UNEP

CBD

Convention on Biological Diversity

Distr.
GENERAL

CBD/CP/MOP/9/INF/3
17 October 2018

ENGLISH ONLY

CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY SERVING AS THE MEETING OF THE PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY
Ninth meeting
Sharm El-Sheikh, Egypt, 17-29 November 2018
Item 15 of the provisional agenda*

SUMMARY OF ACTIVITIES FOR CAPACITY-BUILDING ON RISK ASSESSMENT

I. 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 BS-VIII/3 on capacity-building, Parties also requested the Executive Secretary, subject to the availability of resources and in collaboration with relevant organizations, to facilitate and support implementation of the priority capacity-building activities for supporting the implementation of the Cartagena Protocol on Biosafety as reflected in the Short-term Action Plan (2017-2020) to enhance and support capacity-building for the implementation of the Convention and its Protocols.

3. The current document presents a summary of the activities undertaken by the Secretariat, and is based on the reports of the Latin America and Central and Eastern European training courses on risk assessment.

II. TRAINING COURSES FOR DEVELOPING CAPACITY ON RISK ASSESSMENT

4. In response to the requests in decision BS-VIII/12 and BS-VIII/3 and with support from the Government of the Republic of Korea, through the Korea Biosafety Capacity Building Initiative, and in collaboration with other institutions and Governments, the Secretariat organized two training courses to develop Parties' capacity to conduct risk assessments of living modified organisms.

5. The first course was held in Panama City, from 20 to 24 August 2018 for the Latin American region; and the second one took place in Minsk, from 24 to 28 September 2018 for the Central and Eastern European region.

6. Each of the training courses was coordinated with support from local partners and institutions, which contributed to the success of the activities. In the case of the course for the Latin American region, the Ministry of Environment of Panama, as well as UN Environment, through the UNEP-GEF project for the implementation of the national biosafety frameworks, were key partners providing technical and logistic support to the activity. For the Central and Eastern European course, the Institute of Genetics and Cytology of the National Academy of Sciences of Belarus was instrumental as local host of this course.

* CBD/CP/MOP/9/1.

7. The objectives of the courses 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.

8. The two courses consisted of plenary sessions, where theory and concepts were explained, and break-up groups sessions where participants were able to put in practice the knowledge acquired during the planetary sessions.

9. In total, 51 participants from 30 countries were trained during the courses, out of which 28 received financial support, through the fund provided by the Korea Biosafety Capacity Building Initiative, to participate.

10. In order to evaluate if the objectives of the training courses were achieved, the participants were requested to evaluate the training courses through an assessment form. The results of the evaluation indicate that participants were unanimously of the view that the training improved their understanding of the steps undertaken during risk assessments of living modified organisms and that they had gained practical experience in assessing case studies. A summary of the evaluation is presented as an annex of this document.

A. Summary of topics covered during the training courses

Overview of biosafety and the Cartagena Protocol

11. A presentation was made by the representative of the Secretariat and was aimed at providing an overarching framework for the work on risk assessment that was to be undertaken during the training course.

12. Participants received general information related to concepts, history and main provisions of the Cartagena Protocol. A presentation on the Cartagena Protocol provided information on the history of the Protocol, its importance, its link to the Convention on Biological Diversity, 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.

Risk assessment experiences in the region

13. During this session, participants from the various countries made presentations about how risk assessment was carried out in their countries, highlighting the main challenges and strengths, as well as describing how their biosafety systems operate. This session was particularly useful for sharing experiences between the countries, as well as to identify lessons learned from the various approaches followed by countries in relation to the implementation of their national biosafety frameworks. In addition, information from this session helped the trainers to better understand the main challenges faced by participants, and tailor the presentations and the level of discussions to match the audience needs and expertise.

National biosafety frameworks

14. This section focused on 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. The objective of this 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.

15. The role of the regulators and scientific advisory bodies was also presented, including issues such 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".

Overview of the risk assessment

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

17. Presentations and discussions on quality and relevance of information, identification and consideration of uncertainty gave participants the opportunity to better understand how to deal with these overarching issues of the risk assessment process. The topics discussed included the quality and sources of information as well as where to look for additional information, and how to treat uncertainty in a risk assessment report.

18. With regard to the topic of quality and sources of information, discussions included considerations for 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 risks hypothesis. Participants were guided through the various steps that will lead them to the formulation of risk hypothesis that will eventually be tested during the following steps of the risk assessment.

19. An overview of the information that is necessary for conducting the risk assessment was provided. Some of the elements discussed include: identification of the novel characteristics of the LMOs, 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, receiving environment, among others were part of this topic.

20. This session also provided important information to participants on aspects to consider when drafting risk assessment reports. It was highlighted that a report presented in a well-structured manner, will facilitate the deliberations of decision makers. The presentation included information on the background, and scope of the risk assessment, characterization and estimation of risk, as well as description of risk management and monitoring strategies.

Case studies

21. Two sessions during each of the training courses involved analysing case studies. The first session was conducted in plenary, and it consisted of a case study that was presented by one of the trainers. The groups were guided by the trainer on how that particular case study could be assessed based on the concepts and methodologies presented during previous days. The intention of this exercise was to give the participants an opportunity to see how the concepts and the risk assessment methodology are applied, which was expected to facilitate the next exercise, where participants were requested to analyse another case study.

22. In addition to the guided session referred to in the previous paragraph, another session included the analysis of additional case studies during break-up groups. Participants were requested to identify protection goals, assessment end points, formulate hypothesis and to develop and test risk scenarios. Each group was guided by one of the resource team members. At the end of the session, each group reported back to plenary, presenting their assessment, followed by a group discussion.

Resource mobilization and biosafety clearing house

23. A presentation was made on how to access funds from the Global Environmental Facility (GEF) for projects on biosafety. The presentation included a brief explanation of what GEF is, how it works and how counties could use their GEF resources to among other things, the development of biosafety projects.

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

Annex

EVALUATION QUESTIONNAIRE AND RESULTS

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

A total of 51 participants from the two training courses (Latin America and Central and Eastern European) completed the questionnaire. The number of respondents for each option is shown below.

Overall Assessment			
	Number of "Yes"	**Number of "No"**	**% of "Yes"**
During the course, were you able to acquire knowledge related to:			
The Cartagena protocol and its approach towards risk assessment	48	2	96%
The steps to undertake risk assessment of LMOs	50	0	100%
Practical experience in assessing case studies	49	0	100%

	The training				**% Exceeded expectations**	**% Met Expectations**
	Exceeded expectations	**Met expectations**	**Partly met expectations**	**Did not meet expectations**		
To what extent were your expectations regarding the training course met?	30	20	0	0	60	40
	Very relevant	**Somewhat relevant**	**Not relevant**	**% relevant**	**% somewhat relevant**	
How relevant was the subject matter of the course to your job activities?	41	9	0	98	18	

Content and organization of the course						
	Average rating	**Excellent**	**Good**	**Adequate**	**Poor**	**Very Poor**
Quality of training material	4.5	28	18	4	0	0
Quality of presentations	4.7	37	11	2	0	0
Sufficient time for discussion and participation	4.4	19	26	5	0	0
Balance and relevance of topics	4.5	25	19	3	0	0

Comments section

Summary of most useful topics for participants [1]

- Steps of the risk assessment process
- Preparing a risk assessment report
- Practical sessions and case studies
- Risk assessment experiences in the region
- Problem formulation methodology

Summary of suggestions

- To add a section on risk assessment of new and emerging technologies such as synthetic biology and gene drives.
- To increase the number of resource personnel
- To provide more information or extended sessions on GEF and BCH
- To provide links to complementary bibliography
- To increase the duration of the training
- To increase time for practical sessions
- To provide more information on unintended effects
- To increase the number of case studies to be analysed per group during break-up groups sessions

Summary of comments

The training courses were considered very useful, and in particular, participants highlighted the importance of the practical sessions, where they had the opportunity to better understand how the various steps for the risk assessment methodology are implemented. In addition, the participants also remarked the importance of the experiences shared by other countries in relation with how their biosafety systems operate. Finally, it was also remarked that the expertise of the resource teams was valued by participants.

[1] Topics are not listed on any particular order or relevance.