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Montreal, Canada, 25-30 April 2016
Item 6 of the provisional agenda*

SUMMARY OF THE PEER-REVIEW PROCESS ON SYNTHETIC BIOLOGY

Note by the Executive Secretary

I. BACKGROUND

1. In decision XII/24, the Conference of the Parties requested the Executive Secretary to submit for consideration by a meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) the peer-reviewed reports of the process established in the decision.

2. Accordingly, the Executive Secretary issued a notification[1] inviting Parties, other Governments, relevant organizations and indigenous peoples and local communities to peer review the following reports for consideration by SBSTTA at its twentieth meeting to be held in Montreal, Canada from 25 to 30 April 2016:[2]

(a) Updated report and synthesis of views in response to paragraph 7 (b) of decision XII/24;

(b) Report of the meeting of the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology.

3. A total of 32 submissions were received by the Secretariat. Among the submissions, sixteen were from Parties, one was from a non-Party, and fifteen were from organizations.[3]

4. A synthesis of the comments provided through the peer-review process is provided below.

* UNEP/CBD/SBSTTA/20/1/Rev.1.

[1] Notification SCBD/BS/CG/MPM/DA/58140 is available at http://www.cbd.int/doc/notifications/2015/ntf-2015-139-bs-en.pdf?=download.

[2] Issued as documents UNEP/CBD/SBSTTA/20/INF/11 and UNEP/CBD/SBSTTA/20/INF/12.

[3] Submissions were received from: (i) sixteen Parties: Argentina, Australia, Belgium, Brazil, Brunei Darussalam, Canada, Cuba, Finland, Germany, Hungary, Japan, Malaysia, Mexico, New Zealand, and Slovakia; (ii) one non-Party: United States of America; and (iii) fourteen organizations: Biofuelwatch; Biotechnology Industry Organization; Canadian Friends Service Committee; CropLife International A.I.S.B.L.; ETC Group: Action Group on Erosion, Technology and Concentration; Friends of the Earth U.S.; GenØk - Centre for Biosafety; Japan Bioindustry Association; Public Research and Regulation Initiative; Sociedad Peruana de Derecho Ambiental; SynBioBeta; Synthetic Biology Leadership Council; Third World Network; and Twist Bioscience). The submissions are available in their entirety at http://bch.cbd.int/synbio/peer-review/.

II. SYNTHESIS OF VIEWS

A. Key messages

5. The following are some of the emerging views that were shared by the majority of Parties:

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

(b) The operational definition as proposed by the AHTEG will be useful in guiding and facilitating further discussions on synthetic biology under the Convention. Nevertheless, given the broad scope of the proposed definition, it is also important to identify cases where synthetic biology and modern biotechnology may differ;

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

(d) *Living* organisms developed through current and near future applications of synthetic biology are similar to living modified organisms (LMOs) as defined in the Cartagena Protocol on Biosafety;

(e) *Non-living* components (such as a DNA molecule) and products (such as a chemical substance) of synthetic biology do not fall under the scope of the Cartagena Protocol;

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

6. With regard to possible ways forward, the following elements for future actions were supported by Parties:

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

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

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

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

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

B. Operational definition

7. There was general consensus among the submissions that synthetic biology is a broad term that encompasses multiple disciplines from which tools and techniques may be applied for various purposes.

8. The majority of the submissions made by Parties supported the notion that synthetic biology has elements of both continuity and novelty in relation to modern biotechnology, and agreed that the operational definition as proposed by the AHTEG may be used as a basis for further discussion among Parties and to assist in implementing the provisions of the Convention.

9. Given that synthetic biology is expanding its disciplinary boundaries and areas of application, some submissions emphasized that the operational definition must be understood as a tool to facilitate discussion on and implementation of the Convention and its Protocols rather than as a definition for legal or regulatory purposes.

10. It was also noted, in some submissions, that the proposed operational definition is too broad and does not facilitate the determination of whether or not a component, product or organism is considered to be the result of an application of synthetic biology, nor does it enable a clear differentiation between synthetic biology and modern biotechnology. In order to improve the scope of the operational definition of synthetic biology and help determine the similarities and differences of synthetic biology in relation to modern biotechnology, the compilation of a list of current applications of synthetic biology, including inclusion and exclusion criteria, was suggested.

C. Relationship between synthetic biology and biological diversity

11. In line with the conclusions of the AHTEG, the majority of the submissions were of the view that living organisms, components and products of synthetic biology fall within the scope of the Convention and that their potential benefits and potential adverse effects must be considered in relation to the three objectives of the Convention.

12. Several submissions stressed the importance of considering not only the living organisms resulting from techniques of synthetic biology, but also the non-living components and products when considering the potential benefits and adverse effects of synthetic biology on biological diversity in the context of the objectives of the Convention.

13. Some submissions were of the view that synthetic biology applications may have wider consequences on biodiversity and that it may be harder to predict the impacts of synthetic biology as compared to modern biotechnology. The importance of applying the precautionary approach when considering the adoption of synthetic biology techniques was also noted. On the other hand, some submissions were of the view that the AHTEG report does not provide compelling information to suggest that the interactions between synthetic biology and biodiversity are new or inherently different from those resulting from existing industrial activities or from modern biotechnology.

14. There was a general lack of clarity in how the access and benefit-sharing provisions of the Convention and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization may apply to synthetic biology. In this context, some submissions shared divergent views with regard to the sharing of benefits arising from the use of digital information on genetic resources, for example DNA sequence data. On the one hand, some submissions supported the recommendation of the AHTEG regarding the setting up of mechanisms under the Nagoya Protocol to clarify the issue of digital information on genetic resources as it relates to access and benefit-sharing. They also called for the establishment of traceability tools to ensure the fair and equitable sharing of the benefits arising from the utilization in synthetic biology of digital information on genetic resources. On the other hand, some submissions were of the view that digital genetic information does not fall under the scope of the Convention or the Nagoya Protocol, and regarded the reasons provided by the AHTEG as insufficient to support the setting up of mechanisms for clarifying the issue of the sharing of benefits arising from the use of such information.

15. One submission noted that the deliberations under the Convention must be framed in the context of biosafety and biodiversity, and that matters regarding intellectual property rights relating to synthetic biology, including its living organisms, must be dealt with in accordance with the relevant international treaties and national laws. In contrast, another submission noted that in spite of the Convention's objective of ensuring the fair and equitable sharing of benefits, there is no international arrangement under which intellectual property on genetic resource is adequately protected or that regulates the right to replicate and market natural products produced through the use of synthetic biology.

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

16. With a view to facilitating and advancing the dialogue on synthetic biology, some submissions agreed with the approach taken by the AHTEG in considering the terms "components" as non-living parts of a process, and "products" as the non-living outputs of a process.

17. Furthermore, the majority of the submissions supported the conclusion of the AHTEG that living organisms developed through current and near future applications of synthetic biology are LMOs, as defined in the Cartagena Protocol, and as such, fall under the scope of that Protocol.

18. The majority Parties agreed that the terms "components" and "products" of synthetic biology, when referring to non-living parts and outputs of a process, do not fall under the scope of the Cartagena Protocol. However, a few Parties noted in their submissions that products of synthetic biology could be treated as "products thereof" as per the Cartagena Protocol.

19. Some submissions agreed with the notion presented in the peer-reviewed reports that some applications of synthetic biology may fall outside the scope of the Cartagena Protocol if they are not considered to be "living" (e.g. protocells) or if new developments in synthetic biology lead to living organisms that no longer possess "a novel combination of genetic material obtained through the use of modern biotechnology". These submissions called for a constant review of risk assessment methodologies and noted that new biosafety approaches would be needed to regulate these applications and organisms.

20. In elaborating on the similarities between organisms developed through synthetic biology and LMOs, one submission noted that current techniques of synthetic biology do not develop organisms that are entirely synthetic but rather create artificial genetic material, which is inserted into existing cells from which the original genetic material has been removed.

21. Furthermore, another submission noted that, in the event that no consensus can be reached on whether or not an application of synthetic biology is considered to be "living" or whether an organism resulting from synthetic biology is an LMO, it would be more precautionary to treat such cases as living organisms, unless proved otherwise, in order to ensure that adequate risk assessments take place and more effectively manage the risks associated with their unintentional release.

E. Adequacy of existing national and international instruments to regulate the organisms, components and products of synthetic biology

22. There were diverging views among the submissions with regard to the adequacy of national and international regimes to regulate the components, organisms and products of synthetic biology.

23. Some submissions noted the gaps identified in the peer-reviewed documents and determined that existing information is inconclusive with regards to whether or not existing national and international regimes are adequate to regulate living organisms and non-living components and products of synthetic biology.

24. Some submissions also noted that an effective and transparent review of current instruments is critical for ensuring the establishment of a robust framework for synthetic biology, in particular focusing on countries that lack their own domestic regulations, and supported the AHTEG recommendation to "assess potential gaps in oversight under the Convention and its Protocols with regard to components and products of synthetic biology". In this context, some submissions called for an assessment of potential

gaps under the Convention's framework, which would focus not only on the components and products of synthetic biology, but also on the organisms.

25. On the other hand, some submissions were of the view that not enough evidence was provided in the peer-reviewed reports to demonstrate the existence of gaps in national and international regimes or to support the need for further assessment. In particular, it was noted that "there has been no comprehensive examination of the scope of international and national frameworks applicable to the non-living components and products of synthetic biology by this forum, therefore no conclusions can be drawn on whether or not these include socio-economic considerations, or whether these are even relevant or appropriate in the context".

26. Furthermore, some submissions did not support the conclusion of the AHTEG that "an environmental and commercial release of organisms resulting from synthetic biology must not be performed until procedures and regulatory processes or international regulatory frameworks are in place to ensure the protection of ecological systems" noting that there are regimes already in place, particularly under biosafety regulations, including at national level, that may serve as a basis to ensure the safety of organisms resulting from synthetic biology.

F. Potential benefits and potential adverse effects of organisms, components and products of synthetic biology

27. The majority submissions supported the approach of the AHTEG to examine the potential benefits and potential adverse effects of synthetic biology with reference to the three objectives of the Convention. This approach can help highlight applications that may warrant closer scrutiny. However, it was noted that while the list of potential benefits and potential adverse impacts as compiled by the AHTEG is comprehensive, it is not exhaustive.

28. While some submissions were of the view that the increased complexity of synthetic biology applications will lead to more uncertainty and/or a broader range of impacts, other submissions were of the view that there is no causal link between the complexity of a process and its potential impacts, arguing that synthetic biology could lead to more predictable outcomes than current technologies.

29. There were several submissions that provided feedback on individual potential benefits and potential adverse effects as identified by the AHTEG.

30. To reach a better understanding of the potential benefits and potential adverse effects of synthetic biology effects and to identify which specific applications pose concerns, several submissions noted the importance of continuously collecting and sharing information among all stakeholders.

G. Best practices on risk assessment and monitoring regimes and degree to which the existing arrangements constitute a comprehensive framework in order to address impacts of organisms, components and products of synthetic biology

31. Some submissions regarded the existing principles and methodologies of risk assessment and risk management as established for LMOs under national biosafety frameworks and the Cartagena Protocol as insufficient while others regarded them as fully adequate. However, most submissions considered the existing principles and methodologies of risk assessment and risk management of LMOs as good starting points, and considered that building on existing international, regional and national biosafety frameworks is the best approach for assessing, managing and preventing potential adverse effects arising from components, organisms and products of synthetic biology.

32. Several submissions noted that an assessment of potential impacts based on past experience would not be robust enough to capture key issues of synthetic biology. It was also noted that the continued development and increasing level of complexity of synthetic biology applications are likely to lead to less familiarity with its components, organisms and products and existing methodologies will no longer be sufficient to assess their risks. These submissions further noted the importance of keeping the developments in the synthetic biology under constant review and considering the need to revise and further develop methodologies to fully assess environmental and societal impacts of these applications.

33. The lack of appropriate comparators was identified as one of the existing challenges in applying current methodologies of risk assessment, which are based on a comparative approach, to the assessment of synthetic biology organisms. In contrast, one submission noted that in the event non-modified comparators are lacking, the risks of organisms and products of synthetic biology may be assessed using positive and negative controls as it is done in toxicological and pharmaceutical studies.

34. Furthermore, some submissions noted that stringent risk assessments must also be carried out in relation to applications that are destined for "contained use" as there is always some level of risk of release, either unintentionally or intentionally, and this risk must be assessed and factored into the development and implementation of risk management strategies.

35. Some submissions also noted the importance of assessing the impacts, including the potential benefits and potential adverse effects, of synthetic biology applications from environmental, cultural, ethical and socioeconomic perspectives, on a case-by-case basis and, whenever possible, in an evidence-based manner.

H. Suggestions of possible ways forward

36. The following is a list of some possible ways forward for future action as identified by Parties in their submissions:

General

(a) Further discussion on the application of the precautionary approach in light of a lack of history of safe use of synthetic biology applications and in order to avoid significant reduction or loss of biological diversity;

(b) Reassessment of synthetic biology against the criteria for "new and emerging issues" before carrying out further work;

Relationship between synthetic biology and modern biotechnology

(c) Development of a list compiling current applications of synthetic biology to help determine the similarities and differences of synthetic biology in relation to modern biotechnology;

(d) Further clarification on the differences between organisms developed through synthetic biology and LMOs to determine which of the former, if any, would be outside the scope of the Cartagena Protocol;

Positive and negative impacts of synthetic biology

(e) A continuous monitoring process of the components, organisms and products of synthetic biology, taking into account the feasibility, cost and effectiveness of the process;

(f) Discussions on the potential for and measures to minimize the likelihood of unintentional and illegal transboundary movements of organisms resulting from synthetic biology;

Knowledge and information sharing

(g) The setting up of a central online portal under the Biosafety Clearing-House of the Cartagena Protocol or the clearing-house mechanism of the Convention for sharing knowledge and information and to support an international dialogue on synthetic biology. According to the submissions, the online portal would, among other things:

i. Be easily accessible, open to all interested participants and operate for an indefinite period of time;

ii. Bring together the ideas and concerns of different stakeholders, including the scientific community and general public;

iii. Facilitate discussion on potential benefits and potential adverse effects of synthetic biology;

iv. Facilitate coordination with other international organizations and agreements;

v. Build capacity through the exchange of knowledge and experience between the research community, risk assessors and policymakers, and help bridge the gaps in communication between different actors;

vi. Facilitate the compilation of the existing relevant body of knowledge and information on, for example, best practices on risk assessment, risk management and monitoring; organisms developed through the use of synthetic biology; national laws, decisions and other communications; and submissions by different stakeholders;

(h) Improving the capacity of countries to assess the potential impacts of synthetic biology and to enhance public awareness, education and participation;

Adequacy of existing instruments to regulate the components, organisms and products of synthetic biology

(i) A detailed analysis of the application of the Cartagena Protocol to evolving techniques of synthetic biology, particularly when processes do not involve in vitro nucleic acid techniques and/or novel combination of genetic material, in order to avoid leaving any unidentified gaps or creating unnecessary overregulation relating to living organisms of synthetic biology;

(j) A detailed gap analysis on the level of coverage or the adequacy of existing instruments to regulate the components, products and organisms of synthetic biology, taking into account cultural, socioeconomic and ethical considerations and the extent to which guidance on how to incorporate these considerations is already available in other international forums;

Coordination between the Convention and its Protocols

(k) Coordination with current processes under the Cartagena Protocol on Biosafety in particular with the AHTEG on Socio-economic Considerations and the AHTEG on Risk Assessment and Risk Management (pending decisions of the COP-MOP of the Cartagena Protocol extending these groups);

(l) Discussions on the impacts of synthetic biology in light of access and benefit-sharing and the Nagoya Protocol, including participation of indigenous peoples and local communities, and the development of traceability tools to ensure the fair and equitable sharing of the benefits arising from the utilization of genetic resources in synthetic biology;

Coordination with other international organizations

(m) Addressing synthetic biology in a coordinated manner by establishing synergies with other United Nations and international organizations whose mandates are relevant to synthetic biology, and in particular those that comprise the majority of the CBD members, taking into account potential synthetic biology applications in different fields;

(n) Further analysis of information relating to synthetic biology and knowledge gaps currently being considered under other international forums, including bioethics and biosecurity concerns, in order to avoid duplication of efforts across other international agreements;

(o) Thorough consideration of the objectives of any actions to promote the development of guidelines, public awareness, communication and education, and ethical considerations.

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