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Item 4 of the provisional agenda**

RISK ASSESSMENT AND RISK MANAGEMENT OF LIVING MODIFIED ORGANISMS

Note by the Executive Secretary

INTRODUCTION

1. In decision [CP-VIII/12](#), paragraph 6, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety invited Parties to submit to the Executive Secretary (a) information on their needs and priorities for further guidance on specific topics of risk assessment of living modified organisms (LMOs), (b) proposals on criteria, including the technical justification, that may facilitate the selection of topics for the development of further guidance, and (c) views on perceived gaps in existing guidance materials.
2. In paragraph 7 of the same decision, the meeting of the Parties extended the Online Forum on Risk Assessment and Risk Management to exchange experiences on risk assessment, provide information and views on, and perceived gaps in existing guidance materials, and proposals to address any gaps identified. Furthermore, the meeting of the Parties invited its Bureau to appoint a lead moderator to moderate and report on the online discussions.
3. The Subsidiary Body on Scientific, Technical and Technological Advice was requested to review the information provided and to recommend a way forward to address the needs, priorities and gaps identified by Parties for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its ninth meeting, including the possible establishment of a new ad hoc technical expert group.
4. Section I of the present document describes the activities undertaken in the light of the above-mentioned mandates. Section II provides an overview of the submissions made by Parties and of the online discussions of the online forum risk assessment and risk management. Section III outlines possible elements of a recommendation.

I. OVERVIEW OF ACTIVITIES

5. In accordance with the request in decision CP-VIII/12, paragraph 6, the Executive Secretary issued a notification to Parties on 12 April 2017.¹
6. In response to the notification, a total of 19 submissions were received from Parties (Austria, Belarus, Bolivia, Brazil, Bulgaria, Costa Rica, European Union, Finland, France, Honduras, Italy, Japan, Malaysia,

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** [CBD/SBSTTA/22/1](#).

¹ [SCBD/SPS/DC/MPM/MW/86376](#).

Mexico, New Zealand, Nigeria, Norway, Republic of Moldova and South Africa). In addition, three non-Parties to the Cartagena Protocol (Australia, Canada and United States of America) submitted views. A detailed synthesis of the submissions by Parties is provided in information document CBD/SBSTTA/22/INF/11. The full submissions are available online at: http://bch.cbd.int/protocol/cpb_art15_submissions.

7. Discussions under the Open-ended Online Forum on Risk Assessment and Risk Management were convened through the Biosafety-Clearing House from 29 January to 12 February 2018 and moderated by Mr. Timothy Strabala of New Zealand.² The topics for discussion were drawn from the decision, as follows:

- (a) Sharing experiences on risk assessment of living modified organisms;
- (b) Information and views on existing guidance materials on risk assessment;
- (c) Perceived gaps in existing guidance materials on risk assessment, and proposals to address any gaps identified.

8. A total of 110 interventions were made, during the online discussions on the three topics, by 48 different participants, among which 31 were nominated by Parties, 2 by other Governments and 15 by organizations.

9. A draft report on the online forum discussions was prepared by the lead moderator, with assistance from the Secretariat, and was submitted for peer review by the online forum from 26 February to 12 March 2018. All comments received through the peer-review process are available through the Biosafety Clearing-House.³ The resulting final report of the online forum, as prepared by the lead moderator, is provided in information document CBD/SBSTTA/22/INF/12.

II. OVERVIEW OF SUBMISSIONS AND DISCUSSIONS UNDER THE ONLINE FORUM

10. The importance of sharing knowledge and experience in risk assessment among countries was widely recognized.

11. There was general agreement, both among Parties through their submissions and by individual experts through the online forum, that existing guidance materials on risk assessment are useful and provide a good basis for the assessment of LMOs. Participants in the online forum shared views on the perceived strengths and weaknesses of the various available guidance documents. The interventions included numerous sources of information for risk assessment, including the Biosafety Clearing-House and guidance developed by various governments.

12. However, Parties identified a number of gaps in existing guidance on risk assessment of LMOs, including lack of information on how:

- (a) To perform the assessments when appropriate comparators do not exist;
- (b) To address uncertainty in risk assessment of LMOs with complex traits;
- (c) To adequately address human health and socio-economic considerations during the risk assessment;
- (d) To assess the impact of LMOs on the state and dynamics of biodiversity in interaction with agriculture (for example, farmland birds);
- (e) To manage the risks identified during the risk assessment process;
- (f) To deal with incomplete data from monitoring;
- (g) To draw lessons from the observations currently available;
- (h) To make existing material more accessible to less experienced risk assessors.

² The discussions are available at: https://bch.cbd.int/onlineconferences/forum_ra/discussion.shtml.

³ https://bch.cbd.int/onlineconferences/forum_ra/peer-review.shtml.

13. Views regarding the current need for additional guidance were heterogeneous, with the majority of Parties that had made submissions on this issue indicating the need for development of further guidance on specific topics of risk assessment. However, while many interventions in the online forum indicated gaps in existing guidance and put forward a number of topics as needing more development, the majority of interventions made in the forum were of the view that there are no gaps in the existing guidance materials and, therefore, no new guidance is needed. Furthermore, some Parties and participants of the forum noted the importance of sharing experiences on risk assessment.

14. In their submissions, 12 Parties recommended that new guidance be developed on specific topics of risk assessment to provide additional assistance in addressing issues for which the guidelines already available are not sufficient, in particular in relation to new developments which may pose new challenges for risk assessment and require new approaches. Of these Parties, 8 identified the topic of “risk assessment of organisms developed through synthetic biology, including organisms produced through genome editing and organisms containing engineered gene drives” as priorities. Another 8 Parties identified the topic of “risk assessment of living modified fish” as a priority. Other topics, identified by three Parties were: risk assessments of living modified animals/mammals, arthropods (including insects and molluscs), and of microorganisms and viruses, risk assessment of the effects of LMOs on soil-dwelling organisms, and the co-existence between LMOs and non-LMOs in the context of small-scale farming. These topics were also identified by some participants in the online forum. Justifications for the identification of the topics are provided in the submissions and/or the report of the online forum.

15. The outcomes of the work of the Ad Hoc Technical Expert Group on Synthetic Biology, established under the Convention, are also relevant in this context.⁴

16. Parties also shared views on the process for the selection of topics for the development of new guidance on risk assessment. A process was proposed to assist in the identification of topics for the development, under the Cartagena Protocol, of further guidance on risk assessment, taking into account resources on similar issues that have been developed by national, regional and international bodies, and analysing the extent to which the specific topics:

- (a) Fall within the scope and objective of the Cartagena Protocol;
- (b) Pose challenges to existing risk assessment frameworks and methodologies;
- (c) Involve technical knowledge and expertise that are available in the scientific community at large;
- (d) Concern techniques with a high pace of scientific and technological advancement;
- (e) Concern LMOs that:
 - (i) Have the potential to cause serious or irreversible adverse effects on biodiversity, taking into account the urgent need to protect specific aspects of biodiversity such as an endemic/rare species, or a unique habitat or ecosystem;
 - (ii) May be introduced into the environment either deliberately or accidentally;
 - (iii) Have the potential to disseminate across territorial borders;
 - (iv) Are already, or are likely to be, commercialized or in use somewhere in the world.

17. Another prominent issue discussed during the online forum was whether or not benefit analysis should be included as part of the risk assessment. Opinions diverged between those who supported this view and those who considered that benefit analysis should be done outside the risk assessment. It was also noted by some participants that benefit analysis does not fall under the scope of the Cartagena Protocol.

⁴ See CBD/SBSTTA/22/4.

III. SUGGESTED RECOMMENDATIONS

18. 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 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 decisions BS-[VII/12](#) and [XII/24](#) recommending a coordinated approach on the issue of synthetic biology,

1. *Notes* the availability of numerous guidance documents and other resources to support the process of risk assessment, but *recognizes* the gaps and needs identified by some Parties;

2. *Recognizes* the divergence of views among Parties on whether or not additional guidance on specific topics of risk assessment is needed;

3. *Takes note* of the work of the Ad Hoc Technical Expert Group on Synthetic Biology, and in particular, *notes* that, while there can be potential benefits arising from organisms containing engineered gene drives, additional research and guidance are needed before any such organism can be considered for release into the environment, including into lands and territories of indigenous peoples and local communities;

4. *Calls for* broad international cooperation to assess the potential adverse effects to the conservation and sustainable use of biodiversity, taking into account human health, from organisms produced through genome editing, organisms containing engineered gene drives and living modified fish;

5. *Decides* to carry out a comprehensive study regarding the potential adverse effects to the conservation and sustainable use of biodiversity, taking into account human health, and including considerations that are relevant to the risk assessment of (a) organisms produced through genome editing and organisms containing engineered gene drives, and (b) living modified fish, in order to inform further consideration of whether there is a need for the development of additional guidance materials on risk assessment for these organisms;

6. *Also decides* to establish a process for the identification and prioritization of specific issues of risk assessment of living modified organisms that may warrant future consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol, taking into account the elements listed in the annex to the present draft decision;

7. *Further decides* to establish an ad hoc technical expert group on risk assessment, composed of experts selected in accordance with the consolidated modus operandi of Subsidiary Body on Scientific, Technical and Technological Advice,⁵ to work on issues referred to in paragraphs 5 and 6 above and to prepare a report for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice with a view to enabling the Subsidiary Body to prepare a recommendation for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its tenth meeting;

8. *Decides* to extend the online forum on risk assessment and risk management so that it may assist the ad hoc technical expert group on risk assessment;

9. *Requests* the Executive Secretary:

(a) To collect and synthesize relevant information to facilitate the work of the online forum and the ad hoc technical expert group;

(b) To assist the lead moderator of the online forum in convening discussions and reporting on the results of the discussions;

⁵ [Decision VIII/10](#), annex III.

(c) To convene, subject to the availability of resources, a face-to-face meeting of the ad hoc technical expert group on risk assessment.

Annex

Identification and prioritization of specific issues of risk assessment of living modified organisms that may warrant future consideration

The process for recommending specific issues of risk assessment for consideration by the Parties to the Cartagena Protocol should include a stock-taking exercise to determine if resources on similar issues have been developed by national, regional and international bodies and, if so, whether such resources can be revised or adapted to the objective of the Cartagena Protocol, as appropriate, and a structured analysis to evaluate the extent to which the specific issues:

- (a) Fall within the scope and objective of the Cartagena Protocol;
 - (b) Pose challenges to existing risk assessment frameworks and methodologies;
 - (c) Involve technical knowledge and expertise that are available in the scientific community at large;
 - (d) Concern techniques with a high pace of scientific and technological advancement;
 - (e) Concern living modified organisms that:
 - (i) Have the potential to cause serious or irreversible adverse effects on biodiversity, taking into account the urgent need to protect specific aspects of biodiversity such as an endemic/rare species, or a unique habitat or ecosystem;
 - (ii) May be introduced into the environment either deliberately or accidentally;
 - (iii) Have the potential to disseminate across territorial borders;
 - (iv) Are already, or are likely to be, commercialized or in use somewhere in the world.
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