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REPORT ON THE TRAINING COURSE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS FOR WESTERN, CENTRAL AND EASTERN ASIA, ANTALYA, TÜRKIYE, 17 TO 21 OCTOBER 2022

INTRODUCTION

- 1. At its eighth meeting, in decision <u>CP-VIII/12</u>, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety requested the Executive Secretary to support, subject to the availability of resources, regional and subregional capacity-building activities on risk assessment of living modified organisms.
- 2. Likewise, in decision <u>CP-VIII/3</u> on capacity-building, the Parties also requested the Executive Secretary to facilitate the priority capacity-building activities for supporting the implementation of the <u>Cartagena Protocol</u>.
- 3. With support from the Government of the Republic of Korea, through the Korea Biosafety Capacity-Building Initiative, and in collaboration with the Ministry of Agriculture and Forestry General Directorate of Agricultural Research and Policies of Türkiye, the Secretariat of the Convention on Biological Diversity organized the training course on risk assessment of living modified organisms for the Western, Central and Eastern Asian region, which was held in Antalya, Türkiye, from 17-21 October 2022.
- 4. The objectives of the workshop were to provide theoretical and practical training for participants on:
 - (a) The risk assessment process (concepts, steps, methodology, key issues to consider);
- (b) Hands-on training in the evaluation of case studies of living modified organisms for environmental release, identifying protection goals and applying the risk assessment methodology to develop risk scenarios to assess.
- 5. Seventeen participants from twelve countries¹ and two organizations² from the Western, Central and Eastern Asian region attended the workshop (see annex I).

ITEM 1. OPENING OF THE WORKSHOP

- 6. The workshop was opened at 9.15 a.m. on Monday, 17 October 2022 by Ms. Marianela Araya Quesada. In her opening remarks, Ms. Araya Quesada welcomed the participants to the workshop. She thanked the Government of the Republic of Korea for its generous financial support, as well as the Government of Türkiye and the International Centre for Genetic Engineering and Biotechnology for their support for the meeting. Further, she invited the participants to take advantage of the opportunity and maximize the learning experience by putting the knowledge into practice for the benefit of their countries and supporting the effective implementation of the Cartagena Protocol.
- 7. Next, Mr. Ramazan Bülbül of General Directorate of Agricultural Research and Policies of the Ministry of Agriculture and Forestry of Türkiye welcomed the participants to Türkiye. Mr. Bülbül thanked

¹ Bahrain, Georgia, Iraq, Jordan, Kuwait, Lebanon, Republic of Korea, State of Palestine, Tajikistan, Tunisia, Türkiye and United Arab Emirates.

² Food and Agriculture Organization of the United Nations (FAO) Representation in the Kyrgyz Republic and Korea Institute for Promoting Asia Biosafety Cooperation.

the Government of the Republic of Korea for its financial support for the workshop and the Secretariat of the Convention on Biological Diversity for its organization of the workshop. In his remaining remarks, Mr. Bülbül reminded participants that despite global events and conditions, there was still a need to increase food production, which could be achieved through a better understanding of new technologies and the research and development process within the field of biotechnology.

- 8. Following the opening remarks, a pre-recorded video statement from the Executive Secretary of the Convention on Biological Diversity, Ms. Elizabeth Maruma Mrema, was played. In the video statement, Ms. Maruma Mrema underlined the importance of the Cartagena Protocol, while specifically highlighting the importance of risk assessment of living modified organisms. She highlighted the continued need to reinforce capacities, such that Parties could follow the rapid development within the field of biotechnology. Moreover, she noted that the ability for Parties to assess risks would allow them to respond to global problems and support the post-2020 global biodiversity framework.
- 9. After the opening remarks, the participants introduced themselves, providing a short summary of their experience and current activities related to risk assessment of living modified organisms as well as their expectations of the workshop.
- 10. After the introductions by the participants, Ms. Araya Quesada explained the workshop objectives and organization of work for the meeting.³ She invited the participants to examine the provisional agenda⁴ for more details related to the programme and organization of work for the workshop.

ITEM 2. OVERVIEW OF BIOSAFETY AND THE CARTAGENA PROTOCOL ON BIOSAFETY

2.1. History of the Protocol and main provisions

11. Under this agenda item, Ms. Marianela Araya Quesada reviewed the general concepts in biosafety and in the Cartagena Protocol on Biosafety, including (a) history of the Cartagena Protocol and main provisions; and (b) relevant decisions of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol.

2.2. The Biosafety Clearing-House

12. Mr. Zakir Jafry and Mr. Austein McLoughlin from the Secretariat of the Convention on Biological Diversity presented on the new Biosafety Clearing-House (BCH) and its functions and new features. During the presentation, the importance of the scientific records of the BCH and their link to risk assessment of living modified organisms was emphasized. The participants learned how to navigate on the BCH and use the various filters and sub-filters to find relevant information within it.

2.3. Techniques used in modern biotechnology

13. Following the presentation on the BCH, Mr. Felix Moronta Barrios from the International Centre for Genetic Engineering and Biotechnology (ICGEB) presented an overview of modern biotechnology in terms of common techniques used to modify plants and its historical development. New genomic techniques were also briefly presented.

ITEM 3. NATIONAL BIOSAFETY FRAMEWORKS

3.1. Türkiye's National Biosafety system and experience

14. Under this agenda item, Ms. Remziye Yilmaz from Hacettepe University presented on biosafety implementation in Türkiye, including information on the national biosafety law and regulations. The participants were also familiarized with Türkiye's technical guidelines for risk assessment.

³ Annex to document CBD/CP/RARM/OM/2022/2/1/Add.1.

⁴ <u>CBD/CP/RARM/OM/2022/2/1</u>.

3.2. Competent national authorities, practices and principles

15. Next, Ms. Wendy Craig from ICGEB presented an overview of the structure and role of national biosafety frameworks, including a definition of national competent authorities and examples of biosafety frameworks from various countries.

3.3. Expert advice and the role of the risk assessors

16. Mr. Felix Moronta Barrios presented on the role of regulators and scientific advisory bodies, including such issues as the responsibilities of risk assessors, the roster of biosafety experts and public participation. Examples of scientific advisory bodies in different nations were also provided.

ITEM 4. OVERVIEW OF THE RISK ASSESSMENT

4.1. Methodology

17. Mr. James Rhodes from Biosafety South Africa provided an overview of the risk assessment methodology, including such issues as national protection goals, assessment endpoints, practices and principles, and definition of terms, such as adverse effects, exposure and characterization.

4.2. Overarching issues (quality and relevance of information, uncertainty)

18. Ms. Wendy Craig presented on quality of evidence in terms of appropriateness, reliability, transparency, expertise, strength and robustness. Relevance of sources of information, and the identification and consideration of uncertainty, were also explored.

4.3. The planning phase (context and scope, assessment endpoints, choice of comparators)

19. During this item, Mr. Felix Moronta Barrios explained the context and scope, selecting relevant assessment endpoints or representative species, establishing the baseline for risk assessment, how to choose suitable comparators and how to develop risk hypotheses.

4.4. Conducting the risk assessment (identification of novel characteristics, evaluation of likelihood and consequences, estimation of the overall risk, acceptability of risk)

20. Under this agenda item, Mr. Wendy Craig provided information key for conducting the risk assessment. The identification of the novel characteristics of living modified organisms, how to evaluate the likelihood or occurrence of adverse effects and the possible consequences, as well as the overall estimation of the risk were detailed. Further, concepts such as gene flow, allergenicity and receiving environment were also mentioned.

4.5. Preparing a risk assessment report and recommendation

21. Mr. James Rhodes presented on the important aspects to consider when drafting risk assessment reports. In his presentation he highlighted that a report presented in a well-structured form will not only facilitate the deliberations of decision makers but will also allow for an easier exchange of information and experience. The presentation also included information on the background and scope of the risk assessment, characterization and estimation of risk, and a description of risk management and monitoring strategies.

ITEM 5. CASE STUDY

- 22. For the case study, a hypothetical drought-tolerant wheat for cultivation in Central Asia was selected. Mr. Felix Moronta Barrios briefly presented some key points from the prepared biology and case study documents, including information on the context, trait and a brief description of the molecular biology behind the event.
- 23. Following the presentation, participants were divided into small groups and tasked with applying the theory and concepts from the previous agenda items to assess the environmental release of the drought-tolerant wheat. The resource team members guided the participants in developing their harms, protection goals, pathways to harm, evaluations of risk and mock dossiers. Participants were given opportunities to present their group work.

ITEM 6. CURRENT RISK ASSESSMENT DISCUSSIONS, COOPERATION OPORTUNITIES AND RESOURCE MOBILIZATION

6.1. Biosafety cooperation initiatives within Asia

- 24. Mr. Homin Jang of the Korea Institute for Promoting Asia Biosafety Cooperation (KIPABiC) presented an overview of biosafety in the Republic of Korea, the Asia Biosafety Family and the mission of KIPABiC. In his presentation, Mr. Homin Jang emphasized the importance of regional cooperation in the field of biosafety.
 - 6.2. Risk assessment discussions under the Cartagena Protocol, agenda of the tenth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol and resource mobilization opportunities
- 25. Ms. Marianela Araya Quesada summarized the current work under risk assessment under the Cartagena Protocol, as well as the main issues to be discussed at the upcoming meeting of the Parties. In addition, she also provided information on resource mobilization opportunities, including information on how to access funding from the Global Environmental Facility for projects on biosafety.

ITEM 7. CONCLUSIONS AND RECOMMENDATIONS

7.1. Evaluation of the workshop and feedback

- 26. Under this item, participants were invited to fill out a survey online to evaluate the workshop and provide feedback. The results of the survey are presented in annex II.
- 27. Overall, the participants found the workshop useful. In particular, the participants found the case study to be the most useful element of the workshop. The presentations on the BCH and the Cartagena Protocol were also well received. Some participants suggested that the workshop would have benefited from additional days to perform further practical exercises.

7.2. Closure of the workshop

28. The workshop was closed at 11.30 a.m. on Friday, 21 October 2022.

Annex I

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Annex II

RESULTS OF THE WORKSHOP EVALUATION

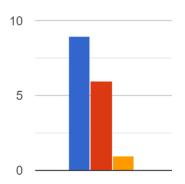
At the end of the training course, a survey was distributed to gather feedback from participants. Graphical representations of the 16 responses are illustrated below.

1) During the workshop, how much did you learn regarding the following:

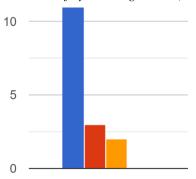
Rate on a scale from 5-1, where 5 is "a significant amount" and 1 is "None".



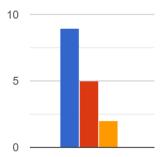
a. The Cartagena Protocol and its approach to risk assessment



b. The Biosafety Clearing-House (BCH)

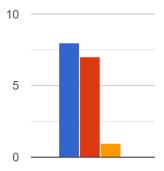


c. The various steps to conduct risk assessment

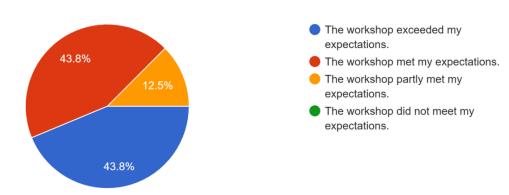




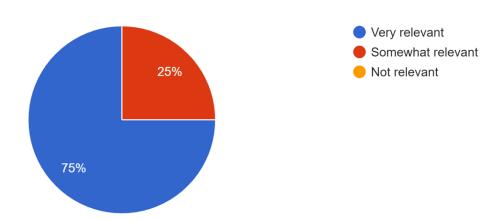
d. Practical (hands-on) experience in assessing mock dossiers



2) To what extent were your expectations regarding the workshop met? 16 responses



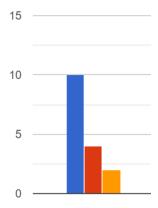
3) How relevant was the subject matter of the course to your job activities? 16 responses



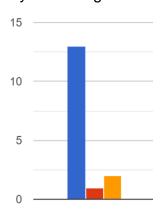
Content and facilitation of the workshop



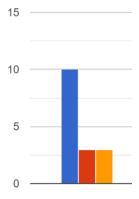
4) The workshop objectives were clear



5) Quality of training materials



6) Organization of sessions

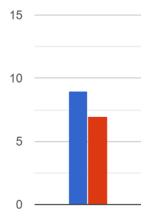


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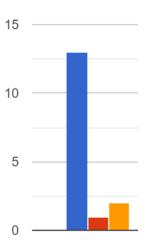
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7) Balance and relevant of topics

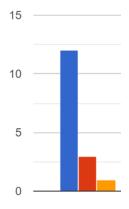


8) Overall assessment of trainers/facilitators

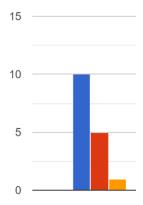




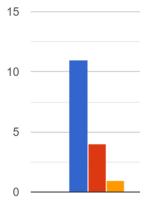
9) Usefulness of each session/topic: Overview of biosafety and the Cartagena Protocol on Biosafety



9.2) Usefulness of each session/topic: National biosafety frameworks

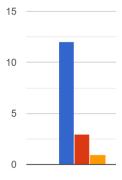


9.3) Usefulness of each session/topic: Overview of the risk assessment

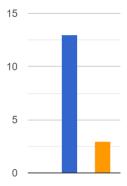




9.4) Usefulness of each session/topic: Case studies



9.5) Usefulness of each session/topic: Current risk assessment discussions, cooperation opportunities and resource mobilization



10) Overall assessment of the workshop

