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Training Course on Risk Assessment of Living Modified Organisms for Western, Central and Eastern Asia

Antalya, Türkiye 17-21 October 2022

Annotated provisional agenda

Introduction

1. At their eighth meeting, in decision [BS-VIII/12](http://bch.cbd.int/protocol/decisions/?decisionID=13521), 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 CP-[VIII/3](http://bch.cbd.int/protocol/decisions/?decisionID=13550) on capacity-building, the Parties also requested the Executive Secretary to facilitate the priority capacity-building activities for supporting the implementation of the [Cartagena Protocol](http://bch.cbd.int/protocol/text/).
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 is organizing the training course on risk assessment of living modified organisms for the Western, Central and Eastern Asian region, to be held in Antalya, Türkiye, from 17-21 October 2022.
4. The objectives of the workshop are 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.

1. The workshop will be conducted in English and will consist of plenary sessions and break-out groups. Documents for the workshop will be posted at <https://www.cbd.int/meetings/CP-RARM-OM-2022-02>. Participants are requested to bring their own copies of the documents in electronic form, if possible, to minimize the environmental impact of the workshop.

**ITEM 1. OPENING OF THE WORKSHOP**

**1.1. Welcoming remarks**

1. The workshop will be opened at 9 a.m. on Monday, 17 October 2022. Representatives of the Ministry of Agriculture and Forestry General Directorate of Agricultural Research and Policies and the Secretariat of the Convention on Biological Diversity will make opening remarks.

**1.2. Introduction of participants**

1. Participants in the workshop will be invited to introduce themselves and provide 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.

**1.3. Organization of work**

1. After the introductions by the participants, a representative of the Secretariat will explain the workshop objectives and logistical arrangements.

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

**2.1. History of the Protocol and main provisions**

1. Under this agenda item, participants will review general concepts in biosafety and in the Cartagena Protocol on Biosafety, including the following:
2. History of the Cartagena Protocol and main provisions;
3. 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**

1. A presentation on the new Biosafety Clearing-House (BCH), its functions and new features will be offered, including the importance of the scientific records of the BCH.

**2.3. Techniques used in modern biotechnology**

1. Under this item a presentation will offer information on common modern biotechnology techniques as well as its advances through the years.

**ITEM 3. NATIONAL BIOSAFETY FRAMEWORKS**

**3.1.** **Türkiye’s National Biosafety system and experience**

**12.** A presentation from a local representative will be offered sharing information on Türkiye’s National Biosafety system and experience with risk assessment.

**3.2 Competent national authorities, practices and principles**

1. 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**

1. The role of regulators and scientific advisory bodies will be presented, including such issues as the responsibilities of risk assessors, the roster of biosafety experts and public participation.

**ITEM 4. OVERVIEW OF THE RISK ASSESSMENT**

**4.1. Methodology**

1. 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, will be presented.

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

1. A presentation will be offered on quality and relevance of information, and identification and consideration of uncertainty.

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

1. This topic will include establishing 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 livelihood and consequences, estimation of the overall risk, acceptability of risk)**

1. Information key for conducting the risk assessment will be presented here. Some of the issues that will be included in this presentation are 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. Concepts such as gene flow, allergenicity and receiving environment, will be part of this topic.

**4.5. Preparing a risk assessment report and recommendation**

1. This topic will include important aspects to consider when drafting risk assessment reports. 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 will include information on the background and scope of the risk assessment, characterization and estimation of risk, and a description of risk management and monitoring strategies.

**4.6. Websites and other sources of information useful for the risk assessment**

1. Useful sources of information related to conducting a risk assessment will be shown.

**ITEM 5. CASE STUDIES**

**5.1. Presentation of case study 1**

1. A case study will be presented during the plenary session and the group will be presented with an example of how that particular case study could be assessed on the basis of the concepts and methodologies previously presented under other items of the agenda. The intention of this exercise is to give the participants the opportunity to see how the concepts are applied. This is expected to facilitate the next exercise, in which participants will analyse another case study.

**5.2. Presentation of case study 2**

1. A second case study will be presented in plenary and participants will then break into groups and undertake an assessment of the information presented on the case study. Participants will be requested to formulate hypotheses, identify protection goals and assessment end-point, and to apply the risk assessment methodology. At the end of the session, each group will report back to the plenary, presenting their assessment, which will lead to a group discussion.

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

**6.1. Biosafety cooperation initiatives within Asia**

22. A presentation will be offered by a representative of Korea Institute for Promoting Asia Biosafety Cooperation (KIPABiC).

**6.2. Risk assessment discussions under the Cartagena Protocol and resource mobilization opportunities**

1. A presentation will be offered to summarize 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, information on resource mobilization opportunities will be provided 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**

1. An evaluation form will be given to participants to collect their opinions on the workshop. Participants will also be given an opportunity to discuss their feedback.

**7.2. Closure of the workshop**

1. The workshop is expected to close at noon (12 p.m.) on Friday 21 October 2022.

*Annex*

**Programme of work for the TRAINING COURSE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS Western, Central and Eastern Asia**

| *Date* | *Activity* |
| --- | --- |
| **Monday, 17 October 2022** | |
|  | **Item 1. Opening of the workshop** |
| 9–9.30 a.m. | Registration of participants |
| 9.30–10 a.m. | Items 1.1, 1.2 and 1.3. Welcoming remarks, organization of work and introduction of participants |
| 10–10.30 a.m. | **Item 2. Overview of biosafety and the Cartagena Protocol on Biosafety**  Item 2.1. History of the Protocol and main provisions (SCBD staff) |
| 10.30–11 a.m. | *Coffee/tea break* |
| 11–11.30 a.m.  11.30 a.m. –12.15 p.m.  12.15–12.30 p.m.  12.30–1.30 p.m.  1.30–2.30 p.m. | Item 2.2. Biosafety Clearing-House  Item 2.2.1. Scientific records on the Biosafety Clearing-House  Item 2.2.2. Biosafety Clearing-House supporting risk assessment  *Lunch Break*  Item 2.3. Techniques used in modern biotechnology.  **Item 3. National Biosafety Frameworks** |
| 2.30–3 p.m.  3.–3.30 p.m.  3.30-4.30 p.m. | Item 3.1 Türkiye’s National Biosafety system and experience  Item 3.2. National protection goals and assessment endpoints, competent national authorities and other national and international obligations  *Coffee/tea break* |
| 4.30–5 p.m. | Item 3.3. Expert advice and the role of the risk assessor(s), scientific advisory body and stakeholder participation. |
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| **Tuesday, 18 October 2022** | |
|  | **Item 4. Overview of the risk assessment** |
| 9–10 a.m. | Item 4.1. Risk assessment methodology (resource team-TBD) |
| 10–10.30 a.m. | Item 4.2. Overarching issues: Quality and relevance of information, uncertainty (resource team-TBD) |
| 10.30–11 a.m. | *Coffee/tea break* |
| 11 a.m. –12 noon | Item 4.3. The planning phase  Context and scope, assessment endpoints, choice of comparators, risk hypothesis (resource team-TBD) |
| 12 noon–1 p.m. | Item 4.4. Conducting the risk assessment Identification of novel characteristics, evaluation of livelihood and consequences, estimation of the overall risk, acceptability of risk (resource team-TBD) |
| 1–2.30 p.m. | *Lunch break* |
| 2.30–3.15 p.m. | Item 4.5. Preparing a risk assessment report and recommendation (resource team-TBD) |
| 3.15–4 p.m. | Item 4.6. Websites and other sources of information useful for the risk assessment |
| 4–4.30 p.m. | *Coffee/tea break* |
| 4.30–5 p.m. | Group discussion - Risk assessment experiences in the region, questions and answers |
| **Wednesday, 19 October 2022** | |
|  | **Item 5. Case studies** |
| 9–9.45 a.m. | Item 5.1. Presentation of case study 1(resource team-TBD) Plenary session to exemplify how to apply the risk assessment methodology |
| 9.45–10.30 a.m. | Item 5.1. (*Continued*) Plenary session on analysis of case study 1: identification of protection goals, operational protection goals and assessment endpoints |
| 10.30–11 a.m. | *Coffee/tea break* |
| 11–12.30 p.m.  12.30–1.30 p.m. | Item 5.1. (*Continued*)  Plenary session on analysis of case study 1: identification of protection goals, operational protection goals and assessment endpoints  *Lunch break* |
| 1.30–3 p.m. | Item 5.1. (*Continued*) Plenary session on analysis of case study 1: development of risk hypothesis, risk scenarios (pathways to harm) hypothesis testing, estimation of risks |
| 3–3.30 p.m. | *Coffee/tea break* |
| 3.30–4.30 p.m. | Item 5.1. (*Continued*) Plenary session on analysis of case study 1: conclusions and information for the risk assessment report |
| **Thursday, 20 October 2022** | |
| 9–9.45 a.m. | Item 5.2. Presentation of case studies (2) |
| 9.45–10.30 a.m. | Item 5.2. (*Continued*) Break-out groups: identification of protection goals, operational protection goals and assessment endpoints |
| 10.30–11 a.m. | *Coffee/tea break* |
| 11 a.m. –12.30 p.m. | Item 5.2. (*Continued*) Break-out groups: development of risk hypothesis |
| 12.30–1.30 p.m. | *Lunch break* |
| 1.30–3 p.m. | Item 5.2. (*Continued*) Break-out groups: development and testing of risk scenarios |
| 3–3.30 p.m. | *Coffee/tea break* |
| 3.30–4.30 p.m.  **Friday 21 October 2022**  9.30–10 a.m.  10- 10.30 a.m.  10.30–11 a.m.  11–11.30 a.m. | Item 5.2. (*Continued*) Plenary session on analysis of case study 1: report of break-out groups on their analysis  **Item 6. Current risk assessment discussions, cooperation opportunities and resource mobilization**  Item 6.1. Biosafety cooperation initiatives within Asia  Item 6.2. Risk assessment discussions under the Cartagena Protocol and resource mobilization opportunities  **Item 7. Conclusions and recommendations**  Item 7.1. Conclusions and recommendations- discussion and survey  Item 7.2. Closure of the workshop |

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