



Convention on Biological Diversity

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English only

Global Risk Assessment Workshop
Montreal, Canada, 30 and 31 October 2023

Report on the global risk assessment workshop*

Note by the Secretariat

Introduction

1. The Global Risk Assessment Workshop in the context of the Cartagena Protocol on Biosafety was held in Montreal, Canada from 30 to 31 October 2023. The workshop was convened in response to decision [CP-10/4](#), where 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). The workshop was one of the activities that was convened to mark the twentieth anniversary of the entry into force of the Cartagena Protocol on Biosafety. In this regard, the workshop was convened under the theme “Advances in risk assessment – Twenty years of theory and practice”. The objective of the workshop was to provide a platform for international experts and stakeholders to come together and exchange knowledge, experiences and best practices related to the risk assessment of LMOs. The workshop was funded by the Government of the Republic of Korea, under the auspices of the Korea Biosafety Capacity-Building Initiative.
2. The workshop was held as a hybrid event, with both in-person and virtual participation options to maximize global accessibility. A total of 43 participants from 25 countries and 13 organizations, attended the workshop in person and 104 experts registered to follow the workshop virtually.
3. The Secretariat and resource persons from the various countries and organizations served as facilitators for the workshop. The list of participants is presented in the annex to this report.
4. The objective of the workshop was to provide a platform for international experts and stakeholders to come together and exchange knowledge, experiences and best practices related to the risk assessment of LMOs. The workshop focused on enhancing understanding of regulatory frameworks, methodologies and decision-making processes surrounding LMO risk assessments, as well as exploring emerging challenges and potential solutions.

Item 1

Opening of the workshop

5. The workshop was opened by the Acting Executive Secretary of the Secretariat of the Convention on Biological Diversity, David Cooper. The Acting Executive Secretary expressed gratitude to the Government of the Republic of Korea for their financial support through the Korea Biosafety Capacity-Building Initiative, acknowledging its vital role in facilitating a series of global risk assessment workshops. The Acting Executive Secretary emphasized the increasing relevance of risk assessment, noting the rapidly evolving biotechnological landscape and highlighted the historic

* The present document is being issued without formal editing.

inclusion of a target directly relating to biosafety and biotechnology in the Kunming-Montreal Global Biodiversity Framework adopted at the fifteenth Conference of the Parties to the Convention on Biological Diversity in decision [15/4](#). The Acting Executive Secretary encouraged participants to actively engage in the workshop, emphasizing collaborative learning and critical evaluation of risk assessment practices and the effective implementation of the Cartagena Protocol on Biosafety.

6. Gi Cheol Kim, the Director of the Korea Biosafety Clearing-House in the Republic of Korea made a video address. In his address, Mr. Kim conveyed his gratitude towards the Secretariat for organizing this pivotal global risk assessment workshop and acknowledged the diverse participation of experts from across the globe. Mr. Kim underscored the dedication of the Republic of Korea to biosafety, emphasizing their commitment to the safe and sustainable application of modern biotechnology. Concluding his statement, Mr. Kim expressed his hope that the workshop would serve as an enriching and educational platform for all attending experts, ultimately aiding in the development and refinement of their respective national biosafety frameworks.

Item 2

Overview and objectives of the workshop

7. A representative of the Secretariat introduced the objectives for the workshop and provided an overview of the programme and expected outcomes. The workshop programme is available in document CBD/CP/RA/OM/2023/1/1/Add.1.

Item 3

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

8. Under this item, participants were invited to discuss key developments, challenges and future trends in LMO risk assessments, drawing insights from national authorities, industry, civil society, and indigenous peoples and local communities.

9. The session commenced with a keynote presentation by a member of the resource team, Helmut Gaugitsch from the Environment Agency in Austria. In his presentation, Mr. Gaugitsch effectively captured the key milestones, notable challenges and prospective pathways in the field of LMO risk assessments. Mr. Gaugitsch underscored the critical role of Annex III of the Cartagena Protocol, emphasizing its foundational significance in shaping the principles and practices of risk assessment within the realm of biosafety.

10. Wendy Craig, a member of the resource team from the International Centre for Genetic Engineering and Biotechnology, made a presentation on the changing landscape of biotechnology and the need for adaptive and comprehensive regulation to ensure safety and ethical considerations are upheld. Ms. Craig highlighted the shift from untargeted genetic modifications to precise, targeted techniques, emphasizing the importance of science-based regulation. Additionally, Ms. Craig prompted a reconsideration of protection goals and assessment endpoints for a more nuanced risk assessment process.

11. Felicity Keiper from the Global Industry Coalition (GIC) highlighted the role of the GIC in contributing to the implementation of the Cartagena Protocol with a focus on biotechnology in her presentation. The central theme underscored the imperative of simplifying living modified (LM) crop regulations through the alignment of fundamental data prerequisites, case-specific evaluation of supplementary data and the utilization of existing knowledge for informed science-driven decisions to advance biotechnological improvements in crop cultivation.

12. Eva Sirinathsinghji of Third World Network presented on the advances in biotechnology and implications for risk assessment from the civil society perspective. Ms. Sirinathsinghji noted the expanding scope of interventions into nature, including public health and conservation and the modification of wild populations. Ms. Sirinathsinghji called for updated risk assessment processes to address novel risks, incorporating diverse scientific perspectives and meaningfully influencing

decision-making. Ms. Sirinathsinghji emphasized the importance of public participation in scrutinizing new technologies in line with the provisions of the Cartagena Protocol.

13. Following the expert presentations, regional and national case studies were presented to highlight the developments in risk assessment globally. The first presenter under this topic was Samuel Timpo, a member of the resource team from the African Union Development Agency. During his presentation, Mr. Timpo discussed LMO risk assessment frameworks and regulations in Africa, emphasizing the commitment to biosafety, notably through the Revised African Model Law on Biosafety. Mr. Timpo recommended enhancing risk assessment guidelines and utilizing resources like the Cartagena Protocol and Biosafety Clearing-House. Mr. Timpo also incorporated the need for regulatory capacity-building and peer-to-peer knowledge-sharing.

14. Marja Ruohonen-Lehto of the Finnish Environment Institute in Helsinki discussed the evolution of LMO risk assessment frameworks and regulations in Finland and the European Union since 1990. Ms. Ruohonen-Lehto outlined the key milestones, including the introduction of risk assessment principles, problem formulation and amendments to European Union directives.

15. Marvis Esther Suárez Romero from the Office of Regulation and Environmental Safety in Cuba outlined the regulatory framework overseeing biological agents, focusing on protecting Cuban maize, conserving biodiversity and supporting non-transgenic honey production. Ms. Romero highlighted the use of comprehensive risk assessment tools and collaborative inter-ministerial decisions in achieving these goals.

16. Kumitaa Theva Das of the Malaysian Genetic Modification Advisory Committee provided insights into the biosafety regulatory system in Malaysia, specifically addressing the case study of the living modified *Aedes aegyptii* (Oxi513A). Ms. Das mentioned the effectiveness of the regulatory framework in addressing emerging biotechnologies while pointing out the increasing challenges and uncertainties in the field of risk assessment, emphasizing the importance of networking and sharing expertise across borders to effectively meet these challenges.

17. Kayla Knilans, of the United States of America, provided an overview of the biotechnology regulations within United States Department of Agriculture (USDA), focusing on three key components: exemptions, regulatory status review and permitting, primarily concerning plants. Additionally, Ms. Knilans outlined the risk assessment process, which considers factors like plant distribution, plant pest risk and impacts on non-target organisms. Overall, the presentation from Ms. Knilans highlighted the approach and aim of the USDA to ensure safety while facilitating biotechnology innovation in agriculture.

Item 4

Emerging technologies and their impact on risk assessment

18. Under this agenda item, introductory expert presentations were made on LMOs developed through synthetic biology, LMOs containing engineered gene drives and advances in genome editing techniques. The presentations were then 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.

19. Jack Heinemann of the Centre for Integrated Research in Biosafety at the School of Biological Sciences at the University of Canterbury provided a virtual presentation on the state of the art in risk assessment for new genomic techniques and the importance of defining the source of hazard and ensuring ongoing regulatory oversight. Mr. Heinemann highlighted the need to assess cumulative risks associated with genetic modifications and stressed the importance of post-release monitoring. The presentation also included a recommendation for a comprehensive and evolving regulatory framework to address the complexities of these techniques and their potential unintended consequences.

20. Ricarda Steinbrecher from the Federation of German Scientists raised questions about the state of risk assessment for synthetic biology LMOs, emphasizing the need for a multidisciplinary approach, comprehensive omics analysis and careful monitoring to assess impacts and unintended changes. In addition, Ms. Steinbrecher cautioned against excessive reliance on modelling and highlighted the importance of registration, labelling and traceability for managing risks effectively.

21. Brinda Dass from the Foundation for the National Institutes of Health highlighted the risk assessment framework for LMOs with engineered gene drives and LM mosquitoes. The presentation also included key elements in risk assessment, along with the critical roles of stakeholder engagement, problem formulation, scoping, modeling and monitoring. Ms. Dass emphasized the necessity of defining clear protection and operational goals to steer the assessment process. Furthermore Ms. Dass presented on the importance of considering comparators, understanding the risk context and establishing criteria for risk evaluation.

22. Following the briefing presentations participants were divided into two facilitated groups to discuss in further detail the potential issues, capacity needs, skills gaps and recommendations for risk assessment for emerging technologies. Two groups were organized with facilitators as follows:

- (a) LMOs containing engineered gene drives (facilitator: Brinda Dass);
- (b) New genomic techniques (facilitator: Wendy Craig).

Item 5

Methodologies and tools for conducting risk assessments

23. Under this agenda item, experts presented on risk assessment methodologies and tools, as well as the role of modelling in risk assessment and risk management. The expert presentations were followed by regional and national examples of applications of risk assessment methodologies in actual cases of risk assessment.

24. Boet Glandorf, a member of the resource team, underscored the importance of establishing clear protection goals and defining assessment endpoints to align risk assessment with these objectives. Additionally, Ms. Glandorf stressed the value of adopting a science-based, transparent and comparative approach. Furthermore, her presentation made a clear distinction between hazards and risks and underscored the pivotal role of problem formulation within the risk assessment process.

25. Keith Hayes with the Commonwealth Scientific and Industrial Research Organisation for Ecological and Environmental Risk Assessment in Australia emphasized the critical role of mathematical and process-based models in risk assessment, particularly in understanding dynamic systems like predator-prey relationships. Mr. Hayes highlighted the application of these models in predicting the persistence of transgenic individuals and underscored the importance of accuracy and realism in ecological risk assessment.

26. Werner Schenkel from the Federal Office of Consumer Protection and Food Safety in Germany discussed the approach for specific regulations and guidelines for LMOs in the European Union. Mr. Schenkel emphasized the importance of conducting field trials and statistical analyses to determine differences and equivalences between LMOs and their conventional counterparts, following detailed requirements outlined in European Union regulation.

27. Luciana Ambrozevicius, a member of the Brazilian National Biosafety Committee as well as the Agricultural Biotechnology Commission, highlighted the risk assessment approach in Brazil for LMOs under its biosafety framework. Ms. Ambrozevicius highlighted the approval of 19 LM soybean events, how it followed a case-by-case, science-based and comparative approach, aligning with international standards. The presentation concluded with a focus on the future of biotechnology in Brazil, underlining the need for innovation and global collaboration.

28. Thato Mogapi of the Department of Forestry, Fisheries and the Environment in South Africa covered extensive experience with LMOs and the importance of rigorous risk assessments in South Africa. Ms. Mogapi mentioned how risk assessments follow the guidelines of the Cartagena Protocol

and encompass case-by-case, scientifically sound, comparative and tiered approaches. The presentation also emphasized the need for comprehensive monitoring and research to address potential environmental impacts and gene flow in crops such as maize.

29. Bao-Rong Lu, from Fudan University in China, highlighted the extensive experiences related to cotton, particularly the commercial cultivation of insect-resistant LM cotton across an expansive area of approximately 5 million hectares. Mr. Lu underscored the robust regulatory system for risk assessment in China, which encompasses a wide array of agricultural LMOs. The presentation by Mr. Lu also included the comprehensive approach to risk assessment, incorporating legal regulations, target organisms and a well-defined application procedure to evaluate the risks associated with LMOs in China.

30. John Connolly, of Imperial College London, provided a comprehensive overview of the role of gene drive technology in malaria vector control, specifically targeting the *Anopheles* species. Mr. Connolly outlined the steps involved in conducting a thorough environmental risk assessment and discussed the regulatory and ethical aspects necessary for the safe implementation of engineered gene drive technology. To conclude his presentation, Mr. Connolly recommended future research and development in this field, underscoring the need for interdisciplinary collaboration and a nuanced understanding of the target organisms.

31. Mathurin Wend-Rabo Rouamba from the National Biosafety Agency in Burkina Faso provided insights into the 15 years of experience with LMO risk assessments in Burkina Faso. Mr. Wend-Rabo Rouamba discussed work with LM crops such as cotton, sorghum, cowpea, and rice and noted the current absence of gene drive technology applications in the country. A significant focus of the presentation was on the importance of public consultation processes, emphasizing that these should be tailored to fit the educational and cultural backgrounds of the local population, a practice integral to informed decision-making.

Item 6

International policy developments relevant to risk assessment

32. Under this agenda item, a representative of the Secretariat offered a detailed presentation that encompassed essential background information pertaining to the Kunming-Montreal Global Biodiversity Framework, with a specific focus on Target 17. Additionally, the representative of the Secretariat provided insights into the Implementation and Capacity-building Action Plans associated with the Cartagena Protocol on Biosafety.

33. In the following session, Sarah Davis of the Canadian Food Inspection Agency presented on the "Environmental Considerations for Risk/Safety Assessment for the Release of Transgenic Plants" consensus document. This document was central to her presentation in discussing its creation and its global guidance role for assessors. Ms. Davis outlined the structure of the document, focusing on considerations and their relevance to environmental risk assessment for transgenic plants.

Item 7

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

34. Under this item, participants shared best practices and success stories in LMO risk assessment from different regions that participated in the Korea Biosafety Capacity-Building Initiative. The participants were 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.

35. Under this agenda item, a representative of the Secretariat presented the best practices and success stories in the context of LMO risk assessment workshops. The presentation highlighted the committed efforts by the Secretariat in organizing 10 workshops on this theme since 2010, with collaboration and support from various governments and host entities. These workshops covered a

comprehensive range of vital topics related to biosafety and the Cartagena Protocol on Biosafety, including risk assessment methodologies, illustrative case studies and strategies for resource mobilization. The representative of the Secretariat emphasized how valuable insights and feedback from participants underscored the importance of practical elements, high-quality training material and skilled facilitators.

36. Lilian Chimphopo, of the Environmental Affairs Department in Malawi, discussed lessons learned, capacity needs, skill gaps and recommendations related to biosafety in Anglophone Africa. Ms. Chimphopo highlighted the institutional framework for biosafety, including the role of the National Biosafety Authority and collaboration with partners such as the New Partnership for Africa's Development. The presentation emphasized the importance of functional biosafety legal frameworks, public awareness, risk management after LMO release, risk communication and peer-to-peer learning. The recommendations included creating an enabling policy environment, enhancing collaboration among parties to address illegal transboundary movement of LMOs and furthering collaboration with biosafety partners.

37. Josephine Amedu of the National Biosafety Management Agency of Nigeria discussed capacity-building initiatives for LM detection in Anglophone African countries. Her presentation highlighted training programs, challenges in LM detection and the need for cooperation and guidelines in this field. Ms. Amedu emphasized the importance of accessing technical support and expertise in LM detection and collaborating with other networks in the region.

38. Galina Mozgova of the National Coordination Biosafety Centre of the Institute of Genetics and Cytology of the National Academy of Sciences in Belarus discussed case studies from previous workshops related to the assessment of LM sugar beet resistant to rhizomania. Ms. Mozgova noted how participants found the training approach by the Secretariat to be informative and valuable for strengthening regional capacities in risk assessment under the Cartagena Protocol. In her presentation, Ms. Mozgova emphasized the need for regular regional activities due to newly emerging LMOs and requested that future training also cover topics such as LMO detection, socio-economic considerations and transportation and documentation requirements for LMOs.

39. Kamal Kumar Rai, representing the Society for Wetland Biodiversity Conservation in Nepal, emphasized the deep bond between indigenous peoples and local communities and nature, noting its integral role in their culture and identity. Mr. Rai highlighted the importance of indigenous knowledge in both sustaining traditional livelihoods and contributing to risk assessment processes. Mr. Rai pointed out the often-overlooked impact of modern science on indigenous lands and traditions and called for a more inclusive risk assessment approach that integrates socio-cultural factors. In his presentation, Mr. Rai addressed challenges like resource access, capacity-building and the need for special focus on empowering women and youth, underscoring the importance of respecting and integrating indigenous relationships with nature into broader environmental strategies.

40. Raja Chalghoumi from the University of Carthage in Tunisia provided an overview of the Secretariat's workshop held in Türkiye in October 2022. Ms. Chalghoumi emphasized how the training covered fundamental concepts, procedural steps, assessment methodologies and included hands-on exercises with a specific case study involving drought-tolerant wheat in Central Asia. Ms. Chalghoumi highlighted how participants engaged in evaluating harm, defining protection goals and analyzing pathways to harm as part of their risk assessment practice. In her presentation, Ms. Chalghoumi emphasized the value of such practical case studies and expressed a desire for more opportunities for hands-on training in LMO risk assessment. Furthermore, her presentation touched upon the importance of addressing gaps in risk communication and monitoring throughout various phases of LMO releases.

Item 8

Considerations for the risk assessment programme of work

41. Under this agenda item, the group facilitators from the discussion held under item 4 summarized the main points raised, focusing on the essential concepts and implications of risk assessment and risk management within the framework of the Cartagena Protocol on Biosafety.

42. Ms. Craig, who facilitated the group discussion on new genomic techniques, provided a balanced overview of their discussions. The primary topic was the potential regulatory exemptions for genome editing products and the necessity for thorough risk assessments. Ms. Craig noted that some group members expressed concerns about the potential cumulative effects of repeated use of this technology and the sufficiency of oversight and product evaluation prior to market release. Ms. Craig also highlighted how the group discussed regulations and market access challenges for smaller companies and the scientific rationale behind the criteria for nucleotide changes that might qualify for exemptions. The summary by Ms. Craig captured the complexity and diverse challenges associated with regulating genome editing.

43. Ms. Dass, who facilitated the group discussion on LMOs containing engineered gene drives, provided an overview from the discussions. Ms. Dass highlighted how the group considered an examination of experiences with modified *Aedes aegyptii* mosquitoes in Malaysia, examining case-by-case and a phased release approach. Ms. Dass also mentioned how the discussions touched upon the off-target effects of Clustered Regularly Interspaced Short Palindromic Repeats-Cas functions and the latest advancements in RNA design to minimize unintended modifications, with a focus on their implications for biosafety. Ms. Dass outlined the discussions on the regulatory landscape for engineered organisms, noting the potential for involvement from multiple ministries depending on national legislation and the intended use of the organisms.

Item 9

Other matters

44. In the final session, participants reflected on the workshop, noting the need for continual adaptation and collaboration in improving risk assessment methods due to the evolving nature of biotechnology and its effects on biodiversity and ecosystems. Some participants shared views on the significant progress made in the last 20 years, with an emphasis on the importance of transparent data collection and analysis across research, academia and regulatory bodies. Topics mentioned included the development of harmonized risk assessment frameworks to address new technologies, the necessity of diversified risk management strategies and the reinforcement of monitoring and control measures. The session underscored the complexities introduced by biotechnologies and the importance of refining risk assessment practices to manage environmental and biodiversity risks effectively.

Item 10

Closure of the workshop

45. During the closing ceremony, a representative of the Secretariat extended gratitude to the Government of the Republic of Korea, the in-person participants, facilitators who skillfully navigated the discussions, and the online participants whose contributions were invaluable. The Secretariat representative highlighted how their collective efforts not only enriched the dialogue but also laid the groundwork for subsequent follow-up activities, ensuring that the momentum gained during the workshop would continue to drive progress and collaboration in the field.

Annex

List of participants

A. Parties

Armenia

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Ministry of the Environment

Belarus

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Brazil

Luciana Pimenta Ambrozevicius
Federal Agricultural Inspector
Ministry of Agriculture and Livestock

Burkina Faso

Mathurin Wend-rabo Rouamba
Biosafety Officer
National Agency of Biosecurity

Cambodia

Monyrak Meng
Deputy Director General
Ministry of Environment

China

Bao-Rong Lu
Professor
Fudan University

Colombia

Gabriel Mutis Namur
Biotechnology Regulatory Affairs Leader
National Institute for Food and Drug
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Cuba

Marvis Esther Suárez Romero
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Tunisia

Raja Chalghoumi
Associate Professor
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B. Other Governments**United States of America**

Kayla Knilans
Scientific Policy Advisor
U.S. Department of Agriculture

C. Indigenous peoples and local communities**Society for Wetland Biodiversity Conservation Nepal**

Kamal Kumar Rai
Chair, Research, Conservation and Advocacy

D. Observers**Nature Canada**

Marc Butler
Senior Advisor

United Nations Framework Convention on Climate Change

Motsomi Maletjane
Team Lead, Adaptation Division

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Lucy Sharratt
Coordinator, Head of Research and Policy
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**Foundation for Future Farming
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Barbara Couto Pilz
Policy Coordinator

United Nations Environment Programme

Alex Owusu-Biney
Biosafety Portfolio of Projects

**Commonwealth Scientific and Industrial
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Keith Hayes
Team Leader and Senior Research Scientist

**Foundation for the National Institutes of
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Brinda Dass
Senior Technical Expert, Policy Lead Gene
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**European Network of Scientists for Social and
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Nicolas Defarge
Researcher, Molecular Biologist

Third World Network

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Felicity Keiper
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Ricarda Steinbrecher

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D. Online presenters

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