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Item 11 of the provisional agenda*

OUTLINE OF GUIDANCE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS DEVELOPED THROUGH SYNTHETIC BIOLOGY

Note by the Executive Secretary

1. In its decision BS-VII/12, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP) welcomed the results of the testing of the Guidance on Risk Assessment of Living Modified Organisms, and invited Parties, other Governments and relevant organizations to test or use, as appropriate, the Guidance in actual cases of risk assessment and as a tool for capacity-building activities in risk assessment.

2. In the same decision, the Parties extended the mandate of the Open-ended Online Expert Forum on Risk Assessment and Risk Management (Online Forum) and the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management, and expanded its composition to include one new member from each region.

3. In the terms of reference for the Online Forum and AHTEG, the Parties established a mechanism for revising and improving the Guidance on the basis of the feedback provided through the testing process with a view to having an improved version of the Guidance by the eighth meeting. The AHTEG was also requested to make an attempt, while revising and improving the Guidance, to take into account the topics prioritized by the AHTEG, on the basis of the needs indicated by the Parties with a view to moving towards operational objectives 1.3 and 1.4 of the Strategic Plan and its outcomes, for the development of further guidance.

4. The annex to the present document contains an outline of guidance on risk assessment of living modified organisms developed through synthetic biology as one of the outcomes of the work of the AHTEG, with input from the Online Forum, in response to decision BS-VII/12 for the consideration of the Conference of the Parties serving as the meeting of the Parties to the Protocol, at its eighth meeting. The annex was not edited.

* UNEP/CBD/BS/COP-MOP/8/1.

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Annex

OUTLINE OF GUIDANCE ON "RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS DEVELOPED THROUGH SYNTHETIC BIOLOGY"

BACKGROUND

The COP-MOP, in its decision BS-VII/12, recommended to the COP a coordinated approach among the two Governing Bodies on the issue of synthetic biology taking into account that the provisions of the Cartagena Protocol may also apply to living organisms resulting from synthetic biology.

The COP, in its decision XII/24, noted the recommendation of the COP-MOP, and urged Parties and invited other Governments to take a precautionary approach, and to establish, or have in place, effective risk assessment and management procedures and/or regulatory systems to regulate environmental release of any organisms, components or products resulting from synthetic biology techniques, consistent with Article 3 of the Convention. The COP also, among other things, established an AHTEG on Synthetic Biology with terms of reference annexed to that decision.

The AHTEG on Synthetic Biology met in September 2015 and, among its conclusions, recommended to the COP to "urge Parties to address synthetic biology in a coordinated manner within the context of the objectives of the Convention and its Protocols, particularly by tapping into existing processes, such as the AHTEG on Risk Assessment and Risk Management".

At its meeting held in November 2015, in response to paragraph 2 of its terms of reference to take into account the previously prioritized topics for the development of further guidance, which included RA of LMOs developed through synthetic biology, the AHTEG on Risk Assessment and Risk Management took into account the recommendations to work in a coordinated manner with other processes under the CBD, and decided to recommend to the COP-MOP the development of additional guidance on the topic. Furthermore, pending the outcomes of the twentieth meeting of SBSTTA that could impact the development of further guidance on the topic, the AHTEG also decided to prepare an outline on the topic for the COP-MOP in order to facilitate its consideration on further development of the topic as separate guidance.

At its twentieth meeting held in April 2016, the SBSTTA, in its recommendation XX/8, noted that (i) the general principles and methodology for risk assessment under the Cartagena Protocol and existing biosafety frameworks provide a good basis for risk assessment regarding living organisms developed through current and near future applications of synthetic biology, but such methodologies may need to be updated and adapted for current and future developments and applications of synthetic biology, and (ii) coordination is needed among current and future processes under the Convention and its Protocols, including with the AHTEG on Risk Assessment and Risk Management.

Following the outcomes of the SBSTTA meeting and to provide input to the AHTEG on Risk Assessment and Risk Management, the Online Forum on Risk Assessment and Risk Management discussed possible considerations during the environmental risk assessment of LMOs developed through synthetic biology.[1] During the online discussions, views diverged as to whether or not guidance on risk assessment of LMOs developed through synthetic biology was presently needed.

INTRODUCTION

At its meeting held in July 2016, taking into account the recommendations for a coordinated approach with other processes under the CBD and with a view to moving towards objective 1.3 of the Strategic Plan for the Cartagena Protocol to "put in place further tools and guidance necessary to make the Protocol fully operational" with an outcome of having "guidance on risk assessment and risk management including guidance on new developments in modern biotechnology", the AHTEG on Risk

1 The discussion is available at http://bch.cbd.int/onlineconferences/onlineconferences/forum_ra/discussion.shtml.

Assessment and Risk Management developed an outline containing specific considerations regarding the risk assessment of LMOs developed through current and near-future applications of synthetic biology.

It is noted that some members of the AHTEG were of the view that guidance should be developed as soon as possible to update and adapt risk assessment methodologies to LMOs developed through synthetic biology. Some other members of the AHTEG were of the view that it is premature to develop guidance on LMOs developed through synthetic biology. The latter AHTEG members were of the view that current methodologies of risk assessment are adequate to address risks of LMOs developed through synthetic biology, and that monitoring of the advances in synthetic biology would be a more appropriate way forward.

This outline and specific considerations for the development of guidance, as contained in the next section of this document, aim at assisting the COP-MOP at its eighth meeting in deliberations under agenda item 11.

SPECIFIC CONSIDERATIONS

Synthetic biology has both aspects of continuity and novelty in relation to modern biotechnology. It may lead to the development of LMOs containing new significantly different features from those in the original organism or from organisms existing in nature.

(a) The choice of comparators

The comparative approach may not be suitable or sufficient for the risk assessment of LMOs developed through synthetic biology in cases where the depth or kind of intervention result in LMOs whose genomes differ substantially from those in existing organisms, such as LMOs with novel genes from multiple sources. The lack of suitable comparators or the need to use multiple comparators may require special consideration by risk assessors.

Particular attention needs also to be given to *de novo* genes and *de novo* metabolic pathways, or where new traits may be introduced into the environment, either intentionally or unintentionally.

(b) LMOs being developed faster and with an increased number of modified traits

Synthetic biology aims at increasing the precision and the predictability of the changes in the resulting organisms, and may also lead to a faster development of LMOs through the use of automation and to more numerous and complex changes and novel traits. The evaluation of the overall risk of such LMOs may become more complex.

With the increased rate and complexity of these new developments, current risk assessment methodologies may not be adequate and may need to be adapted.

(c) Potential to alter wild populations, species and ecosystems

Synthetic biology techniques may make efficient use of existing mechanisms called “gene drives” to modify traits that are intended to be passed on to entire wild populations, instead of only to some members of the population. Gene drive systems may be able to address serious threats to health and ecosystems by, for example, eliminating diseases and eradicating invasive alien species, but gene drives may also cause irreversible adverse effects on beneficial organisms and ecosystems by, for example, causing “gene erosion”.

Tools that support synthetic biology, such as high throughput DNA sequencing and computational analyses, may make it easier to develop LMOs containing gene drive systems. Risk assessment methodologies may need to be adapted in order to fully assess the potential adverse effects of gene drive systems.

(d) LM microorganisms resulting from synthetic biology

Some applications of synthetic biology aim at developing microorganisms for intentional release into the environment. Current risk assessment methodologies may not be adequate to assess environmental risks

of complex LM microorganism developed through synthetic biology and therefore may need to be adapted.

(e) Increased accessibility to techniques of synthetic biology

In some countries, synthetic biology approaches are becoming more accessible and easy to use by the general public through "do-it-yourself" citizen scientist projects in particular in jurisdictions that do not have regulations to limit their use or the means to ensure compliance to existing regulations.

The increased number of LMOs developed outside of formally established laboratory facilities may change the way in which public awareness and risk management methodologies are used to avoid or minimize the potential adverse effects of such LMOs.

LMOs developed by citizen scientists may escape containment and be introduced into the environment. Therefore, considerations of the risks of such LMOs may guide future policy makers in adopting measures to ensure the safe handling and use of such LMOs.

(f) Detection of LMOs developed through synthetic biology using genome editing

Synthetic biology may use genome editing to modify organisms. Methods to detect and identify LMOs, and their specificity, sensitivity and reliability are a point to consider in Annex III of the Protocol. Genome editing may create multiple simultaneous changes across the genome. The resulting LMOs may not be easily characterized or detected through methods that are currently in use for this purpose.

It may be difficult to assess the rate of outcrossing of LMOs containing small off-target changes at the DNA level during pre-market risk assessments and to detect such LMOs during post-market risk management and monitoring.

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