



Convention on Biological Diversity

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English only

International training course on risk assessments of living modified organisms Brasilia, 2–6 June 2025

Annotated provisional agenda

Introduction

1. In its decisions [BS-VI/12](#), [CP-VIII/12](#) and [CP-11/7](#), the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity requested the Executive Secretary of the Secretariat of the Convention, subject to the availability of resources, to support capacity-building and development activities on the risk assessment of living modified organisms, including on living modified organisms containing engineered gene drives.
2. In response to those requests, and with support from the European Commission, the Secretariat and the Government of Brazil are organizing an international training course on risk assessments of living modified organisms, to be held in Brasilia from 2 to 6 June 2025.
3. The objective of the training course is to provide theoretical training on risk analysis and risk assessment processes, encompassing the concepts, steps, methodology and key issues to be considered during those processes, together with practical hands-on training on the evaluation of a case study of a living modified organism containing an engineered gene drive for environmental release. The *Training Manual on Risk Assessment of Living Modified Organisms in the Context of the Cartagena Protocol on Biosafety*¹ and the *Additional Voluntary Guidance Materials to Support Case-by-Case Risk Assessments of Living Modified Organisms Containing Engineered Gene Drives*² will serve as the basis for the conduct of the course.
4. The training course will also provide participants with an opportunity to discuss the integration of biosafety targets into the revision of national biodiversity strategies and action plans, with a view to enhancing the implementation of the Cartagena Protocol and the Kunming-Montreal Global Biodiversity Framework.
5. The training course will be conducted in English and will consist of plenary sessions and activities in breakout groups. Documents for the course will be posted on the website of the Secretariat. To minimize the environmental impact of the course, no documents will be printed on site.

¹ [UNEP/CBD/BS/COP-MOP/7/INF/6](#).

² [CBD/CP/MOP/11/9](#).

Item 1

Opening of the workshop

6. The training course will be opened by a representative of the Secretariat at 8.30 a.m. on 2 June 2025. Representatives of the Ministry of Agriculture and Livestock of Brazil and the Secretariat will deliver opening remarks.
7. Participants will be invited to briefly introduce themselves and provide a short summary of their experience and current activities related to the risk assessment of living modified organisms, and to share their expectations concerning the training course.
8. After the introductions, a representative of the Secretariat will explain the objectives of the training course and present the proposed organization of work (see annex).

Item 2

Overview of biosafety

(a) Introduction to the Cartagena Protocol on Biosafety

9. A representative of the Secretariat will introduce the general concepts and provisions set forth in the Cartagena Protocol.

(b) Techniques used in modern biotechnology

10. A representative of the Secretariat will give an overview of common techniques and new developments in the field of modern biotechnology.

Item 3

National biosafety frameworks

(a) Competent national authorities, practices and principles

11. A representative of the Secretariat will present information on the structure and role of national biosafety frameworks, and participants will be invited to discuss the role of competent national authorities.

(b) Expert advice and the role of risk assessors

12. A representative of the Secretariat will give a presentation on the role of regulators and scientific advisory bodies, including with regard to the responsibilities of risk assessors, the roster of biosafety experts and public participation.

(c) National experiences related to biosafety and risk assessments

13. A series of presentations will be made on national experiences on biosafety and risk assessment, providing an overview of various ways in which biosafety and risk assessment are managed globally.
14. A representative of Brazil will give a presentation the experience of Brazil in managing biosafety and living modified organisms. A number of participants will then be invited to present their countries' experience.

Item 4

Overview of risk assessments

15. An overview of the full risk assessment process based on annex III to the Cartagena Protocol will be provided through a series of presentations.

(a) Methodology

16. A presentation will be given on the risk assessment methodology, including such issues as national protection goals, assessment end points and practices and principles, as well as on the definition of such terms as “adverse effect”, “exposure” and “characterization”.

(b) Planning phase

17. A presentation will be given on the planning phase of the risk assessment process, providing detailed information on the establishment of context and scope, the selection of relevant assessment end points or representative species, the establishment of a baseline for risk assessment, the choice of suitable comparators and the development of risk hypotheses.

(c) Conducting risk assessments

18. A presentation will be given on information that is key for conducting risk assessments, including the identification of the novel characteristics of living modified organisms, the evaluation of the likelihood or occurrence of adverse effects, possible consequences and the overall estimation of risk. Such concepts as gene flow, allergenicity and the receiving environment will also be discussed.

(d) Overarching issues in risk assessments

19. Overarching issues related to the quality and relevance of information and the identification and consideration of uncertainty will be explored in the context of risk assessment, and the concepts of modelling and weight of evidence will be introduced.

(e) Preparation of a risk assessment report and recommendation

20. A presentation will be given on important elements to be considered in the drafting of risk assessment reports, including information on the background and scope of the risk assessment and the characterization and estimation of risk. A description of risk management and monitoring strategies will also be provided.

Item 5**Related issues and decision-making considerations**

21. A representative of the Secretariat will give a presentation on related issues and considerations typically taken into account by decision makers after a risk assessment, such as human health and socioeconomic considerations, the assessment of potential benefits, indigenous peoples and local communities, public awareness and liability and redress.

Item 6**Introduction to the Biosafety Clearing-House**

22. Representatives of the Secretariat will give a presentation on the Biosafety Clearing-House, providing an overview of how it can be used in risk assessment and of the scientific information that it contains.

Item 7**Case studies**

23. Participants will be invited to apply the concepts discussed under agenda item 4 through a practical exercise on the environmental release of a living modified mosquito containing an engineered gene drive.

24. Participants will first hear a general introduction to living modified organisms containing engineered gene drives and a presentation on the case study related to a living modified mosquito containing an engineered gene drive.

25. Afterwards, participants will be divided into groups and asked to undertake an assessment of the information provided in the case study. They will be requested to formulate hypotheses, identify protection goals and assessment end points and apply the risk assessment methodology. Groups will then present their assessments in plenary, which will be followed by discussions.

26. Each group will then be requested to develop prospective risk management approaches for the critical identified risks and to incorporate them into a draft rudimentary recommendation report, to be presented for peer review in plenary session.

Item 8

Other matters

(a) Related programmes of work under the Cartagena Protocol

27. Work programmes under the Cartagena Protocol will be introduced through a series of short presentations that will cover the detection and identification of living modified organisms, socioeconomic considerations, the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol, the Implementation Plan and the Capacity-building Action Plan for the Protocol and the fifth national report. The discussion will conclude with an overview of the activities planned for the 2025–2026 intersessional period.

(b) Supporting the integration of biosafety targets into the revision of national biodiversity strategies and action plans

28. A representative of the United Nations Environment Programme will give a presentation on the integration of biosafety targets into revised national biodiversity strategies and action plans, with a view to supporting alignment with the Cartagena Protocol. Harmonization strategies, country case studies and available support will be discussed in the context of strengthened biosafety governance and improved coordination and synergies between biodiversity and biosafety implementation.

(c) International Centre for Genetic Engineering and Biotechnology

29. A representative of the International Centre for Genetic Engineering and Biotechnology will present the Centre and its work in the fields of biosafety and regulatory science, including institutional capacity-building, academic and vocational trainings, and the development of regulatory frameworks, administrative processes, supporting documentation and resource materials.

Item 9

Conclusions

30. Participants will be invited to provide feedback on the training course through an anonymous survey and to share their reflections.

31. The training course is expected to be closed at 1 p.m. on 6 June 2025.

Annex

Proposed organization of work

<i>Date and time</i>	<i>Agenda item</i>
Monday, 2 June 2025	
8–8.30 a.m.	<i>Registration of participants</i>
8.30–9.15 a.m.	Item 1. Opening of the workshop
9.15–9.45 a.m.	Item 2. Overview of biosafety: (a) Introduction to the Cartagena Protocol on Biosafety
9.45–10.30 a.m.	Item 2 (<i>continued</i>) (b) Techniques used in modern biotechnology
10.30–11 a.m.	<i>Coffee break</i>
11–11.30 a.m.	Item 3. National biosafety frameworks: (a) Competent national authorities, practices and principles
11.30 a.m.–noon	(b) Expert advice and the role of risk assessors
Noon–12.30 p.m.	(c) National experiences related to biosafety and risk assessments
12.30–2 p.m.	<i>Lunch break</i>
2–3 p.m.	Item 3 (c) (<i>continued</i>)
3–3.30 p.m.	<i>Coffee break</i>
3.30–5 p.m.	Item 4. Overview of risk assessments: (a) Methodology
5–5.15 p.m.	Summary of activities of day 1 and question-and-answer session
Tuesday, 3 June 2025	
9–10 a.m.	Item 4 (<i>continued</i>) (b) Planning phase
10–11 a.m.	(c) Conducting risk assessments
11–11.30 a.m.	<i>Coffee break</i>
11.30 a.m.– 12.30 p.m.	Item 4 (<i>continued</i>) (d) Overarching issues in risk assessments
12.30–1 p.m.	(e) Preparation of a risk assessment report and recommendation
1–2.30 p.m.	<i>Lunch break</i>
2.30–3.15 p.m.	Item 5. Related issues and decision-making considerations
3.15–3.45 p.m.	<i>Coffee break</i>
3.45–5 p.m.	Item 6. Introduction to the Biosafety Clearing-House
5–5.15 p.m.	Summary of activities of day 2 and question-and-answer session

Wednesday, 4 June 2025

9–10.30 a.m.	Item 7. Case studies
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10.30–11 a.m.	<i>Coffee break</i>
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11 a.m.–1 p.m.	Item 7 (<i>continued</i>)
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1–2.30 p.m.	<i>Lunch break</i>
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2.30–4.45 p.m.	Item 7 (<i>continued</i>)
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4.45–5 p.m.	Summary of activities of day 3 and question-and-answer session
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Thursday, 5 June 2025

9–10.30 a.m.	Item 7 (<i>continued</i>)
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10.30–11 a.m.	<i>Coffee break</i>
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11 a.m.–1 p.m.	Item 7 (<i>continued</i>)
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1–2.30 p.m.	<i>Lunch break</i>
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2.30–4.45 p.m.	Item 7 (<i>continued</i>)
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4.45–5 p.m.	Summary of activities of day 4 and question-and-answer session
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Friday, 6 June 2025

9–10 a.m.	Item 7 (<i>continued</i>)
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10–10.45 a.m.	Item 8. Other matters:
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	(a) Related programmes of work under the Cartagena Protocol
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10.45–11 a.m.	<i>Coffee break</i>
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11 a.m.–noon	(b) Supporting the integration of biosafety targets into the revision of national biodiversity strategies and action plans
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Noon–12.30 p.m.	(c) International Centre for Genetic Engineering and Biotechnology
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12.30–1 p.m.	Item 9. Conclusions
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