



## Convention on Biological Diversity

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LATIN AMERICAN TRAINING COURSE ON  
RISK ASSESSMENT OF LIVING  
MODIFIED ORGANISMS  
Panama City, Panama, 20-24 August 2018

### ANNOTATED PROVISIONAL AGENDA

#### INTRODUCTION

1. At their eighth meeting, in decision [BS-VIII/12](#), 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 their decision [VIII/3](#) 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.
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 Environment of Panama, the Secretariat of the Convention on Biological Diversity is organizing the workshop on risk assessment of living modified organisms for the Latin American region, to be held in Panama City from 20 to 24 August 2018.
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.
5. The workshop will be conducted in Spanish, with simultaneous English/Spanish interpretation (if needed), 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-CB-2018-01>. 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

6. The workshop will be opened by a representative of the Ministry of Environment at 10 a.m. on Monday, 20 August 2018. Representatives of the [United Nations Environment Programme's Regional Office for Latin America and the Caribbean](#), and the Secretariat of the Convention on Biological Diversity will also make opening remarks.

## **1.2. Introduction of participants**

7. 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**

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

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

9. Under this agenda item, participants will review general concepts in biosafety and the Cartagena Protocol on Biosafety, including the following:

- (a) History of the Cartagena Protocol and main provisions;
- (b) Relevant decisions of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol and the [Strategic Plan for the Cartagena Protocol for the period 2011-2020](#);
- (c) Techniques used in modern biotechnology;
- (d) Synthetic biology and biosafety.

### **ITEM 3. RISK ASSESSMENT EXPERIENCES IN THE REGION**

#### **3.1. Experience of Panama with risk assessment and the regulatory system for living modified organisms**

10. A representative of the national biosafety commission will present the country's national biosafety system, including a description of the main components and operations associated with the implementation of the Cartagena Protocol, in particular with risk assessment.

#### **3.2. Presentations from participants: national experience with risk assessment and the application of the Cartagena Protocol**

11. Participants will offer short presentations (5-10 minutes each) about how risk assessment is carried out in their countries, highlighting main challenges and strengths.

### **ITEM 4. NATIONAL BIOSAFETY FRAMEWORKS**

#### **4.1. Competent national authorities, practices and principles**

12. 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.

#### **4.2. Expert advice and the role of the risk assessors**

13. 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 5. OVERVIEW OF THE RISK ASSESSMENT**

#### **5.1. Methodology**

14. 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.

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

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

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

16. 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.

### **5.4. Conducting the risk assessment (identification of novel characteristics, evaluation of livelihood and consequences, estimation of the overall risk, acceptability of risk)**

17. 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.

### **5.5. Preparing a risk assessment report and recommendation**

18. This topic will include important aspects to consider when drafting risk assessment reports. A report presented in a well-structured form, will not only facilitates 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.

## **ITEM 6. CASE STUDIES**

### **6.1. Presentation of case study 1**

19. 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.

### **6.2. Presentation of case study 2**

20. A second case study will be presented in plenary, and the 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 7. RESOURCE MOBILIZATION AND BIOSAFETY CLEARING HOUSE**

### **7.1. Biosafety resource mobilization**

21. A presentation will be offered on how to access funding from the [Global Environmental Facility](#) for projects on biosafety.

### **7.2. Biosafety Clearing-House**

22. A presentation will be offered on how to use the Biosafety Clearing-House.

## **ITEM 8. CONCLUSIONS AND RECOMMENDATIONS**

### **8.1. Evaluation of the workshop**

23. An evaluation form will be given to participants to collect their opinions on the workshop.

### **8.2. Closure of the workshop**

24. The workshop is expected to close at 1 p.m. on Friday, 24 August 2018.

*Annex*

**PROGRAMME OF WORK FOR THE LATIN AMERICAN TRAINING COURSE ON RISK  
ASSESSMENT OF LIVING MODIFIED ORGANISMS**

<i>Date</i>	<i>Activity</i>
<b>Monday, 20 August 2018</b>	
	Item 1. Opening of the workshop
9 a.m.	Registration of participants
10 a.m.	Item 1.2. Welcoming remarks, organization of work and introduction of participants
11-11.15 a.m.	Coffee/tea break
	Item 2. Overview of biosafety and the Cartagena Protocol on Biosafety
11.15-11:45 a.m.	Item 2.1. History of the Protocol and main provisions
11.45 a.m.- 12.15 p.m.	Item 2.2. Techniques used in modern biotechnology
12.15-1 p.m.	Item 3.1. Risk assessment experiences in the region: experience of Panama with risk assessment and the regulatory system for living modified organisms
1-2 p.m.	Lunch break
2-2.30 p.m.	Item 3.1 ( <i>continued</i> ). Experience of Panama with risk assessment and the regulatory system for living modified organisms
2.30-3.30 p.m.	Item 3.2. Presentations from participants: national experience with risk assessment and the application of the Cartagena Protocol
3.30-4 p.m.	Coffee/tea break
4-5 p.m.	Item 3.2 ( <i>continued</i> )
<b>Tuesday, 21 August 2018</b>	
	Item 4. National biosafety frameworks
9-9.30 a.m.	Item 4.1. Competent national authorities, practices and principles
9.30-10 a.m.	Item 4.2. Expert advice and the role of risk assessors
	Item 5. Overview of the risk assessment
10-10.45 a.m.	Item 5.1. Methodology
10.45-11.15 a.m.	Coffee/tea break
11.15 a.m.-12 p.m.	Item 5.2. Overarching issues Quality and relevance of information, uncertainty
12-1.30 p.m.	Lunch break
1.30-2.30 p.m.	Item 5.3. The planning phase Context and scope, assessment endpoints, choice of comparators, risk hypothesis
2.30-3:30 p.m.	Item 5.4. Conducting the risk assessment Identification of novel characteristics, evaluation of livelihood and consequences, estimation of the overall risk, acceptability of risk
3.30-4 p.m.	Coffee/tea break
4-5 p.m.	Item 5.5. Preparing a risk assessment report and recommendation
<b>Wednesday, 22 August 2018</b>	
	Item 6. Case studies
9-9.45 a.m.	Item 6.1. Presentation of case study 1 Plenary session to exemplify how to apply the risk assessment methodology

<i>Date</i>	<i>Activity</i>
9.45-10.30 a.m.	Item 6.1 ( <i>continued</i> ) 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 a.m.-12 p.m.	Item 6.1 ( <i>continued</i> ) Plenary session on analysis of case study 1 (development of risk hypothesis)
12-1.30 p.m.	Lunch break
1.30-3.30 p.m.	Item 6.1 ( <i>continued</i> ) Plenary session on analysis of case study 1: development of risk scenarios (pathways to harm) hypothesis testing, estimation of risks
3.30-4 p.m.	Coffee/tea break
4-5 p.m.	Item 6.1 ( <i>continued</i> ) Plenary session on analysis of case study 1: conclusions and information for the risk assessment report
<b>Thursday, 23 August 2018</b>	
9-9.45 a.m.	Item 6.2. Presentation of case study 2 and practical session (break-out groups)
9.45-10.30 a.m.	Item 6.2 ( <i>continued</i> ) 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 p.m.	Item 6.2 ( <i>continued</i> ) Break-out groups: development of risk hypothesis
12-1.30 p.m.	Lunch break
1.30-3.30 p.m.	Item 6.2 ( <i>continued</i> ) Break-out groups: development and testing of risk scenarios (pathways to harm, estimation of risks)
3.30-4 p.m.	Coffee/tea break
4-5 p.m.	Item 6.2 ( <i>continued</i> ) Plenary session on analysis of case study 1: report of break-out groups on their analysis
<b>Friday, 24 August 2018</b>	
	Item 7. Resource mobilization and the Biosafety Clearing-House
9-9.45 a.m.	Item 7.1. Biosafety resource mobilization
9.45-10.30 a.m.	Item 7.2. Biosafety Clearing-House
10.30-11 a.m.	Coffee/tea break
	Item 8. Conclusions and recommendations of the workshop
11 a.m. -12 p.m.	Item 8.1. Evaluation of the workshop
12.00-1 p.m.	Item 8.2. Closure of the workshop