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REPORT ON THE LATIN AMERICAN TRAINING COURSE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

Panama City, 20-24 August 2018

INTRODUCTION

1. At its eighth meeting, in decision CP-VIII/12, 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 (LMOs).

2. Similarly, in their decision CP-VIII/3 on capacity-building, the Parties also requested the Executive Secretary to facilitate 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 organized a training course on risk assessment of living modified organisms for the Latin American region, which was held in Panama City from 20 to 24 August 2018.

4. The objectives of the course were to provide theoretical and practical training for participants on:

(a) The risk assessment process (concepts, steps, methodology, key issues to consider);

(b) 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 training course consisted of plenary sessions and break-out groups. Documents for the course are posted at https://www.cbd.int/meetings/CP-RARM-CB-2018-01.

ITEM 1. OPENING OF THE COURSE

6. The course was opened by Mr. Emilio Sempris, Minister of Environment of Panama, at 10 a.m. on Monday, 20 August 2018. In his remarks, Mr. Sempris welcomed the participants to Panama and emphasized the importance of effective training in the field of risk assessment of LMOs as well as the importance of cooperation among countries of the region.

7. Mr. Leo Heileman, Regional Director of the United Nations Environment Programme's office for Latin America and the Caribbean, also welcomed the participants and the Secretariat to Panama. He stressed the importance of the Cartagena Protocol and the actions taken to ensure safe use of biotechnology developments. He also expressed the hope that the participants would take advantage of the knowledge being shared during the course to reinforce existing capacities in their countries.

8. Ms. Marianela Araya of the Secretariat welcomed the participants to the course. She highlighted the cross-cutting nature of biosafety, and the importance of risk assessment for the effective implementation of the Cartagena Protocol. She expressed gratitude to the Government of the Republic of Korea for its generous financial support and the Government of Panama for hosting the meeting.

9. Following the opening remarks, Ms. Araya introduced the course objectives and the provisional programme of work.

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

10. Under this agenda item, the representative of the Secretariat gave a presentation to provide an overarching framework for the work on risk assessment that was to be undertaken during the training course, including concepts, history and main provisions of the Cartagena Protocol. The presentation provided information on the history of the Protocol, its importance, and its links to the Convention on Biological Diversity, the Aichi Biodiversity Targets and the Sustainable Development Goals. The presentation also included a description of some of the articles of the Protocol, in particular Article 15 on risk assessment, Article 16 on risk management, and Annex III.

ITEM 3. RISK ASSESSMENT EXPERIENCES IN THE REGION

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

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

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

12. Participants from the countries represented at the training course offered short presentations about how risk assessment was carried out on their countries, highlighting main challenges and strengths. This session was particularly useful for sharing experiences between the countries, as well as identifying lessons learned from the various approaches followed by countries in relation to the implementation of their national biosafety frameworks.

ITEM 4. NATIONAL BIOSAFETY FRAMEWORKS[1]

4.1. Competent national authorities, practices and principles

13. An overview of the structure and role of national biosafety frameworks, including definition of national competent authorities, and examples of biosafety frameworks from various countries, were covered under this session. The rationale behind the session was to provide participants with a better understanding of the main role of national competent authorities using examples of the various approaches that have been followed by different countries.

4.2. Expert advice and the role of the risk assessors

14. The role of the regulators and scientific advisory bodies was presented, including such issues as the responsibilities of the risk assessors, the roster of biosafety experts and public participation. The presentation supported the better understanding of the risk assessor's function and the difference between "expert advice" and "decision-making".

ITEM 5. OVERVIEW OF THE RISK ASSESSMENT

5.1. Methodology

15. This session covered an overview of the risk assessment methodology, including such issues as national protection goals, assessment endpoints, practices and principles, and definition of such terms as adverse effects, exposure and risk characterization. Participants benefited from a detailed description of the various steps that are considered when undertaking a risk assessment.

[1] Presentations for items 4, 5, and 6 were provided by a team of three resource persons: Ms. Sol Ortiz, Ms. Leticia Pastor and Mr. Gutemberg Delfino Sousa.

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

16. A presentation on quality and relevance of information, and identification and consideration of uncertainty, gave the participants the opportunity to better understand how to deal with these overarching issues of the risk assessment process. Topics such as the quality and sources of information, as well as where to look for additional information and how to indicate uncertainty on a risk assessment report, were discussed.

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

17. This topic included establishing the context and scope of the risk assessment, selecting relevant assessment endpoints or representative species, establishing the baseline for risk assessment, how to choose suitable comparators and how to develop risk hypotheses. Participants were guided through the various steps leading to the formulation of risk hypotheses that would eventually be tested during the next steps of the risk assessment.

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

18. Information key for conducting the risk assessment was offered during this session. Among the issues included were identification of the novel characteristics of the LMOs, how to evaluate the likelihood of occurrence of adverse effects and the possible consequences, and the overall estimation of the risk. Concepts such as gene flow, allergenicity, and receiving environment, among others, were part of this topic.

5.5. Preparing a risk assessment report and recommendation

19. This topic provided participants with important information on aspects to consider when drafting risk assessment reports. It was highlighted that a report presented in a well-structured form facilitated the deliberations of decision makers. The presentation included information on the background and scope of the risk assessment, characterization and estimation of risk, and descriptions of risk management and monitoring strategies.

ITEM 6. CASE STUDIES

6.1. Presentation of case study 1

20. A case study on an insect-resistant and herbicide-tolerant maize was presented during the plenary session, and the group was guided by one of the resource persons on how that particular case study could be assessed on the basis of the concepts and methodologies presented during the previous days. The intention of this exercise was to give the participants an opportunity to see how the concepts are applied.

6.2. Presentation of case studies 2, 3 and 4

21. Three additional case studies (genetically modified goats, mosquitos and cotton) were presented in plenary, and the participants were then divided into groups to undertake an assessment of the information presented in the case studies. Participants were requested to identify protection goals, to formulate hypotheses, identify assessment end-points, and to apply the risk assessment methodology. Each group was guided by one of the resource team members. At the end of the session, each group reported back to the plenary, presenting their assessment, which led to a group discussion.

ITEM 7. RESOURCE MOBILIZATION AND BIOSAFETY CLEARING-HOUSE

7.1. Biosafety resource mobilization

22. A presentation was made on how to access funding from the Global Environment Facility (GEF) for projects on biosafety. The presentation included a brief explanation of what GEF is, how it works and how countries could use their resources under the System for Transparent Allocation of Resources (STAR) towards, among other things, the development of biosafety projects.

7.2. Biosafety Clearing-House

23. During this session, information was presented on how to use the Biosafety Clearing-House portal. The presentation covered such issues as the roster of experts, where to find information and what can be found in the Biosafety Clearing-House, and national and reference records, among others.

ITEM 8. CONCLUSIONS AND RECOMMENDATIONS

8.1. Evaluation of the course

24. An evaluation form was given to participants to collect their opinions on the course. The results of this evaluation are presented in annex II below.

8.2. Closure of the course

25. The course had a closing ceremony at which representatives of the Ministry of Environment and the Secretariat of the Convention on Biological Diversity thanked the participants, other donors and partners for the opportunity to host this activity. The course closed at 12.40 p.m. on Friday, 24 August 2018.

Annex I

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Annex II

EVALUATION QUESTIONNAIRE AND RESULTS

Participants were invited to evaluate the course by completing the questionnaire below. Participants were instructed to select the answer that best reflected their assessment of the course.

A total of 25 participants completed the questionnaire. The number of respondents for each option is shown below.

A. Overall assessment			
	# Yes	**# No**	**% Yes**
(1) During the workshop, were you able to acquire knowledge related to:			
The Cartagena Protocol and its approach towards risk assessment	33	2	94%
The steps to undertake risk assessment of LMOs	35	0	100%
Practical experience in assessing case studies	34	0	97%

	The workshop exceeded my expectations	**The workshop met my expectations**	**The workshop partly met my expectations**	**The workshop did not meet my expectations**	**% Exceeded**	**% Met**
(2) To what extent were your expectations regarding the workshop met?	19	16	0	0	54	46
	Very relevant	**Somewhat relevant**	**Not relevant**	**% relevant**	**% somewhat relevant**	
(3) How relevant was the subject matter of the course to your job activities?	31	4	0	89	11	

B. Content and conduct of the workshop							
	Average rating	**Excellent**	**Good**	**Adequate**	**Poor**	**Very poor**	**Not applicable**
Quality of training material	4.4	16	17	2	0	0	0
Quality of presentations	4.7	24	10	1	0	0	0
Sufficient time for discussion and participation	4.1	8	23	4	0	0	0
Balance and relevance of topics	4.3	13	17	2	0	0	0