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CENTRAL AND EASTERN EUROPEAN TRAINING COURSE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS
Minsk, 24-28 September 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 Institute of Genetics and Cytology of Belarus, the Secretariat of the Convention on Biological Diversity is organizing the workshop on risk assessment of living modified organisms for the Central and Eastern European region, to be held in Minsk from 24 to 28 September 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 English and Russian with simultaneous English/Russian interpretation 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-2018-02. 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

6. The workshop will be opened by a representative of the Ministry of Natural Resources and Environmental Protection at 10 a.m. on Monday, 24 September 2018. Representatives of the National Academy of Sciences, the Institute of Genetics and Cytology 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 Belarus with risk assessment and the regulatory system for living modified organisms

10. A representative of Belarus 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.

3.3. Tour of the Institute of Genetics and Cytology

12. A representative of the Institute of Genetics and Cytology will guide the group on a tour that will offer the possibility for participants to understand the work that is done at the workshop's host institution.

ITEM 4. NATIONAL BIOSAFETY FRAMEWORKS

4.1. Competent national authorities, practices and principles

13. 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

14. 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

15. 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)

16. 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)

17. 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)

18. 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

19. 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

20. 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

21. 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

22. A presentation will be offered on how to access funding from the Global Environmental Facility for projects on biosafety.

7.2. Biosafety Clearing-House

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

ITEM 8. CONCLUSIONS AND RECOMMENDATIONS

8.1. Evaluation of the workshop

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

8.2. Closure of the workshop

25. The workshop is expected to close at 1 p.m. on Friday, 28 September 2018.

Annex

PROGRAMME OF WORK FOR THE CENTRAL AND EASTERN EUROPEAN TRAINING COURSE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

Date	*Activity*
Monday, 24 September 2018	
	Item 1. Opening of the workshop
8.30-9.00 a.m.	Registration of participants
9-9.45 a.m.	Item 1.2. Welcoming remarks, organization of work and introduction of participants
	Item 2. Overview of biosafety and the Cartagena Protocol on Biosafety
9.45-10.15 a.m.	Item 2.1. History of the Protocol and main provisions
10.15-10.45 a.m.	Coffee/tea break
10.45 a.m.-11.30 a.m.	Item 2.2. Techniques used in modern biotechnology
11.30 a.m.-12.15 p.m.	Item 3.1. Synthetic biology and Biosafety
12.15 p.m.-1.45 p.m.	Lunch break
1.45-2.15 p.m.	Item 3.2 Risk assessment experiences in the region: experience of Belarus with risk assessment and the regulatory system for living modified organisms
2.15-3.45p.m.	Item 3.2. Presentations from participants: national experience with risk assessment and the application of the Cartagena Protocol
3.45-4 p.m.	Coffee/tea break
4-5 p.m.	Item 3.2 (*continued*)
Tuesday, 25 September 2018	
	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
10-10.15 a.m.	Coffee/tea break
	Item 5. Overview of the risk assessment
10.15-11.15 a.m.	Item 5.1. Risk Assessment Methodology
11.15 a.m.-12 p.m.	Item 5.2. Overarching issues: Quality and relevance of information, uncertainty
12-1.45 p.m.	Lunch break
1.45-2.30 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.	Tour of the Institute of Genetics and Cytology

Date	*Activity*
Wednesday, 26 September 2018	
9-9.45 a.m.	Item 5.5. Preparing a risk assessment report and recommendation
	Item 6. Case studies
9.45-10.30 a.m.	Item 6.1. Presentation of case study 1 Plenary session to exemplify how to apply the risk assessment methodology
10.30-11 a.m.	Coffee/tea break
11 a.m.-12 p.m.	Item 6.1 (*continued*) Plenary session on analysis of case study 1: identification of protection goals, operational protection goals and assessment endpoints
12-1.45 p.m.	Lunch break
1.45-3.30 p.m.	Item 6.1 (*continued*) Plenary session on analysis of case study 1: development of risk hypothesis, risk scenarios (pathways to harm) hypothesis testing, estimation of risks
3.30-4 p.m.	Coffee/tea break
4-5 p.m.	Item 6.1 (*continued*) Plenary session on analysis of case study 1: conclusions and information for the risk assessment report
Thursday, 27 September 2018	
9-9.45 a.m.	Item 6.2. Presentation of case study 2
9.45-10.30 a.m.	Item 6.2 (*continued*) Break-out groups: identification of protection goals, operational protection goals and assessment endpoints
10.30-11 a.m.	Coffee/tea break
11a.m. -12 p.m.	Item 6.2 (*continued*) Break-out groups: development of risk hypothesis
12-1.45 p.m.	Lunch break
1.45-3.30 p.m.	Item 6.2 (*continued*) Break-out groups: development and testing of risk scenarios
3.30-4 p.m.	Coffee/tea break
4-5 p.m.	Item 6.2 (*continued*) Plenary session on analysis of case study 1: report of break-out groups on their analysis
Friday, 28 September 2018	
	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