenda item 3.1) was a broad topic while synthetic biology applications in early stages of research and developments (addressed under item 3.2) was more concrete. It also noted that the discussions under a number of items, particularly 3.1, 3.2 and 3.4, could inform consideration of the process

for broad and regular horizon scanning, monitoring and assessment33 addressed under item 3.5.

2. The AHTEG recognized that the submissions of information and the online forum had provided important and useful information for its deliberations. It also recognized, however, that the online forum may have had limitations, for example, for those who come from an oral tradition of communication or whose mother tongue is not English.

3. The AHTEG also expressed its appreciation for the compilation of the bibliographic references (CBD/SYNBIO/AHTEG/2019/1/INF/3), which had served as a useful source of information. It agreed that it would be beneficial if the Secretariat continued to update this document as new research on synthetic biology was published.

I. New technological developments in synthetic biology

4. The AHTEG recalled the discussions on recent technological developments in the field of synthetic biology during its 2017 meeting, and noted that the outcomes of that discussion remain relevant.

5. The AHTEG noted that new technological developments could be grouped into trends that could inform a process for horizon scanning, monitoring and assessment. The Group identified a number of trends as follows, recognizing that this list is not exhaustive:

(a) Increased field testing of organisms, components and products derived from new developments in synthetic biology;

(b) Increased development of technologies that genetically modify organisms directly in the field;

(c) A shift to the development of synthetic biology for environmental, conservation, agricultural and health uses (some examples are provided in paragraph 12 below);

(d) Increasing sophistication of methods, including, for example, new genome editing techniques, more complex metabolic engineering, the recoding of genomes, and the use of artificial intelligence/machine learning for the redesign of biological systems;

(e) The use of transient modification of organisms, including, for example, through the use of synthetic double-stranded RNA molecules, nano-particles and genetically modified viruses;

(f) Ability to produce new synthetic biomolecules using non-canonical nucleotides and amino acids;

(g) The use of synthetic biology for non-biological purposes, for example in data storage.

6. It was noted that the technological developments mentioned within the various trends referred to above could be at different stages of progress and may be more advanced in some countries than in others.

7. The potential dual use nature of some advances in synthetic biology might raise biosecurity concerns in relation to the three objectives of the Convention.34

33 In decision 14/19, paragraph 3, the Conference of the Parties agreed "that broad and regular horizon scanning, monitoring and assessing of the most recent technological developments is needed for reviewing new information regarding the potential positive and potential negative impacts of synthetic biology vis-à-vis the three objectives of the Convention and those of the Cartagena Protocol and Nagoya Protocol". The phrase "horizon scanning, monitoring and assessment" is used in the text that follows to refer to this process.

34 See also paragraph 19 of the 2017 AHTEG report (CBD/SYNBIO/AHTEG/2017/1/3).

8. In taking stock of new technological developments in synthetic biology, the AHTEG acknowledged the importance of considering the speed of development, geographic spread and availability and accessibility of tools and expertise. These factors may, among other things, pose challenges to the capacity to conduct risk assessment and the ability to understand the full range of possible impacts.

II. Synthetic biology applications that are in early stages of research and development, vis-à-vis the three objectives of the Convention

9. The AHTEG recognized that synthetic biology applications are at different stages of research and development and that, therefore, their relation to the objectives of the Convention should not be generalized.

10. The AHTEG recalled that, in decision 14/19, paragraph 5, the Conference of the Parties had recognized that synthetic biology applications could pose challenges to the ability of some countries, especially developing countries which might lack the necessary capacity, to assess the potential impacts in relation to the three objectives of the Convention. Such applications could, for example, have cultural and socioeconomic impacts over a large geographic area and in locations far from the place of use.

11. It was noted that indigenous peoples and local communities could have different perspectives, different ways of perceiving potential impacts and be impacted differently by synthetic biology applications in relation to the objectives of the Convention, since, for indigenous peoples and local communities, natural elements are living entities. It was recalled that the free, prior informed consent of potentially affected indigenous peoples and local communities should be sought or obtained.

12. Recognizing the similarities between this topic and the discussion on new technological developments in synthetic biology (see section I above), the AHTEG identified the following as examples of specific synthetic biology applications, chosen primarily from those that are in early stages of research and development (R and D), that may be relevant to the three objectives of the Convention:

(a) Applications intended for use in the environment in managed and wild populations:

(a) Genetically engineered nitrogen-fixing bacteria and other genetically engineered bacteria/viruses for agriculture – some close to or at field trials;

(b) Genetically engineered bacteria for such environmental applications as bioremediation, biodegradation and biomining – various stages of R and D;

(c) Engineered gene drive system in mice for conservation purposes, control of vector-borne disease and agricultural pests, medical research – early laboratory R and D stage;

(d) Engineered gene drives in a few mosquito species for potential control of vector-borne diseases through either population collapse or to interrupt the ability to transmit disease – laboratory R and D stage;

(e) Engineered gene drive for an agricultural pest (spotted wing *Drosophila*) – laboratory R and D stage;

(f) Genetically engineered sorghum to produce a new synthetic protein to improve digestibility for food and feed – early field trial stage;

(g) Insect delivery of modified viruses for the modification of crops (horizontal environmental genetic alteration agents (HEGAAs)) for biodefense, agriculture – early laboratory R and D stage;

(h) Improving the resilience of wild animal and plant populations, for example the ability of genetically engineered corals to withstand stress – early laboratory R and D stage;

(i) Transient modification of agricultural plants through, for example RNAi spray (non-living biopesticide) – laboratory R and D stage;

(j) Cyanobacteria production platforms (i.e. engineered for the photosynthetic production of fuels and fine chemicals) in contained environmental facilities – laboratory R and D stage;

(b) Applications intended for use in the laboratory:

(a) Development of protocells and minimal cells for basic research – early stage laboratory research;

(b) Applications to produce non-native nucleotides and amino acids inside the cell (novel engineered synthetic pathways) for basic research and production of pharmaceuticals – early stage R and D;

(c) Development of synthetic virus-like assemblies for drug delivery and vaccine applications (synthetic nucleocapsids) for human health and perhaps animal health – early laboratory R and D stage;

(d) Re-creation of an extinct infectious horsepox virus from chemically synthesized DNA fragments, for the purpose of creating a smallpox vaccine. This demonstrated proof of concept of *de novo* synthesis of a complex virus (health implications, biosecurity concerns);

(c) Applications with intended use in both the environment and the laboratory:

(a) Genetically engineered bio-containment systems within the cell, primarily for use in the environment but also some laboratory applications – various stages of R and D;

(b) Biofoundries (i.e., highly automated service laboratories) that engineer microbes for a variety of purposes – biofoundries exist now, products in various stages of R and D and on the market;

(c) Genetically engineered plants to produce recombinant polyclonal antibodies against snake venom toxins – early laboratory R and D stage.

III. Synthetic biology organisms that may fall outside the definition of living modified organisms as per the Cartagena Protocol

13. The AHTEG noted that both legal and technical considerations inform the question of whether a synthetic biology organism falls within or outside the definition of "living modified organism" as per the Cartagena Protocol.

14. The AHTEG recalled the statement from its 2017 report whereby it had noted that "indigenous peoples and local communities regarded all components of Mother Nature as living entities."

15. The AHTEG discussed a number of examples that had been identified through the submissions and the online forum, of synthetic biology organisms that may fall outside the definition of "living modified organism" (see CBD/SYNBIO/AHTEG/2019/1/2, para. 17).

16. From these examples, it was acknowledged that both virus-like macromolecular assemblies and protocells were not living organisms.

17. Views differed on whether organisms whose genomes had been edited without the use of nucleic acids using only protein reagents introduced into the cell, for example by ZFN/TALEN/MN applications, would fall under the definition of "living modified organism".

18. In addition, the AHTEG considered that it was unclear whether some transiently modified organisms fall within or outside the definition of "living modified organism".

19. In this light, the AHTEG recalled the related discussion reflected in its 2017 report in which the AHTEG concluded "that most living organisms already developed or currently under research and development through techniques of synthetic biology, including organisms containing engineered gene drives, fell under the definition of LMOs as per the Cartagena Protocol." The AHTEG agreed that this conclusion was still valid.

20. The AHTEG also noted, however, that, given the rapid developments in the field, it may be possible that synthetic biology organisms developed in the future could fall outside the definition of "living modified organism" in the Protocol. Were such a situation to arise, it was recognized that the relevant obligations in the Convention would continue to apply.

21. In discussing the use of terms in Article 3 of the Cartagena Protocol, the AHTEG considered how interpretations of these definitions are now being challenged by new technological developments. It was noted, however, that the Convention contains a definition of "biotechnology" which is broader than the definition of "modern biotechnology" in the Cartagena Protocol, and it was recognized that all Parties to the Convention have obligations with regard to biotechnology and living modified organisms and that the Conference of the Parties has adopted decisions with regard to organisms, components and products of synthetic biology.

22. The AHTEG agreed that it would be important to take a coordinated, complementary and non-duplicative approach on issues related to synthetic biology under the Convention and the Cartagena Protocol.

IV. The current state of knowledge by analysing, including but not limited to peer reviewed published literature, on the potential positive and negative environmental impacts of current and near future applications of synthetic biology, including those applications that involve organisms containing engineered gene drives, taking into account human health, cultural and socioeconomic impacts, especially with regard to the value of biodiversity to indigenous peoples and local communities

23. The AHTEG highlighted the challenges associated with addressing its mandate under point (c) of its terms of reference, noting that undertaking a review of the current state of knowledge is a complex task.

24. The AHTEG noted that the review of the current state of knowledge may provide valuable contributions towards a broad and regular horizon scanning, monitoring and assessment exercise.

25. It also noted that there were multiple factors highlighted in the terms of reference which may require a structured approach or framework in order to undertake this task in a proper way. A consideration of potential benefits and risks is useful but would not be sufficient; it would also be important to identify knowledge gaps in a broad perspective that would continue to be relevant in the future.

26. It was pointed out that multiple dimensions need to be considered when assessing the current state of knowledge, including environmental, human heath, cultural, socioeconomic and ethical dimensions as well as the implications for indigenous peoples and local communities. Likewise, the need to consider what kind of technology assessment tools should be used was highlighted as an important aspect that could inform a proper assessment of potential impacts.

27. The following current challenges were pointed out concerning the identification of potential gaps with respect to data and information as well as tools and instruments as a basis for compiling and assessing the state of knowledge:

(a) Information on the potential receiving environment and its interaction with some organisms, products and components of synthetic biology intended for release into the environment;

(b) Analytical tools to detect, identify and monitor some organisms, products and components of synthetic biology;

(c) Tools to complement risk assessment methods, e.g. regarding assessment of ethical, cultural and socioeconomic factors, including potential benefits, in addition to environmental and human health factors.

28. The AHTEG recalled its discussion on risk assessment and risk management during its 2017 meeting as reflected in section 3.5 of the report on that meeting and agreed that these considerations were still valid.

29. The AHTEG noted that more information for assessing potential impacts may become available in the future (e.g. during contained use experiments, field trials, at the time of release, by modelling), highlighting that the state of knowledge will be constantly evolving as new information becomes available.

30. The AHTEG also pointed out that experience from the risk assessment of LMOs as well as other fields, such as technology assessment and experience with and management of invasive alien species, could be a useful source of information to anticipate potential impacts. The usefulness of the Biosafety Clearing-House as a source of information was also highlighted.

31. The AHTEG noted that some applications of synthetic biology aimed at biodiversity conservation could raise a number of conceptual and legal issues with regard to the status of protected or threatened species, regulation of trade in wildlife products and the compatibility of these approaches with conservation and the cultural practices of indigenous peoples and local communities. These issues may warrant further consideration in cooperation with the appropriate bodies, e.g. CITES.

32. The AHTEG also noted that synthetic biology could raise more general issues regarding the nature of biological diversity.

33. The AHTEG recognized that the state of knowledge on potential impacts of current and near future applications of synthetic biology should consider that, for indigenous peoples and local communities, those applications that may impact their traditional knowledge, innovation, practices, livelihoods and use of land, resources and water should seek their free, prior and informed consent, and the assessment of those applications is usually undertaken in a participatory manner involving the whole community.

34. The AHTEG noted that the online forum and the submissions on synthetic biology raised a number of general considerations related to potential positive and negative impacts from current and near-future applications of synthetic biology, recognizing that these were similar to the points reflected in the 2015 meeting of the AHTEG. These considerations are summarized in CBD/SYNBIO/AHTEG/2019/INF/4, paragraph 3.

V. Options for regular horizon scanning, monitoring and assessment

35. The AHTEG recalled that the Conference of the Parties, in decision 14/19, paragraph 3, agreed that broad and regular horizon scanning, monitoring and assessment of the most recent technological developments was needed for reviewing new information regarding the potential positive and potential negative impacts of synthetic biology vis-à-vis the three

objectives of the Convention and those of the Cartagena Protocol and Nagoya Protocol, and had mandated the AHTEG to recommend options in this regard.

36. The AHTEG considered this agenda item in the light of the other agenda items which provided some relevant experience in reviewing information regarding the potential impacts of synthetic biology vis-à-vis the Convention and the protocols.

37. The AHTEG considered that the process for horizon scanning, monitoring and assessment requires the following steps:

(a) Information gathering;

(b) Compilation, organization and synthesis of information;

(c) Assessment;

(d) Reporting on outcomes.

38. The AHTEG suggested that:

(a) The steps of information gathering and of compiling, organizing and synthesizing of information, should be coordinated by the Secretariat;

(b) The steps of assessing the information and of reporting on outcomes should be undertaken primarily by a multidisciplinary technical expert group, and/or another assessment body. The Subsidiary Body on Scientific, Technical and Technological Advice may have a role in approving the main conclusions of the process;

(c) Other actors could be involved in the steps as further elaborated in paragraph 41 and the table in the appendix.

39. The outcomes of the process would be reviewed by the Subsidiary Body on Scientific, Technical and Technological Advice, and its conclusions and recommendations would be submitted to the Conference of the Parties and, where appropriate, the Parties to the Cartagena Protocol and/or the Parties to the Nagoya Protocol, for consideration. The outcomes of the assessment, related conclusions and recommendations of the Subsidiary Body on Scientific, Technical and Technological Advice, and related decisions of the Conference of the Parties and the Parties to the protocols, may also be used by other bodies under the Convention and the protocols (such as the compliance committees), may be communicated to relevant bodies in the United Nations system, may be used to inform decision-making by individual Parties and others, and may be used to support capacity-building.

40. The process, comprising the four steps, would be a periodic one, with each cycle occurring over an intersessional period (i.e. a biennium). The process would be kept under review by the Subsidiary Body on Scientific, Technical and Technological Advice and the Conference of the Parties with a periodic review of the effectiveness of the process.

41. The AHTEG also noted the following considerations:

(a) Possible mechanisms for the step of information gathering include: submissions of information through notifications, outreach to relevant institutions and intergovernmental organizations, online forums and other existing tools, such as national reports, and the clearing-house mechanism;

(b) Mechanisms for information gathering should seek inputs from a diverse range of actors, facilitate the engagement of indigenous peoples and local communities, among other major groups, and build on the work done by other processes (including relevant horizon scanning or technology assessment processes, such as those under United Nations bodies and processes);

(c) All of the information compiled and synthesized could be made available, including through the clearing-house mechanism;

(d) Some issues identified during one cycle may need to continue to be considered in subsequent cycles with a view to supporting ongoing monitoring of these issues;

(e) Consistency in the way the process is carried out would be important with a view to obtaining results that could be comparable over time;

(f) Expertise from a broad range of disciplines, as well as interdisciplinary and intercultural expertise, would be necessary, especially for the assessment step;

(g) The selection of experts for the multidisciplinary technical expert group, and/or another assessment body will be undertaken in accordance with the consolidated modus operandi of Subsidiary Body on Scientific, Technical and Technological Advice;

(h) The assessment step should employ tools and approaches to enable a participatory assessment process;

(i) The assessment step may be supported by, among other things, commissioning technology assessment exercises and/or collaborative activities with regional and national technology assessment platforms;

(j) Key actors in the horizon scanning, monitoring and assessment process, including consultants and members of any assessment body, should be subject to the procedure for avoiding or managing conflicts of interest set out in decision 14/33;

(k) Online mechanisms could support the various steps of the process, but face-to-face meetings would be necessary for the assessment step;

(l) External review of the draft outcomes of the process would be desirable to ensure their quality;

(m) Efforts would be needed to communicate the outputs effectively to a broad range of potential users, in a culturally appropriate format and in the official languages of the United Nations and, where possible, in local languages;

(n) The capacity, cost implications and effectiveness of the process, including the foregoing considerations, would need to be taken into account;

(o) Collaboration with other bodies in the United Nations system could be explored to support the horizon scanning, monitoring and assessment process;

(p) Efforts should be made to ensure the transparency of the process;

(q) Other bodies under the Convention and the protocols (e.g. the Informal Advisory Committee to the Clearing-House Mechanism, the Informal Advisory Committee on Biosafety Clearing-House) should contribute to various steps of the process and make use of the outcomes, as appropriate.

42. An overview of the options for the process is also presented in table 1 below[35].

VI. Relationship between synthetic biology and the criteria set out in decision IX/29, paragraph 12

35 Table 1 below is a modified version of the appendix to the report of the AHTEG. The changes made are as follows: the title has been revised, the reference to the role of consultants in supporting the work of the Secretariat has been moved to the column on coordinating actors, the reference to commissioning technology assessments exercises and/or collaborative activities has been moved from step "c" to step "a" and the language of Multidisciplinary Technical Expert Group has been used throughout. The original version of the table can be found in the report of the AHTEG, CBD/SYNBIO/AHTEG/2019/1/3.

43. The AHTEG deliberated extensively on how synthetic biology developments could be related to each of the criteria listed below as per decision IX/29.

44. The AHTEG recognized the challenge in bringing the criteria into context, understanding the criteria and the lack of guidance as to how they should be applied. The AHTEG noted the difficulty in applying the criteria to a broad topic, such as synthetic biology. There were questions regarding the suitability and wording of the criteria for identifying new and emerging issues. Recalling its mandate,[36] the AHTEG noted that it would be for the Subsidiary Body on Scientific, Technical and Technological Advice and the Conference of the Parties to take its advice into account in considering whether synthetic biology should be a new and emerging issue.

Criterion (a)
Relevance of the issue to the implementation of the objectives of the Convention and its existing programmes of work

45. The AHTEG agreed that organisms, products and components developed through the use of synthetic biology were relevant to the implementation of the Convention and its programmes of work.

Criterion (b)
New evidence of unexpected and significant impacts on biodiversity

46. Experts had a range of perspectives regarding this criterion. There was an extensive discussion on the nature of evidence and what is considered evidence.

Criterion (c)
Urgency of addressing the issue/imminence of the risk caused by the issue to the effective implementation of the Convention as well as the magnitude of actual and potential impact on biodiversity

47. Experts had a range of perspectives regarding this criterion, including with respect to the imminence of possible release of organisms, components and products of synthetic biology. The interconnections between criteria (c), (d) and (e) were noted.

48. It was acknowledged that current regulatory mechanisms, including the Cartagena Protocol, already provide a framework for addressing the potential adverse effects of most organisms resulting from synthetic biology, including organisms that are likely to be produced by synthetic biology in the near future. On the other hand, some experts identified the lack of control strategies for engineered gene drives, including those with a greater potential for transboundary movement, as well as the lack of traceability and detectability methods for certain genome edited organisms and products thereof.

Criterion (d)
Actual geographic coverage and potential spread, including rate of spread, of the identified issue relating to the conservation and sustainable use of biodiversity

49. Views differed on the actual geographical coverage and potential spread, including the rate of spread, of organisms, components and products produced from synthetic biology. It was noted that some of the applications of synthetic biology, such as engineered gene drives, have not been released, and, thus, the actual geographical spread of these cannot be assessed. It was also noted that applications, such as gene drives or horizontal

36 Decision 14/19, annex, paragraph (a): "The Ad Hoc Technical Expert Group on Synthetic Biology shall provide advice on the relationship between synthetic biology and the criteria set out in decision IX/29, paragraph 12, in order to contribute to the completion of the assessment requested in decision XII/24, paragraph 2, building on the preliminary analysis prepared by the Executive Secretary in document CBD/SBSTTA/22/INF/17".

engineered genetic alteration agents, may have the potential for rapid spread over a wide geographical range.

50. It was noted that, for genome-edited organisms, the current lack of tools to detect these organisms could lead to them spreading more widely.

51. The continued expansion of access to the tools of synthetic biology was highlighted with regard to its potential to enable rapid spread and development of synthetic biology and its applications. Likewise, the increased accessibility of these tools could facilitate the release of organisms, components and products of synthetic biology by new actors (e.g. for example, do it yourself (DIY) practitioners and artists), which could pose challenges to the conservation and sustainable use of biodiversity.

Criterion (e)
Evidence of the absence or limited availability of tools to limit or mitigate the negative impacts of the identified issue on the conservation and sustainable use of biodiversity

52. Experts had a range of perspectives regarding this criterion.

53. It was acknowledged that current regulatory mechanisms, including the Cartagena Protocol, provide a framework for addressing the potential adverse effects of most organisms resulting from synthetic biology. However, some experts highlighted the lack of analytical tools for the detection, identification, and monitoring of some products and organisms of synthetic biology, and the lack of control measures as posing challenges for the mitigation of negative impacts. It was noted that the detectability of single nucleotide or small genomic changes could pose further challenges for some countries. Further, some noted that there is a lack of appropriate tools for performing risk assessment to address the specific challenges from some organisms, products and components of synthetic biology.

Criteria (f) and (g)
Magnitude of actual and potential impacts of the identified issue on human well-being

Magnitude of actual and potential impact of the identified issue on productive sectors and economic well-being as related to the conservation and sustainable use of biodiversity

54. The AHTEG considered criteria (f) and (g) together. Experts had a range of perspectives regarding these criteria.

55. Potential health impacts were noted with respect to the reduction in vector-borne diseases, the reduction of the cost of pharmaceuticals through the utilization of synthetic biology, and the production of new vaccines. Potential impacts were noted regarding the challenges of shifting land use, lack of informed consent for society and lack of free, prior informed consent for indigenous peoples and local communities, and economic losses for small farmers. However, it was noted that the magnitude of impacts of synthetic biology, positive or negative, cannot be predicted in a generalized manner and should be assessed on a case-by-case basis, taking into account a broad range of areas beyond an environmental context.

56. The AHTEG recalled that the issue of digital sequence information on genetic resources and fair and equitable benefit-sharing was initially identified during its 2015 meeting and is now being considered through the process set out in decision 14/20. It noted the relevance of the issue to synthetic biology and human and economic well-being.

Annex II

Broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology

A. Process for the horizon scanning, monitoring and assessment	
1. The process for broad and regular horizon scanning, monitoring and assessment consists of the following steps: (a) Information gathering; (b) Compilation, organization and synthesis of information; (c) Assessment; (d) Reporting on outcomes.	No comment.
2. For each step, the coordinating actors, other actors and main considerations for the process are as set out in table 1.	No comment.
3. The Subsidiary Body on Scientific, Technical and Technological Advice shall review the outcomes of the horizon scanning, monitoring and assessment and prepare conclusions and recommendations on technological developments in synthetic biology and their potential positive and negative impacts for the objectives of the Convention.	Support this, particularly for its language pertaining to "the *positive*...impacts for the objectives of the Convention.
4. The effectiveness of the process for broad and regular horizon scanning, monitoring and assessment of technological developments in synthetic biology shall be reviewed four years following its adoption.	Agree.
B. Terms of reference for the Multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology to support the process for broad and regular horizon scanning, monitoring and assessment	
1. The Multidisciplinary Ad Hoc Technical Expert Group shall:	

(a) Employing tools and approaches to enable a participatory assessment process, review and assess the information gathered through the process for broad and regular horizon scanning, monitoring and assessment described in Annex II, Part A, and, on this basis, consider technological developments in synthetic biology and their implications for the objectives of the Convention, both positive and negative;	(a) ongoing concerns regarding the 'starting point' definition of synthetic biology (XIII/17, paragraph 4), as a number of identified issues have quite long histories. The second text change here is meant to recognise that examination of the trends and techniques identified are being considered under the convention, not the Cartagena Protocol (if they don't meet its criteria), which only covers risk.
(b) Identify and distinguish between developments identified during one cycle that may or may not need to continue to be considered in subsequent cycles, as well as additional developments that may be considered priorities during the next intersessional period;	(b) changes to connect item 1(b) to the Multidisciplinary AHTEG's activities described in 1(a), as well as edits to ensure pruning of the issues under consideration by the Multidisciplinary AHTEG
(c) Prepare a report on the outcomes of its assessment to be presented to the Subsidiary Body on Scientific, Technical and Technological Advice;	(c) agree.
(d) Make recommendations to the Subsidiary Body on Scientific, Technical and Technological Advice on specific issues that may or may not require further consideration by the Conference of the Parties and/or the Parties to the Cartagena Protocol and the Parties to the Nagoya Protocol.	(d) again, to attempt to ensure that the list of items under consideration by the Multidisciplinary AHTEG remains of a manageable size.
2. The Multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology will be constituted according to section H of the consolidated modus operandi of Subsidiary Body on Scientific, Technical and Technological Advice, including whenever possible, expertise from a broad range of disciplines, as well as interdisciplinary and intercultural expertise.	Agree, with particular attention to the limited duration of the group's existence (see suggested paragraph 5 below).

3. The procedure for avoiding or managing conflicts of interest in expert groups set out in the annex to decision 14/33 shall apply to the Multidisciplinary Ad Hoc Technical Expert Group.	Agree.
4. The Multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology will work through a combination of face to face meetings, held physically and/or online, supported, as needed by online discussions.	Agree.
5. The Mandate of the Multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology will be reviewed four years after its establishment, (and if necessary, biennially thereafter) by the Subsidiary Body on Scientific, Technical and Technological Advice, which will make a recommendation on the need for the group's continuation, subject to approval by the Conference of the Parties.	Propose this text to be added to ensure that the multidisciplinary AHTEG does not continue indefinitely, and/or unnecessarily.

Table 1. Process for broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology

Process and steps		Coordinating actors	Other actors and considerations
Horizon scanning, monitoring and assessment process	**(a) Information gathering**	• Secretariat, with the support of consultants as necessary	• Possible mechanisms include submissions of information through notifications; outreach to relevant institutions and intergovernmental organizations; online forums; and other existing tools, such as national reports, and the clearing-house mechanism. • Seek inputs from a diverse range of actors, facilitate engagement of indigenous peoples and local communities, among others, and build on the work done by other relevant horizon scanning or technology assessment processes. • Some issues identified during one cycle may need to continue to be considered in subsequent cycles, with consistency in the way the process is carried out with a view to obtaining results that could be comparable over time.
	(b) Compilation, organization and synthesis of information	• Secretariat, with the support of consultants as necessary	• The information compiled and synthesized will be made available, including through the clearing-house mechanism.
	(c) Assessment	• Multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology • Consultants commissioned by the Multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology • Subsidiary Body on Scientific, Technical and Technological Advice (approval of the main conclusions of the process)	• Expertise from a broad range of disciplines, as well as interdisciplinary and intercultural expertise necessary. • Face-to-face meetings with support of online mechanisms. • Employ tools and approaches to enable a participatory assessment process. • Selection of experts for the Multidisciplinary Ad Hoc Technical Expert Group will be undertaken in accordance with the consolidated modus operandi of the Subsidiary Body on Scientific, Technical and Technological Advice. • commissioned technology assessment reports and/or collaborative activities with regional and national technology assessment platforms;

Process and steps		Coordinating actors	Other actors and considerations
			• Key actors in the horizon scanning, monitoring and assessment process, including consultants and members of the Multidisciplinary Ad Hoc Technical Expert Group, will be subject to the procedure for avoiding or managing conflicts of interest set out in decision 14/33.
	(d) Reporting on outcomes	• Multidisciplinary Ad Hoc Technical Expert Group reports to Subsidiary Body on Scientific, Technical and Technological Advice • Subsidiary Body on Scientific, Technical and Technological Advice reports to Conference of the Parties (and/or the meeting of the Parties to the Cartagena Protocol, the meeting of the Parties to the Nagoya Protocol)	• External review of the draft outcomes. • Communicate the outputs effectively to a broad range of potential users, in a culturally appropriate format and languages.
Use of outcomes in support of decision-making		• Subsidiary Body on Scientific, Technical and Technological Advice (review of outcomes, preparation of conclusions and recommendations) • Conference of the Parties and/or the meeting of the Parties to the Cartagena Protocol, the meeting of the Parties to the Nagoya Protocol (decision-making) • Parties and others, including other United Nations bodies	
Review of process and its effectiveness		• Conference of the Parties on basis of periodic review by	

Process and steps	Coordinating actors	Other actors and considerations
	Subsidiary Body on Scientific, Technical and Technological Advice	

Background

The operational definition of synthetic biology that was agreed in decision XIII/17 covers a very broad range of current and future trends and applications. As can be seen in the comments on the report of the AHTEG, there are many "trends" identified that are not new at all, and represent lines of research that have roots dating back to the 1980s, if not earlier. This was an issue that was identified as a difficulty with the definition at COP13. However, given the many other issues with Risk Assessment and Risk Management at that Conference, Parties agreed that the definition was "a useful starting point". However, there has been no effort made to revise it since COP13.

While New Zealand will not raise these issues in the informal SBSTTA sessions in relation to the proposal that Synthetic Biology should be considered as a "new and emerging" issue by Parties. However, this may be raised in formal sessions, so the following talking point is placed here, in case of need.

- The operational definition of synthetic biology that was agreed in decision XIII/17 covers a very broad range of current and future trends and applications, including the use of organisms with engineered gene drives. As noted in decision 14/19, such organisms require case-by-case risk assessment. The same is true of the seven trends and 17 applications of synthetic biology identified by the AHTEG in its horizon-scanning exercise[37], with the note that the lists are not exhaustive. We note that many of the applications identified by the AHTEG have research histories dating back as far as the 1970s and 1980s[38]. This demonstrates that "synthetic biology" as we have defined it is neither new, nor emerging, but simply a name given to cover long-standing activities that often now have engineering principles applied to them. Thus, we endorse SBSTTA23's recommendation "not to add to the agenda of the Subsidiary Body in the coming biennium a new and emerging issue".[39]

EPA, May 2021

37 Annex I, paragraphs 5 and 12, respectively

38 Annex I, paragraphs 12(a)(ix); 12(b)(i, ii, iii), 12(c)(iii)

39 CBD/SBSTTA/REC/23/7, paragraph 3.

SBSTTA item 5: Risk assessment and risk management of living modified organisms

Agenda item 5 – Risk Assessment and Risk Management

Relevant documents

BS-VIII/12 CP-9/13
CP/RA/AHTEG/2020/1/5

Issue

In decision CP-9/13, Parties decided to establish a process for the identification and prioritization of specific issues regarding risk assessment of living modified organisms for consideration at COP-MOP10, with a view to as to whether or not the development of further guidance on the risk assessment of living modified (LM) fish and LM gene drive organisms is needed. To achieve this, Parties also decided to convene a new AHTEG on Risk Assessment to consider these two topics, as well as requesting the Secretariat to commission studies to assist the new AHTEG in informing the decision-making criteria of CP-9/13's Annex I, which sets out requirements that must be met before the development of new guidance may be considered.

Due to the COVID-19 pandemic, the AHTEG met virtually, using live sessions and an online forum from 30 March to 3 April 2020. As stated in the second annex below, the AHTEG evaluated LM fish and LM gene drive organisms against the criteria established in CP-9/13 (Annex I). The AHTEG concluded that the development of further guidance for LM fish was not required, but that the development of guidance on the risk assessment of LM gene drive organisms should be undertaken.

The AHTEG further recommended that no adjustment to its terms of reference as described in CP-9/13 Annex I was required, in accordance with paragraph (c)(ii) of its Terms of reference (CP-9/13 Annex II).

Based on these conclusions, the draft decision calls for the formation of a new AHTEG to develop guidance for the risk assessment of LM gene drive organisms. While it was recognised at COP-MOP9 that this recommendation was a fait accompli, it was useful to see the criteria applied to both LM gene drive organisms and LM fish, and to arrive at different conclusions on the two issues.

New Zealand position

New Zealand is supportive of the AHTEG's conclusions and recommendations on the whole, with some strong reservations regarding the resulting draft decision as prepared by the Secretariat. These are addressed in the Talking Points and in tracked changes in the text of the draft decision below.

New Zealand objectives

- To avoid a repetition of the eight-year process undertaken by the AHTEG established after COP-MOP4 (BS-IV/11) which failed to produce a Guidance document on LM mosquitos and LM trees that was considered acceptable by the Parties (BS-VIII/12). We consider that the development of risk assessment guidance on "gene drive organisms" has great potential to follow the same path, given the range of gene drive technologies, organisms that may be modified, and scenarios under which such organisms may be released.
- To support the conclusion of the AHTEG that additional guidance for the risk assessment of living modified fish is not required.
- To support the conclusion of the AHTEG for the development of guidance for the risk assessment of living modified gene drive organisms, provided that the guidance is ~~specific~~ pertinent to organisms currently under development, scientifically- and evidence-based, and supports case-by-case risk assessments.

Talking points

- New Zealand commends the substantial effort undertaken by the Risk Assessment AHTEG, notes its report and endorses its conclusion that the development of further guidance for living modified fish is not required at this time. Further, New Zealand supports the AHTEG's conclusion that the development of guidance regarding living modified gene drive organisms is warranted, with certain reservations.
- Recalling that both decisions 14/19 on synthetic biology and CP-9/13 on risk assessment of LMOs contain the statement "*...as there could be potential adverse effects arising from organisms containing engineered gene drives, before these organisms are considered for release into the environment, research and analysis are needed, and specific guidance may be useful, to support case-by-case risk assessment.*"[40] We are particularly concerned that the draft decision and Terms of Reference for the AHTEG, as written, do not account for the development of "specific guidance" to support "case by case" risk assessments of living modified gene drive organisms. It is New Zealand's view that the purpose of the new AHTEG described in paragraph 6 must be clarified to align it with the original intention of decisions 14/19 and CP-9/13 in this draft decision and its supporting annex.
- To this end, we propose textual changes to paragraphs 6 and 9 of the draft decision, as well as paragraph 1(c) of the annex to the decision, which we will submit in writing to the Secretariat, to account clearly for the intent of decisions 14/19 and CP-9/13 for guidance that supports case-by-case risk assessment.

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[40] Paragraphs 9 and 3, respectively.

- In addition to these changes, New Zealand suggests two minor changes to the text to correct a grammatical error and a possibly erroneous internal reference. Specifically:
    - In paragraph 1, the phrase '*Recalling* of' should simply be '*Recalling*'.
    - In paragraph 8(c), we note a reference to paragraph 5, which we believe should be a reference to paragraph 7.
- Finally, we note that the draft decision does not provide a mechanism by which Parties may submit information regarding their needs on issues of risk assessment. We propose changes to the text of paragraph 10 to enable the submission of identified needs to the Secretariat. We will submit this suggested change to the text to the Secretariat in writing.

Text changes proposed (for the Secretariat)

Preamble to recommendation: *Recalling* decision CP-9/13, paragraph 7, in which it decided to consider, at its tenth meeting, whether additional guidance materials on risk assessment are needed for (a) living modified organisms containing engineered gene drives, and (b) living modified fish,

6. *Decides* to establish an Ad Hoc Technical Expert Group on Risk Assessment to develop guidance materials that are pertinent to organisms currently under development, that are scientifically- and evidence-based, and which support case-by-case risk assessment of living modified organisms containing engineered gene drives, as described in decisions 14/19 and CP-9/13 and in accordance with the terms of reference annexed hereto;

9. Requests the Subsidiary Body on Scientific, Technical and Technological Advice to consider the outcomes of the Ad Hoc Technical Expert Group on Risk Assessment in the context of paragraph 3 of decision 14/19 and paragraph 9 of decision CP-9/13, and make a recommendation for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its eleventh meeting;

10. *Invites* Parties to submit to the Executive Secretary, including through their national reports,41 additional issues on which guidance materials on risk assessment may be needed, further to the process for the identification and prioritization of specific issues of risk assessment of living modified organisms established in decision CP-9/13, and *decides* to consider them, at its eleventh meeting.

Annex to draft decision: 1(c). Develop guidance that is pertinent to organisms currently under development, is scientifically- and evidence-based, and supports case-by-case risk assessments of living modified organisms containing engineered gene drives in accordance with decisions 14/19, CP-9/13, and annex III of the Protocol;

41 A synthesis of relevant information provided in the fourth national reports is available as CBD/CP/--.

Draft recommendation (if there is one)

57. Further to the request of the Conference of the Parties serving as the meeting of the Parties to the Protocol in decision CP-9/13, paragraph 12, and in the light of the outcomes of the discussions of the AHTEG, the Subsidiary Body on Scientific, Technical and Technological Advice may wish to recommend that the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, at its tenth meeting, adopt a decision along the following lines:	No comment.
The Conference of the Parties serving as the meeting to the Parties to the Cartagena Protocol on Biosafety, *Recalling* decision CP-9/13, paragraph 7, in which it decided to consider, at its tenth meeting, whether additional guidance materials on risk assessment are needed for (a) living modified organisms containing engineered gene drives, and (b) living modified fish,	'*Recalling* of' should simply be '*Recalling*'. See Talking Points.
1. *Welcomes* the outcomes of the discussions of the Ad Hoc Technical Expert Group on Risk Assessment;[43]	No comment.
2. *Takes note* of the clarifications made by the Ad Hoc Technical Expert Group to annex I of decision CP-9/13 regarding the process for identification and prioritization of specific issues of risk assessment of living modified organisms that may warrant consideration;[44]	No changes were recommended. No comment.
3. *Notes* the analysis done by the Ad Hoc Technical Expert Group on the topics of (a) living modified organisms containing engineering gene drives and (b) living modified fish according to decision CP-9/13, annex I;	Agree.
4. *Notes* the range of perspectives on the need for the development of guidance on risk assessment of living modified fish, and	Support. Oppose any call to ignore this recommendation and to add language to

[43] CBD/CP/RA/AHTEG/2020/1/5.

[44] See CBD/CP/RA/AHTEG/2020/1/5, annex I, sect. III.

decides not to develop, at this stage, additional guidance materials on risk assessment regarding living modified fish;	the draft decision for the development of guidance on LM fish. If this is unsuccessful, then our fallback position must be that any guidance developed must be pertinent to organisms currently under development, is scientifically- and evidence-based, and supports support case-by-case risk assessment, consistent with the intent of 14/19 and CP-9/13, as we are saying with gene drive organisms.
5. *Endorses* the recommendation of the Ad Hoc Technical Expert Group that guidance for the risk assessment on living modified organisms containing engineered gene drives should be developed;	Support any proposal to change to "*Takes note*", or "*Accepts*", because while we commend the effort of the AHTEG (see first Talking Point), we have reservations regarding the draft recommendation as written (see below).
6. *Decides* to establish an Ad Hoc Technical Expert Group on Risk Assessment to develop guidance materials that are pertinent to organisms currently under development, that are scientifically- and evidence-based, and which support case-by-case risk assessment of living modified organisms containing engineered gene drives, as described in decisions 14/19 and CP-9/13 and in accordance with the terms of reference annexed hereto;	Propose the changes at left, as tracked. These changes are necessary to bring the current decision in line with the intent of decisions 14/19 and CP-9/13.
7. *Invites* Parties, other Governments, indigenous peoples and local communities and relevant organizations to submit to the Executive Secretary information relevant to the work of the Ad Hoc Technical Expert Group, prior to its first meeting;	Agree.
8. *Requests* the Executive Secretary: (a) To convene online discussions of the Open-ended Online Forum on Risk Assessment and Risk Management to support the work of the Ad Hoc Technical Expert Group; (b) To collect and synthesize relevant information to facilitate the work	 (a) Agree. (b) Agree.

of the Online Forum and the Ad Hoc Technical Expert Group; (c) To synthesize the views referred to in paragraph 5 above and the discussions in the Online Forum and make them available for the Ad Hoc Technical Expert Group; (d) To convene, subject to the availability of resources, two meetings of the Ad Hoc Technical Expert Group on Risk Assessment;	(c) Agree, but it appears that the reference here should be to paragraph 7 above, rather than paragraph 5, as stated here. See Talking Points. (d) Agree.
9. *Requests* the Subsidiary Body on Scientific, Technical and Technological Advice to consider the outcomes of the Ad Hoc Technical Expert Group on Risk Assessment in the context of paragraph 3 of decision 14/19 and paragraph 9 of decision CP-9/13, and make a recommendation for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its eleventh meeting;	Agree, with the addition of the tracked qualifying clause at left.
10. *Invites* Parties to submit to the Executive Secretary, including through their national reports,45 additional issues on which guidance materials on risk assessment may be needed, further to the process for the identification and prioritization of specific issues of risk assessment of living modified organisms established in decision CP-9/13, and *decides* to consider them, at its eleventh meeting.	The paragraph as written does not provide a mechanism for Parties to submit their needs on guidance issues, as Decision CP-9/13 refers specifically to issues identified in BS-VIII/12. Additionally, the phrasing of this paragraph is not ideal. It would be useful to limit the use of national reports to the 4th national reports, to prevent re-hashing of old arguments regarding the development of guidance (refer to LM trees and LM mosquitos which were the subjects of the last guidance development effort rejected by the Parties at COP-MOP8). We should support any intervention of this nature, although it isn't a red line issue for us, and we should focus on ensuring that the guidance is pertinent to organisms currently under development, is scientifically- and evidence-based, and which supports case-by-case risk assessments.

45 A synthesis of relevant information provided in the fourth national reports is available as CBD/CP/--.

Annex (to the draft decision)
Terms of reference for the Ad Hoc Technical Expert Group on Risk Assessment

1. The Ad Hoc Technical Expert Group (Group) on Risk Assessment shall:	
(a) Be composed of experts selected in accordance with the consolidated modus operandi of the Subsidiary Body on Scientific, Technical and Technological Advice;	(a) Agree.
(b) Meet twice, subject to the availability of funds and prior to the eleventh meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, and perform necessary tasks between its two meetings;	(b) Agree.
(c) Develop guidance that is pertinent to organisms currently under development, is scientifically- and evidence-based, and supports case-by-case risk assessments of living modified organisms containing engineered gene drives in accordance with decisions 14/19, CP-9/13, and annex III of the Protocol;	(c) Suggest the changes at left. See Talking Points.
(d) Prepare a report, including draft guidance, for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice.	(d) Agree.
2. In undertaking its work, the Group shall consider the synthesis of views from the submissions and discussions in the online forum prepared by the Executive Secretary; existing resources identified in the stock-taking exercise of the "study on risk assessment: application of annex I of decision CP-9/13 to living modified organisms containing engineering gene drives";[47] and any other relevant information collected by the Executive Secretary further to paragraph 6(b) of decision CP-10/--.	Agree.

Annex (NB: this annex is also the annex of CP/RA/AHTEG/2020/1/5)

47 CBD/CP/RA/AHTEG/2020/1/4.

Outcomes of the meeting of the Ad Hoc Technical Expert Group on Risk Assessment

I. living modified fish

A. Review of the study and analysis according to annex I of decision CP-9/13

58. The AHTEG agreed that the "Study on risk assessment: application of annex I of decision CP-9/13 to living modified fish" was a good basis from which to work in order to conduct its analysis. The AHTEG also identified that more information on the potential impacts of living modified fish on biodiversity would be useful to complement the research presented in the study. As part of the review of the study by the AHTEG, some specific points were raised concerning risk assessment of living modified fish and these points are included as part of the analysis below.

(a) They are identified by Parties as priorities, taking into account the challenges to risk assessment, particularly for developing country Parties and countries with economies in transition.

The AHTEG recognized that the issue of living modified fish has been identified by some Parties as a priority through various sources, including the submissions of information pursuant to decision CP-VIII/12, the online forum in 2018, the survey conducted as part of the study, and the fourth national reports on the implementation of the Cartagena Protocol on Biosafety.

The AHTEG acknowledged that different Parties may have different challenges for risk assessment of living modified fish and that these challenges may result in some Parties placing a higher priority on this topic. Further information on some of the challenges related to risk assessment of living modified fish are included in the analysis by the AHTEG under criterion (c) below.

(b) They fall within the scope and objective of the Cartagena Protocol on Biosafety.

The AHTEG considered that living modified fish fall within the scope and objective of the Cartagena Protocol on Biosafety.

(c) They pose challenges to existing risk assessment frameworks, guidance and methodologies, for example, if the issue at hand has been assessed with existing risk assessment frameworks but poses specific technical or methodological challenges that require further attention.

The AHTEG recognized that existing risk assessment methodologies would apply for living modified fish but noted that there are specific technical or methodological challenges that require further attention. These challenges may be due to:

(a) A lack of data or methods to collect data to inform the risk assessment process;
(b) Limited applicability of some risk assessment methodologies to living modified fish;
(c) Lack of tools to estimate consequences, likelihoods and uncertainty;
(d) Difficulties in establishing comparator baselines;
(e) Difficulties in relation to monitoring;
(f) Lack of experience or capacity;
(g) The specific nature of the biology of fish;
(h) The specific nature of the possible genetic modifications.

Recognizing the linkages between criteria (c) and (d), the AHTEG further described the challenges related to living modified fish, as further detailed under criterion (d) below.

(d) The challenges in addressing the specific issue are clearly described.

Regarding the specific challenges related to the risk assessment of living modified fish, the AHTEG discussed the following potential challenges:

(a) Related to fish biology:

(i) Insufficient knowledge on fish biology, genetics and ecology;

(ii) Fish mobility (for example, ability to swim vast distances), and therefore to enter different ecosystems;

(iii) Fish have the potential to be invasive and to hybridize with wildtype populations;

(iv) Fish demonstrate diverse morphological, genetic, physiological, and behavioural adaptations to highly variable aquatic environments;

(b) Related to genetic modification:

(i) Introduced genetic modification (for example, enhanced growth) may confer competitive advantages within the environment;

(ii) Uncertainties associated with next generation effects, including considerations of evolutionary dynamics;

(iii) Some transformations of fish can result in pleiotropic and secondary effects, which can have pronounced effects on the phenology and behaviour of fish.

(c) Related to data collection and availability:

(i) Challenges in simulating natural environments under experimental conditions;

(ii) Data on environmental behaviour (for example, interactions with different species), environmental factors which influence living modified fish reproduction and monitoring is very limited;

(iii) Knowledge on aquatic environments and genotype-environment interactions;

(iv) Difficulty in determining whether survival, migration, spawning, hybridization and introgression of living modified fish would occur under natural conditions and in different environments.

(d) Related to experience:

(i) Limited experience performing risk assessments of living modified fish;

(ii) The experience in undertaking risk assessment of living modified fish varies among countries;

(iii) Experience with risk assessment of living modified fish is limited to containment conditions.

(e) Related to risk assessment methodologies:

(i) Difficulties in establishing baselines;

(ii) Need for additional tools to estimate consequences and likelihoods of risks and uncertainty because of the complexity of the species and the receiving environment.

(f) Related to monitoring and risk management:

(i) Methods to monitor living modified fish in the environment.

Data on releases of non-modified, non-indigenous fish was noted as being available (for example, the United States Geological Survey's Non-Indigenous Aquatic Species Program). Similarly, it was suggested that data from non-modified fish species, such as invasive alien fish species, and lessons from commercial fish farming may be a source of experience that can inform potential environmental effects of living modified fish, without assuming an equivalence.

It was noted that while some tools exist to predict the survival and dissemination of fish species in the environment (for example, the Fish Invasiveness Screening Kit), it was also suggested that an agreed standard model for estimating dispersal and population dynamics would be useful.

Further, some AHTEG members noted that obtaining reliable data for risk assessment can be a challenge, but it does not necessarily mean a challenge to the risk assessment methodology itself.

(e) The specific issues concerning living modified organisms that:
(i) Have the potential to cause adverse effects on biodiversity, in particular those that are serious or irreversible, taking into account the urgent need to protect specific aspects of biodiversity, such as an endemic/rare species or a unique habitat or ecosystem, taking into account risks to human health and the value of biological diversity to indigenous peoples and local communities;
(ii) May be introduced into the environment either deliberately or accidentally;
(iii) Have the potential to disseminate across national borders;
(iv) Are already, or are likely to be, commercialized or in use somewhere in the world.

The AHTEG noted that the study's analysis of criterion (e)(i) contained relatively little information on potential impacts of living modified fish on biodiversity and additional information would be useful, while also noting the potential relevance of information in section 6.4 of the study. Building on the information in the study, experts identified potential adverse effects of living modified fish on biodiversity, for example, the potential for faster growing living modified salmon to out-compete naturally occurring smaller salmon.

Experts shared perspectives on the importance of many wild fish species to indigenous peoples and local communities and highlighted the importance of the relationship between indigenous peoples and local communities and biodiversity. It was suggested that there is a need to consider sociocultural impacts related to adverse effects on native fish populations resulting from a release of living modified fish, ensuring the full and effective participation of indigenous peoples and local communities.

It was recalled that no living modified fish have been developed for release into the environment and those living modified fish that have been released unintentionally, for example, ornamental fish, were not likely to survive in the environment. It was also suggested, however, that the important consideration was that living modified fish had been released into the environment, and whether or not these fish would persist was not relevant for this criterion.

The AHTEG agreed that living modified fish have the potential to disseminate across national borders.

The AHTEG recognized that several species of living modified ornamental fish as well as living modified Atlantic salmon have been commercialized.

B. Stocktaking of resources on similar issues

The AHTEG recognized that resources related to risk assessment of living modified fish do exist, including documents prepared by the European Food Safety Authority and the

Organisation for Economic Co-operation and Development and in the context of the Cartagena Protocol on Biosafety as well as resources on risk assessment of living modified animals in general. For some experts, these documents were sufficient for risk assessment of living modified fish, noting that additional guidance would not be able to address challenges related to the lack of data. Other experts were of the view that specific considerations related, for example, to prolonged exposure or next generation effects, were missing from these documents and, so, more detailed guidance was needed. It was also suggested that most existing resources are for animals in general and guidance focused on fish would be useful and better adapted to the specific challenges they posed.

The AHTEG also acknowledged the compilation of bibliographic references that had been prepared by the Secretariat as an information document for the meeting (CBD/CP/RA/AHTEG/2020/1/INF/3). It noted that the compilation would be revised and updated with additional references, including those provided by AHTEG members, and made available for the twenty-fourth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice.

C. Need for guidance to be developed on risk assessment of living modified fish

The AHTEG noted a range of perspectives on the need for the development of guidance on risk assessment of living modified fish.

Some experts were of the view that all the criteria in decision CP-9/13, annex I, had been met and that, accordingly, there was a clear need and rationale for guidance to be developed on this topic. It was suggested that there are specific issues and challenges related to risk assessment of living modified fish that would be well suited to guidance and also that the development of guidance would help to pool resources and experiences on risk assessment in this area.

Other experts recognized that there could be a need for guidance but were of the view that existing documents can help to address this need and accordingly, the development of guidance on risk assessment of living modified fish should not prioritized at the moment.

Some experts were of the view that not all the criteria were met and there was no need for the development of guidance on risk assessment of living modified fish. They suggested that the focus should be on capacity-building, sharing of experience as well as sharing of existing guidance materials, including in different languages. Experts suggested that given that approvals are for confined use and there are no indications that commercial fish species are being developed for environmental release to date, the development of guidance on risk assessment of living modified fish was not a priority.

One expert considered that she had insufficient information to reach a decision on the need for the development of guidance on living modified fish.

There were also some questions concerning what was meant by "guidance" in decision CP-9/13 and what types of guidance should be considered.

II. living modified organisms containing engineered gene drives

A. Review of the study and analysis according to annex I of decision CP-9/13

The AHTEG agreed that the "Study on risk assessment: application of annex I of decision CP-9/13 to living modified organisms containing engineered gene drives" was a good basis for its work, and it was noted that it provided a useful overview of the current status of engineered gene drive technologies and potential applications. The AHTEG noted that the scope of the study was engineered (or synthetic) gene drives of sexually reproducing organisms. It noted that some of the terms used in the study, such as "reversibility" and

"population replacement drive", were not necessarily used in line with the understanding of some of the experts of the AHTEG. It was also recognized that there was additional information not covered by the study that could support the AHTEG's deliberations. Specific points relevant to annex I of decision CP-9/13 that were raised during the review are included as part of the analysis below.

The importance of benefit analysis in relation to potential applications of living modified organisms containing engineered gene drives was noted in the context of decision-making.

(a) They are identified by Parties as priorities, taking into account the challenges to risk assessment, particularly for developing country Parties and countries with economies in transition.

The AHTEG noted that the issue of living modified organisms containing engineered gene drives has been identified as a priority by Parties through various sources, including the submissions of information in response to decision CP-VIII/12, the "Study on risk assessment: application of annex I of decision CP-9/13 to living modified organisms containing engineered gene drives", and fourth national reports on the implementation of the Cartagena Protocol on Biosafety. The cross-cutting nature of the issue of organisms containing engineering gene drives with other areas or work under the Convention on Biological Diversity (for example, synthetic biology) was also noted. The AHTEG further noted that developing countries could be the first ones to be confronted with the need to perform a risk assessment for organisms containing engineered gene drives, for example living modified mosquitos containing engineered gene drives. The importance of proper assessment of potential risk from the release of organisms containing engineered gene drives for indigenous peoples and local communities was also noted to ensure free, prior informed consent and full and effective participation.

Further information regarding the challenges related to risk assessment of living modified organisms containing engineered gene drives are included in the analysis of the AHTEG under criteria (c) and (d) below.

(b) They fall within the scope and objective of the Cartagena Protocol on Biosafety.

The AHTEG considered that LMOs containing engineered gene drives fall within the scope and objective of the Cartagena Protocol on Biosafety.

(c) They pose challenges to existing risk assessment frameworks, guidance and methodologies, for example, if the issue at hand has been assessed with existing risk assessment frameworks but poses specific technical or methodological challenges that require further attention.

The AHTEG recognized that, while existing risk assessment methodology may still be applicable for LMOs containing engineered gene drives, there are specific technical or methodological challenges that require further attention. These include: a lack of data to inform the risk assessment process; the limited applicability of some aspects of risk assessment methodologies to living modified organisms containing engineered gene drives, such as challenges to the comparative risk assessment framework and monitoring methods, lack of guidance on how to assess uncertainty, lack of validated modelling tools; and lack of experience or capacity.

The AHTEG also recognized that solutions to the challenges posed by LMOs with engineered gene drives will entail reconsideration of risk assessment and monitoring methods, as well as making more widely available the necessary expertise, training and resources required and the participation of indigenous peoples and local communities.

The AHTEG also noted that LMOs containing engineered gene drives have the potential to result in an irreversible impact on biodiversity at various scales up to the global level, and international cooperation may be required for risk assessment.

The AHTEG pointed out that no actual release of an LMO with engineered gene drives has been assessed to date.

Recognizing the linkages between criteria (c) and (d), the AHTEG further described the challenges related to living modified organisms containing engineering gene drives as detailed in criterion (d) below.

(d) The challenges in addressing the specific issue are clearly described.

Regarding the specific challenges related to the risk assessment of living modified organisms containing engineered gene drives, the AHTEG described the following challenges, recognizing that some of these challenges may relate to more than one of the categories below and may not relate to all types of drives:

(a) Related to the engineered gene drive system:

(i) Super-Mendelian inheritance, genetic and phenotypic stability, and persistence and invasiveness;

(ii) Difficulty in predicting all relevant genomic effects that could emerge in the next and subsequent generations, and from interactions with the receiving environments;

(iii) Controllability of engineered gene drive systems after release;

(iv) Evaluation of off-target changes and their consequences over time in different genetic backgrounds and their potential accumulation in populations;

(v) The potential for the engineered gene drive to evolve after release, including through unexpected genetic drift;

(b) Related to the target organism/species:

(i) Need for information on the potential genetic diversity of the target species;

(ii) Need for information on the functional role of the targeted species and potential interfertile species in the various ecosystems that may be encountered;

(iii) Consideration of the reproductive strategies, population dynamics and life cycle of the target organism;

(iv) Consideration of possible development of resistance in pathogens regarding vector control;

(c) Related to the receiving environment:

(i) Limited information on the potential interactions with natural receiving environments;

(ii) Limited information on long-term evolutionary processes occurring in these ecosystems;

(iii) Need for information on potential for cross-hybridization with non-target species;

(iv) Diversity of potential receiving environments;

(d) Related to risk assessment methodologies:

(i) Difficulties of applying the stepwise approach of environmental release;

(ii) Challenges to the comparative risk assessment framework;

(iii) Assessing and taking into consideration uncertainty;
(iv) Need to address the broader temporal and spatial scale;
(v) Higher dependency on model-based predictions (for example, to address the long temporal and wide spatial scale of some engineered gene drive applications and to anticipate the range of scenarios for the possible evolution of the engineered gene drive in the environment);
(vi) Difficulty to comprehensively assess risks prior to release;
(vii) Difficulties in assessing next generation effects of organisms containing engineered gene drives;
(viii) Potential adverse effects may differ depending on the type of gene drive mechanism (for example, population suppression drives versus modification drives);
(ix) The need to develop knowledge and procedures for assessing the engineered gene-drive's long-term effects on ecosystems;

(e) Related to data collection and analysis:

(i) Additional information needed on the molecular characterization of both the engineered gene drive mechanism and the engineered gene drive-bearing organism;
(ii) Information to predict off-target effects and potential consequences in the target organism;
(iii) Lack of environmental and ecological data;
(iv) Difficulties with obtaining data for relevant modelling;
(v) Difficulties with validation and calibration of modelling data before the occurrence of an environmental release;

(f) Related to risk management and monitoring:

(i) Post-release environmental monitoring is challenging;
(ii) Evaluation of impacts over long periods of time;
(iii) Need for monitoring plans at supranational level to follow the spread of the engineered gene drive;
(iv) Proven strategies for controlling the spread of an engineered gene drive, should monitoring data show that it has some negative impact on health or the environment;
(v) Unavailability of management plans for possible reversion.

(e) The specific issues concerning living modified organisms that:
(i) Have the potential to cause adverse effects on biodiversity, in particular those that are serious or irreversible, taking into account the urgent need to protect specific aspects of biodiversity, such as an endemic/rare species or a unique habitat or ecosystem, taking into account risks to human health and the value of biological diversity to indigenous peoples and local communities;
(ii) May be introduced into the environment either deliberately or accidentally;
(iii) Have the potential to disseminate across national borders;
(iv) Are already, or are likely to be, commercialized or in use somewhere in the world.

The AHTEG recognized the need for information on potential impacts of living modified organisms containing engineered gene drives on biodiversity and noted that the study's analysis of criterion (e)(i) contained relatively little such information. For example, the AHTEG suggested that effects on biodiversity and ecosystems should not be limited to keystone species, valued species or ecosystem services as currently reflected in the study but, rather, examined in a more comprehensive manner. Notwithstanding this, the experts acknowledged the potential for living modified organisms containing engineered gene drives to cause adverse, and in some cases irreversible, effects on biodiversity. It was further suggested that the potentially global spread of living modified organisms containing engineered gene drives could then impact endemic/rare species or a unique habitat or ecosystems. It was also suggested that LMOs containing engineered gene drives could adversely affect disease transmission.

Experts noted the perspectives of indigenous peoples and local communities, and the particular importance of nature and biodiversity for them. It was recognized that more information was needed to better understand the potential implications of the release of organisms containing engineered gene drives for indigenous peoples and local communities. In particular, when the broad spread of an LMO with an engineered gene drive is likely, it would be challenging for instance, to obtain the free, prior and informed consent of indigenous peoples and local communities and their full and effective participation, although it was also noted that this was a necessary step.

Regarding criterion (e)(ii), the AHTEG noted that living modified organisms containing engineered gene drives could be introduced into the environment, either accidentally or deliberately.

Concerning criterion (e)(iii), the AHTEG agreed that living modified organisms containing engineered gene drives have the potential to disseminate across national borders.

Regarding criterion (e)(iv), the AHTEG noted that living modified organisms containing engineered gene drives were likely to be utilized and/or released in the near future.

B. Stocktaking of resources on similar issues

The AHTEG concluded that resources related to risk assessment of living modified organisms containing engineered gene drives do exist and could be useful for the purpose of undertaking risk assessments. However, it was acknowledged that the resources currently available are not applicable on a global level.

The AHTEG noted the compilation of bibliographic references that had been prepared by the Secretariat as an information document for the meeting (CBD/CP/RA/AHTEG/2020/1/INF/3) and that the compilation would be revised and updated with additional references, including those provided by AHTEG members, and made available for the twenty-fourth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice.

C. Need for guidance to be developed on risk assessment of living modified organisms containing engineered gene drives

Having undertaken the review of the study and performed an analysis of the topic of living modified organisms containing engineered gene drives against annex I of decision CP-9/13, the AHTEG recommended that guidance for the risk assessment on living modified organisms containing engineered gene drives should be developed, noting that all criteria have been fulfilled.

III. adjustments to annex I of decision CP-9/13

The AHTEG considered possible adjustments to annex I of decision CP-9/13, including taking into account its experience in applying it to the specific issues of living modified fish and living modified organisms containing engineered gene drives.
The AHTEG discussed the different elements in annex I. It noted that criteria (a) through (d) should be understood as mandatory criteria while criterion (e) was "for consideration".
The AHTEG discussed the relationship between criteria (c) and (d) and noted that criterion (d) was meant to gather information and further details to substantiate the challenges identified under criterion (c).
The AHTEG noted that criterion (e)(iv) was not limited to those living modified organisms that are already or are likely to be commercialized, as the criterion also referred to those that are already or are likely to be "in use".
It was recognized that the stock-taking exercise provided for in annex I would also include work undertaken by other international bodies.
The AHTEG did not recommend any adjustments to annex I.

IV. ANALYSIS ON NEEDS AND PRIORITIES FOR FURTHER GUIDANCE IDENTIFIED BY PARTIES IN RESPONSE TO DECISION CP-VIII/2

The AHTEG considered the various topics suggested by Parties in their submissions made in response to decision CP-VIII/12, summarized in document CBD/CP/RA/AHTEG/2020/1/2 and further elaborated in the SBSTTA/22/INF/11 and SBSTTA/22/INF/12 documents. In doing so, it was noted that the mandate of the AHTEG for this task had not been elaborated very clearly.
There were different views on whether some of the topics that were identified by Parties as priorities in response to decision CP-VIII/12 should be considered under the process for identification and prioritization of specific issues on risk assessment of living modified organisms.
The AHTEG also took note of the horizon scanning process proposed by the AHTEG on Synthetic Biology and additionally suggested that there could be potential synergies between the two AHTEGs.

Background

Guidance documents (Item 15)

The history of the development and use of guidance documents under the CP is fraught. An eight year process undertaken by an AHTEG established after COP-MOP4 (BS-IV/11) failed to produce a Guidance document that was considered acceptable by the Parties (BS-VIII/12). A major difficulty that many Parties identified with the voluntary guidance was that it identified a broad range of rather generic, and often highly improbable, risks in a way that did not allow the case-by-case risk assessment of LM trees or LM mosquitos on the merits of any specific characteristics of a given modification. The difficulty with the process led to the termination of the Risk Assessment AHTEG, and the removal of the guidance document it developed from the Secretariat's Biosafety Technical Series. The AHTEG's guidance document (generally referred to as "the voluntary guidance") is available to download from the BCH website, but in draft form only.

17 months later at SBSTTA-22, there was clear consensus amongst Parties that evaluation of the need for additional guidance materials would be done through an AHTEG process, supplemented with an online forum, rather than the online forum alone, as was favoured by New Zealand. Thus, at SBSTTA-22, Parties agreed on the process that was ratified at COP-MOP10 that provided criteria for the AHTEG to evaluate a stated need for guidance. These criteria constitute Annex I of CP-9/13, and they must be fulfilled before the development of new guidance can be recommended.

It was also clear at SBSTTA-22 that little enough was known about gene drives and gene drive organisms that it would be impossible to prevent the inclusion of the development of guidance for such organisms in CP-9/13, despite the fact that any such guidance would likely be very high level, and probably not case-by-case, since gene drive organisms are still under development, and still years away from any potential release. It was clear even at SBSTTA that the outcome of any AHTEG evaluation would be to recommend the development of guidance.

This concern was accounted for in part by Parties in parallel statements regarding risk assessment of organisms resulting from Synthetic Biology in decision 14/19 as well as other LMOs in decision CP-9/13. This statement can be found in the Talking Points above, but essentially, the decisions note that any guidance developed under the auspices of the CBD should be "specific" and should also "support case-by-case risk assessment". This is to ensure that the fundamental principles of risk assessment can be taught to enable their application to specific LMOs, thereby strengthening capability amongst Parties who have identified a need for guidance.

The AHTEG that met earlier this year was the first to be convened since CP-9/13 was ratified. From a New Zealand perspective it was successful, in that the AHTEG evaluated LM fish against the criteria and decided that the development of further guidance was not warranted. As expected, the AHTEG recommended that guidance be developed for gene drive organisms. Our suggested changes to the draft decision are meant to ensure that the guidance developed remains aligned with the intent of decisions 14/19 and CP-9/13.

We note that there is a wide range of guidance for risk assessment of LMOs, and we consider the available guidance to be adequate to meet the needs of Parties that have expressed a need for guidance. However, the Secretariat has historically taken the view that the only guidance documents that are acceptable for use in maintaining compliance with the CP are those that only apply the criteria in Annex III of the CP. Annex III only allows for the assessment of risk, and not the benefit of the release of an LMO. This is inconsistent with New Zealand's national legislation (the HSNO Act) which allows for the assessment of the potential benefits of a GMO in decision making, in addition to its risks.

Thus, while New Zealand supports capability building for risk assessors, our view on guidance documents that are consistent with only Annex III of the CP and/or do not take into account case-by-case risk assessment can be described as guarded at best. While there is very little we can do about this, we can work to ensure that risk assessments are

conducted in a scientifically rigorous way, on the merits of the specific LMO under assessment.

EPA/MfE, December 2020