





Ad Hoc Technical Expert Group on Risk Assessment activities

Valeria Giovannelli

Italian Institute for Environmental Protection and Research

Training session on SBSTTA 27 substantive agenda items / 2 September 2025



Views and opinions expressed are those of the author(s) only and do not necessarily reflect those of the European Union or the European Commission. Neither the EU nor the EC can be held responsible for them.

Background decisions

- CBD/CP/MOP/11/7: Invites Parties to submit information on their needs and priorities for further guidance materials on specific topics of RA of LMOs, including a rationale following the criteria set out in annex I to decision CP-9/13;
 - Decides to establish an AHTEG on risk assessment tasked with the evaluation of the needs and priorities identified by the Parties
 - Decides to extend the Open-ended Online Forum on RA and RM to support the analysis of the topics identified by the Parties

CBD/CP/MOP/DEC/9/13: Decides to <u>establish a process</u> for the identification and prioritization of specific issues regarding RA of LMO for consideration by the COP-MOP to the Cartagena Protocol with a view to developing further guidance on risk assessment on the specific issues identified, taking into account the criteria listed in annex I to the decision



Criteria for the identification and prioritization of specific issues regarding RA of LMO (Annex I of CBD/CP/MOP/DEC/9/13)

- (a) They are identified by Parties as priorities;
- (b) They fall within the scope and objective of the Cartagena Protocol;
- (c) They pose challenges to existing risk assessment frameworks, guidance and methodologies;
- (d) Challenges in addressing the specific issue;
- (e) The specific issues concerning living modified organisms that:
 - (i) Have the potential to cause adverse effects on biodiversity;
 - (ii) May be introduced into the environment either deliberately or accidentally;
 - (iii) Have the potential to disseminate across national borders;
 - (iv) Are already, or are likely to be, commercialized or in use somewhere in the world;



Stock-taking exercise to determine if resources on similar issues have been developed

Submissions by Parties on their needs and priorities for specific topics of risk assessment https://bch.cbd.int/en/submissions-to-notification=2025-017.

12 Parties submitted responses: Brazil, Chad, Colombia, Egypt, Malaysia, Mauritania, Mexico, Niger, Pakistan, Panama, Peru and South Africa.

- 15 topics identified by Parties for the further development of guidance
- **3** Parties indicated that there was a need for further capacity building on the topic of the RA of LMOs.
- **Open-Ended Online Forum on Risk Assessment and Risk Management** to gather information to complement the submissions by Parties and support the analysis of the proposed topics.



Terms of reference for the AHTEG on Risk Assessment (CBD/CP/MOP/11/7)

The AHTEG on Risk Assessment convened from 8 to 11 July 2025
At the Secretariat of the CBD in Montreal, Canada

- Analyse the information submitted by Parties and the discussions in the Open-ended Online Forum on RA and RM:
- Prepare a list of prioritized topics on which further guidance materials on risk assessment may be needed according to the criteria set out in annex I to decision CP-9/13;
- Consider the document CBD/CP/RA/AHTEG/2025/1/INF/1 prepared by the Secretariat;
- Prepare a report for the consideration of SBSTTA 27.



15 topics identified by Parties for the further development of guidance

- (a) Detection and monitoring of LMOs;
- (b) Genome-edited mammals for use in agriculture;
- (c) Living modified algae;
- (d) Living modified animals;
- (e) Living modified fish;
- (f) Living modified microorganisms;
- (g) LMOs containing stacked events;
- (h) LMOs expressing genome editing machinery for pest or pathogen control;
- (i) LMOs for food, feed and processing;

- (j) LMOs produced through new biotechnologies;
- (k) Long-term and cumulative effects of genetic constructs and LMOs;
- (I) Operationalizing protection goals into relevant assessment and measurement end points;
- (m) Simplified procedures (Article 13 of the Protocol) and agreements and arrangements
- (Article 14);
- (n) Transportability of data for risk assessment of LMOs;
- (o) Use of LMOs in centres of origin and in traditional agricultural systems.



Topics that met all the criteria

- a) Living modified algae;
- b) Living modified fish;
- c) Living modified microorganisms;
- d) LMOs expressing genome editing machinery for pest or pathogen control;
- e) Long-term and cumulative effects of genetic constructs and LMOs;
- f) Operationalizing protection goals into relevant assessment and measurement end points;
- g) Use of LMOs in centres of origin and in traditional agricultural systems

AHTEG conclusions

Topics that partially met the criteria

- a) Detection and monitoring of LMOs;
- b) Genome-edited mammals for use in agriculture;
- c) Living modified animals;
- d) LMOs containing stacked events;
- e) LMOs for food, feed and processing;
- f) LMOs produced through new biotechnologies;



AHTEG conclusions

Topics for which the analysis was inconclusive with respect to criteria (c) and (d) and criterion (e) was considered not applicable

- 1. Simplified procedures (Article 13 of the Protocol) and agreements and arrangements (Article 14)
- 2. Transportability of data for risk assessment of LMOs

Criteria:

- (c) They pose challenges to existing risk assessment frameworks, guidance and methodologies
- (d) Challenges in addressing the specific issue
- (e) The specific issues concerning living modified organisms



Topics identified as priorities

- a) Living modified algae;
- b) Living modified microorganisms;
- c) LMOs expressing genome editing machinery for pest or pathogen control;

The Group also recognized the need for additional guidance materials on **living** modified fish.

The AHTEG recognizes that the topic continued to be a priority for some Parties



Topics that can be addressed with the development of technical notes

Long-term and cumulative effects of genetic constructs and LMOs;

Operationalizing protection goals into relevant assessment and measurement end points;

Use of LMOs in centres of origin and in traditional agricultural systems;

Technical notes are considered as practical supplements to existing guidance material that would be useful for supporting Parties in addressing specific challenges or contexts



Official documents

CBD/SBSTTA/27/6: Risk assessment and risk management of living modified organisms (Note by the Secretariat including SBSTTA recommendation)

CBD/CP/RA/AHTEG/2025/1/2: Considerations on risk assessment

<u>CBD/CP/RA/AHTEG/2025/1/INF/1</u>: Synthesis of submissions of information on risk assessment and the discussions of the Open-Ended Online Forum on Risk Assessment and Risk Management

<u>CBD/CP/RA/AHTEG/2025/1/INF/2</u>: List of bibliographic references provided in the submissions from Parties and during the discussions of the Open-ended Online Forum on Risk Assessment and Risk Management

CBD/CP/RA/AHTEG/2025/1/3: Report of the Ad Hoc Technical Expert Group on Risk Assessment

Other relevant documents

CBD/CP/RA/AHTEG/2020/1/5: Report of the Ad Hoc Technical Expert group on Risk Assessment

CBD/CP/MOP/11/9: Additional voluntary guidance materials to support case-bycase risk assessment of living modified organisms containing engineered gene drives

UNEP/CBD/BS/COP-MOP/8/8/Add.1: Guidance on Risk Assessment of Living Modified Organisms and Monitoring in the context of Risk Assessment



Thank you for your attention!

Valeria Giovannelli

valeria.giovannelli@isprambiente.it



