





# Convention on Biological Diversity

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CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY SERVING AS THE MEETING OF THE PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY

Seventh meeting

Pyeongchang, Republic of Korea, 29 September - 3 October 2014

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

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

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

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

Also recalling decision BS-VI/12, in particular that the Guidance on Risk Assessment of Living Modified Organisms<sup>1</sup> is not prescriptive and does not impose any obligations on Parties,

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

- 1. Welcomes the results of the testing of the Guidance on Risk Assessment of Living Modified Organisms;
- 2. *Invites* Parties, other Governments and relevant organizations to test or use, as appropriate, the Guidance in actual cases of risk assessment and as a tool for capacity-building activities in risk assessment;
- 3. Establishes the mechanism outlined in the annex to this decision for revising and improving the Guidance on the basis of the feedback provided through the testing with a view to having an improved version of the Guidance by its eighth meeting;

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

- 4. *Extends* the Open-ended Online Expert Forum (Online Forum) on Risk Assessment and Risk Management and the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management to work, primarily online and, subject to the availability of funds, through a face-to-face meeting, with revised terms of reference as annexed to this decision, and *expands* the composition of the AHTEG to add one new member from each region;
- 5. *Invites* Parties to submit (a) information on their needs and priorities for further guidance on specific topics of risk assessment of living modified organisms, and (b) existing guidance on specific topics of risk assessment of living modified organisms;
- 6. *Requests* the Executive Secretary to synthesize the views submitted through paragraph 5 above for consideration of the eighth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol;
- 7. Agrees to consider, at its eighth meeting, the need for the development of further guidance on topics prioritized on the basis of the needs indicated by the Parties with a view to moving towards operational objectives 1.3 and 1.4 of the Strategic Plan and its outcomes;
- 8. *Invites* Parties, other Governments and relevant organizations to confirm the nominations of their experts who are currently participating in the Online Forum on risk assessment and risk management, *requests* the Executive Secretary to remove the records of experts whose nominations have not been confirmed, and further *invites* Parties, other Governments and relevant organizations to nominate additional experts to join the Online Forum using the format for the nomination of experts to the Roster of Experts;
- 9. *Requests* the Executive Secretary to continue facilitating the work of the Online Forum and the AHTEG;
- 10. Also requests the Executive Secretary to improve the mechanism established in paragraph 6 of decision BS-VI/12 for updating background documents to the Guidance as follows:
- (a) Extend the period for commenting on the background documents to three weeks and send an automatic reminder after two weeks to the group operating the mechanism;
- (b) Raise awareness of the background documents linked to the Guidance by, for example, adding information and links in the Biosafety Clearing-House and inviting experts in the specific topics of the Guidance to submit background documents;
- (c) Index the background documents for author affiliation, for example, government, academic institutions, non-governmental organizations and business;
  - 11. Welcomes the package that aligns the Guidance and Training Manual;
- 12. *Invites* Parties and other Governments and relevant organizations to test or use, as appropriate, the package as a tool for, inter alia, capacity-building in risk assessment;
- 13. *Requests* the Executive Secretary, subject to the availability of funds, to conduct capacity-building activities in risk assessment using the aligned package;
- 14. *Invites* Parties, other Governments and international organizations to provide funds and in-kind assistance to implement the capacity-building activities referred to in paragraph 13 above;
- 15. Welcomes the creation of sections in the Biosafety Clearing-House where scientific information can be submitted and retrieved regarding living modified organisms or specific traits that may have or that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health;
- 16. *Invites* Parties, other Governments and relevant organizations to continue submitting, through the Biosafety-Clearing House, the information referred to in paragraph 15 above;

17. *Recommends* to the Conference of the Parties to the Convention on Biological Diversity a coordinated approach with the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety on the issue of synthetic biology, taking into account that the provisions of the Protocol may also apply to living organisms resulting from synthetic biology.

#### Annex

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

### Methodology

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

### Expected outcome

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

### Reporting

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

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