



Convention on Biological Diversity

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

Report of the international training course on risk assessments of living modified organisms

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 living modified organisms containing engineered gene drives.
2. In response to those requests and with support from the European Commission, the Secretariat of the Convention and the Government of Brazil organized an international training course on risk assessments of living modified organisms, which was held in Brasilia from 2 to 6 June 2025.
3. The objective of the training course was 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 served as the basis for the conduct of the course.
4. The training course provided 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 consisted of plenary sessions and activities in breakout groups, with the first two days focused on the theoretical aspects related to risk assessments of living modified organisms and the following two days devoted to practical exercises. The last day of the workshop focused on the integration of biosafety targets into the revision of national biodiversity strategies and action plans.

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 was opened by a representative of the Secretariat at 8.45 a.m. on 2 June 2025. The Vice-Minister of Agriculture and Livestock and the First Secretary of the Ministry of Foreign Affairs of the Government of Brazil delivered opening remarks on behalf of the organizing institutions. A pre-recorded statement by the Executive Secretary of the Secretariat was heard following the remarks of the representatives of the Government of Brazil.
7. The participants briefly introduced themselves and provided a short summary of their experience and current activities related to the risk assessment of living modified organisms and shared their expectations concerning the training course.
8. A representative of the Secretariat explained the objectives of the training course and presented the proposed organization of work.

Item 2

Overview of biosafety

(a) Introduction to the Cartagena Protocol on Biosafety

9. A representative of the Secretariat introduced the general concepts and provisions set forth in the Cartagena Protocol on Biosafety, providing information on its historical context and objective, scope and provisions. Those provisions that related to risk assessment in line with annex III of the Protocol were highlighted.

(b) Techniques used in modern biotechnology

10. A representative of the Secretariat provided an overview of common techniques and new developments in the field of modern biotechnology and a brief account of the history of biotechnology, touching on how living modified organisms were created, the meaning of the term “transformation cassette” and how transgenes functioned in a living modified organism. The presentation concluded with a brief description of new genomic techniques and recent 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 gave a presentation on the structure and role of national biosafety frameworks and the role of competent national authorities in risk assessment, noting that national circumstances might result in differing practices and principles across Parties. He demonstrated the different approaches taken using information found on the Biosafety Clearing-House. Examples were further shared by representatives of Germany and South Africa.

(b) Expert advice and the role of risk assessors

12. A representative of the South African National Biodiversity Institute provided a presentation on the role of regulators and scientific advisory bodies, including on the responsibilities of risk assessors, the roster of biosafety experts and public participation. An example derived from the South African context was shared.

(c) National experiences related to biosafety and risk assessments

13. A representative of the Ministry of Agriculture and Livestock of Brazil gave a presentation on the national experience in managing biosafety and living modified organisms, as well as on the implementation of the Cartagena Protocol and regional regulatory cooperation.

14. Participants from Honduras, Malaysia, Tunisia, Türkiye and Kenya briefly shared their national experiences with respect to the risk assessment of living modified organisms.

Item 4**Overview of risk assessments****(a) Methodology**

15. A representative of the International Centre for Genetic Engineering and Biotechnology delivered a presentation on the risk assessment methodology, including such issues as national protection goals, assessment end points and practices and principles and the definition of such terms as “adverse effect”, “exposure” and “characterization”. The importance of annex III to the Protocol was emphasized.

(b) Planning phase

16. A representative of the International Centre for Genetic Engineering and Biotechnology gave a presentation 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 and 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

17. A representative of the South African National Biodiversity Institute delivered a presentation on information that was key for conducting risk assessments, including on the identification of the novel characteristics of living modified organisms, the evaluation of the likelihood or occurrence of adverse effects, possible consequences of adverse effects and the overall estimation of risk. Further, the concepts of acceptability of risk and risk management were introduced.

(d) Overarching issues in risk assessments

18. A representative of the Federal Office of Consumer Protection and Food Safety of Germany provided an overview of the overarching issues associated with the risk assessment process. Quality and relevance of information, identification and consideration of uncertainty, modelling and weight of evidence were detailed in the context of risk assessment of living modified organisms.

(e) Preparation of a risk assessment report and recommendation

19. A representative of the International Centre for Genetic Engineering and Biotechnology gave a presentation on the important elements to be considered when drafting risk assessment reports, including information on the background and scope of the risk assessment and the characterization and estimation of risk. Examples of recent risk assessment reports from Australia, Brazil, the European Union and India were provided.

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

20. A representative of the Secretariat gave a presentation on related issues typically taken into account by decision makers after a risk assessment, such as human health and socioeconomic considerations, assessment of potential benefits, considerations related to indigenous peoples and

local communities, public awareness and liability and redress. The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety was overviewed.

Item 6

Introduction to the Biosafety Clearing-House

21. Representatives of the Secretariat gave a presentation on the Biosafety Clearing-House, providing an overview of how the Clearing-House could be used in risk assessment and the scientific information that it contained. Participants were asked to perform some brief practical exercises related to finding scientific information on the Biosafety Clearing-House.

Item 7

Case studies

22. A representative of the Federal Office of Consumer Protection and Food Safety of Germany provided a general introduction to the subject of engineered gene drives, including history, mechanistic and molecular concepts, modelling and the various types of systems under research and development.

23. A representative of the Secretariat provided a general introduction to a case study concerning the environmental release of a living modified mosquito containing an engineered gene drive.

24. The session began with brainstorming by participants related to protection goals, assessment end points and potential harms, followed by their identification of the potential harms to be focused on. The participants were then divided into groups and undertook an assessment of the information provided in the case study. They were requested to apply the risk assessment methodology, focusing on the exposure receiving environment, to the living modified organism containing an engineered gene drive and articulate the causal chain of events leading to the potential harm.

25. Each group was requested to develop prospective risk management approaches for the critical identified risks and to incorporate them into a draft rudimentary recommendation report.

26. At the end of the session, a representative of the Secretariat and a representative of the Federal Office of Consumer Protection and Food Safety of Germany presented the additional voluntary guidance materials and other key technical resources.

Item 8

Other matters

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

27. A representative of the United Nations Environment Programme gave 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 and available support were discussed in the context of strengthened biosafety governance and improved coordination and synergies between biodiversity and biosafety implementation.

28. Participants from Pakistan, Peru, Thailand and Zimbabwe delivered brief presentations on national experiences with the integration of biosafety elements into national biodiversity strategies and action plans.

(b) International Centre for Genetic Engineering and Biotechnology

29. A representative of the International Centre for Genetic Engineering and Biotechnology gave a presentation on 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 were invited to provide feedback on the training course through an anonymous survey and to share their reflections. The results of the survey and the feedback collected are available online.³
 31. The training course closed at 12.25 p.m. on 6 June 2025.
 32. Interested participants were invited to take a tour of the Brazilian Agricultural Research Corporation. Two representatives of the corporation introduced the organization and its work in the field of agricultural biotechnology. The participants then proceeded to tour one of the plant biotechnology laboratories, the synthetic biology facilities and the seed bank.
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³ See www.cbd.int/documents/6894f80d0a098d9468a6aa1f.