



## Convention on Biological Diversity

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English only

### Global risk assessment workshop Montreal, Canada, 30 and 31 October 2023

#### Annotated provisional agenda

1. In its decision [CP-10/4](#), the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety adopted the Capacity-building Action Plan for the Cartagena Protocol on Biosafety for the period to 2030 which includes specific goals to support Parties to carry out scientifically sound risk assessments of living modified organisms (LMOs).
2. Furthermore, in decision [CP-10/10](#), the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety requested the Executive Secretary to explore ways to facilitate and support capacity-building and knowledge-sharing and technology transfer regarding risk assessment and risk management of living modified organisms.
3. In response to decision [BS-VII/12](#) on risk assessment and risk management, the Republic of Korea created the “Korea Biosafety Capacity-Building Initiative” for the implementation of the Protocol. The Korea Biosafety Capacity-Building Initiative was aimed at supporting Parties to implement the Cartagena Protocol on Biosafety through capacity-building activities for the period 2015 to 2020. The key focus of the initiative was to strengthen the capacities of Parties to (a) conduct and evaluate risk assessments and manage, monitor and control risks of LMOs; (b) detect and identify LMOs; (c) use the Biosafety Clearing-House; and (d) conduct a safety management (training) programme. Following the delays in the completion of the programme as a result of the global pandemic, the initiative was extended until 2024.
4. Against this background, and with the generous support of the Government of the Republic of Korea, the Secretariat of the Convention on Biological Diversity is organizing a global workshop under the theme “Advances in risk assessment – Twenty years of theory and practice”, to be convened in Montreal, Canada on 30 and 31 October 2023. The workshop will contribute to the advancement of LMO risk assessment and risk management practices, ultimately ensuring the safe and responsible use of LMOs in a way that protects human health and the environment.
5. The objective of this workshop is to provide a platform for experts and stakeholders from around the world to come together and exchange knowledge, experiences, and best practices related to the risk assessment of LMOs. The workshop will focus on enhancing understanding of regulatory frameworks, methodologies and decision-making processes surrounding LMO risk assessments, as well as exploring emerging challenges and potential solutions.
6. The workshop is being organized by the Secretariat of the Convention on Biological Diversity back-to-back with the meeting of the Ad Hoc Technical Expert Group on Risk Assessment established in decision [CP-10/10](#) scheduled to be held from 1 to 3 November 2023, and is funded by the Government of the Republic of Korea through the Korea Biosafety Capacity-Building Initiative.
7. The workshop will be held as a hybrid event, with both in-person and virtual participation options to maximize global accessibility. The workshop will be conducted in English only. Documents for the workshop will be made available at [www.cbd.int/meetings/CP-RA-OM-2023-01](http://www.cbd.int/meetings/CP-RA-OM-2023-01).

## **Item 1**

### **Opening of the workshop**

8. The workshop will be opened by a representative of the Secretariat of the Convention on Biological Diversity at 9 a.m. on 30 October 2023. A representative of the Government of the Republic of Korea will also make opening remarks.

## **Item 2**

### **Overview and objectives of the workshop**

9. Under this item, a presentation on the objectives and expected outcomes of the workshop will be made. Participants will be invited to consider the provisional agenda and organization of work as contained in the annex to the present document will be introduced.

## **Item 3**

### **Milestones, challenges, and future directions in risk assessment of living modified organisms**

10. Under this agenda item, invited experts will deliver keynote speeches highlighting important milestones, challenges, and future directions in LMO risk assessments from the perspectives of national competent authorities, industry, civil society and indigenous peoples and local communities. The scene-setting presentations will consider developments in risk assessment over the past 20 years with a view to setting the scene for the discussions in the workshop.

11. Following the expert presentations, regional and national case studies will be presented to highlight the developments in risk assessment globally.

## **Item 4**

### **Emerging technologies and their impact on risk assessment (group discussions)**

12. Under this agenda item, introductory expert presentations will be made on LMOs developed through synthetic biology, engineered living modified gene drive organisms and advances in genome editing. These presentations will be used as a basis for facilitated group discussions on key concepts and implications of risk assessment and risk management in the context of the Cartagena Protocol on Biosafety. The outcomes of the facilitated discussions will be considered in the recommendations for further deliberations under item 8 of the agenda.

13. Participants will be divided into breakout groups to discuss, in further detail, the potential issues, capacity needs, skills gaps and recommendations for risk assessment for emerging technologies.

## **Item 5**

### **Methodologies and tools for conducting risk assessments**

14. Under this item, expert presentations will be made on risk assessment methodologies and tools, as well as the role of modelling in risk assessment and risk management. These expert presentations will be followed by regional and national examples of applications of risk assessment methodologies in actual cases of risk assessment. Participants will be invited to make presentations of about 15 minutes each, providing a summary of the extent to which, and ways in which, risk assessment methods and tools have been applied in their countries.

## **Item 6**

### **International policy developments relevant to risk assessment**

15. Under this agenda item, the Secretariat and a resource person will present background information on the relevant aspects of the Kunming-Montreal Global Biodiversity Framework, and the Implementation and Capacity-building Action Plans for the Cartagena Protocol on Biosafety.

16. An introductory presentation will be made on the consensus document on the “Environmental Considerations for Risk/Safety Assessment for the Release of Transgenic Plants” developed by the

Working Group on the Harmonisation of Regulatory Oversight in Biotechnology of the Organisation for Economic Cooperation and Development.

**Item 7**

**Lessons learned, capacity needs, skills gaps and recommendations on capacity-building for risk assessment**

17. Under this item, participants will share best practices and success stories in LMO risk assessment from different regions that participated in the Korea Biosafety Capacity-Building Initiative. The participants will be invited to reflect on the relevant aspects under the Capacity-building Action Plan that could be further elaborated upon for the development of a new capacity-building initiative for risk assessment.

**Item 8**

**Considerations for the risk assessment programme of work**

18. Under this agenda item, the participants will consider the outcomes of the facilitated discussions under agenda item 4. Based on the discussions held during the workshop, participants will also discuss high-level elements and outcomes in preparation for the eleventh meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol.

**Item 9**

**Other matters**

19. Under this item, other matters relevant to the topic of the workshop may be discussed.

**Item 10**

**Closure of the workshop**

20. During the final session, a representative of the Secretariat will provide a short overview of the results of the workshop and follow-up activities. The participants will be asked to complete a workshop evaluation form.

21. The workshop is expected to close at 5.30 p.m. on 31 October 2023.

## Annex

### Provisional organization of work

<i>Date and time</i>	<i>Agenda item</i>
<b>Monday, 30 October 2023</b>	
8–9 a.m.	Registration
9–10 a.m.	<b>Item 1. Opening of the workshop</b> <ul style="list-style-type: none"><li>- Secretariat of the Convention on Biological Diversity and Government of the Republic of Korea</li></ul>
10–10.30 a.m.	<b>Item 2. Overview of workshop objectives</b> <ul style="list-style-type: none"><li>- Secretariat of the Convention on Biological Diversity</li></ul>
10.45–11.15 a.m.	Coffee/tea break
11.15–11.45 a.m.	<b>Item 3. Milestones, challenges, and future directions in risk assessment of living modified organisms</b> <ul style="list-style-type: none"><li>- Keynote presentation highlighting important milestones, challenges, and future directions in LMO risk assessments (<i>presentations by participants</i>)</li></ul>
11.45 a.m.–12 p.m.	<ul style="list-style-type: none"><li>- Advances in biotechnology and implications for risk assessment (<i>presentations by participants</i>)</li></ul>
12–12.15 p.m.	<ul style="list-style-type: none"><li>- Advances in biotechnology and implications for risk assessment – industry perspective (<i>presentations by participants</i>)</li></ul>
12.15–12.30 p.m.	<ul style="list-style-type: none"><li>- Advances in biotechnology and implications for risk assessment – civil society perspective (<i>presentations by participants</i>)</li></ul>
12.30–1 p.m.	<ul style="list-style-type: none"><li>- General discussion</li></ul>
1–2 p.m.	Lunch break
2–3 p.m.	<b>Item 3 (continued)</b> <ul style="list-style-type: none"><li>- Regional and national experiences of advances in LMO risk assessment frameworks and existing regulations (<i>presentations by participants</i>)</li></ul>
3–3.30 p.m.	<b>Item 4. Emerging technologies and their impact on risk assessment</b> <ul style="list-style-type: none"><li>- Technical presentations on the state of the art of risk assessment for synthetic biology LMOs (<i>presentations by participants</i>)</li><li>- Technical presentations on the state of the art of risk assessment for engineered gene drives (<i>presentations by participants</i>)</li><li>- Technical presentations on the state of the art of risk assessment for new genomic techniques (<i>presentations by participants</i>)</li></ul>
3.30–4 p.m.	Coffee/tea break
4–5.30 p.m.	<ul style="list-style-type: none"><li>- Interactive discussion on risk assessment requirements for emerging areas (<i>facilitated group discussions</i>)</li></ul>
5.30–7.30 p.m.	Cocktail reception for the celebration of the twentieth anniversary of the Cartagena Protocol on Biosafety

<b>Tuesday, 31 October 2023</b>	
9–9.30 a.m.	<p><b>Item 5. Methodologies and tools for conducting risk assessments</b></p> <ul style="list-style-type: none"> <li>- Keynote presentation on methodologies and tools (<i>presentations by participants</i>)</li> <li>- Keynote presentation on modelling and risk assessment (<i>presentations by participants</i>)</li> </ul>
9.30–10.30 a.m.	<ul style="list-style-type: none"> <li>- Regional approaches to conducting risk assessments (<i>presentations by participants</i>)</li> </ul>
10.30–11 a.m.	Coffee/tea break
11–11.15 a.m.	<p><b>Item 6. International policy developments relevant to risk assessment</b></p> <ul style="list-style-type: none"> <li>- Overview presentation on Kunming-Montreal Global Biodiversity Framework</li> </ul>
11.15–11.45 a.m.	<ul style="list-style-type: none"> <li>- Implementation Plan and Capacity-building Action Plan elements on risk assessment</li> </ul>
11.45 a.m.–12 p.m.	<ul style="list-style-type: none"> <li>- Environmental considerations of the Organisation for Economic Cooperation and Development for release of transgenic plants</li> </ul>
12–1 p.m.	<p><b>Item 7. Lessons learned, capacity needs, skills gaps and recommendations on capacity-building for risk assessment</b></p> <ul style="list-style-type: none"> <li>- Sharing of best practices and success stories in LMO risk assessment from the Korean Biosafety Initiative</li> </ul>
1–2 p.m.	Lunch break
2–3.30 p.m.	<p><b>Item 8. Considerations for the risk assessment programme of work</b></p> <ul style="list-style-type: none"> <li>- Report back from interactive discussions on recommendations on advancing risk assessment</li> </ul>
3.30–4 p.m.	Coffee/tea break
4–5 p.m.	<ul style="list-style-type: none"> <li>- Looking forward – Recommendations on advancing risk assessment</li> </ul>
5–5.30 p.m.	Closing ceremony