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REPORT ON THE ANGLOPHONE AFRICAN TRAINING COURSE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

PRETORIA SOUTH AFRICA, 8-12 APRIL 2019

INTRODUCTION

1. At their eighth meeting, in decision CP-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 (LMOs).

2. Likewise, in their decision CP-VIII/3 on capacity-building, Parties also requested the Executive Secretary to facilitate priority capacity-building activities in support of 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 Department of Environmental Affairs of the Government of South Africa, the Secretariat of the Convention on Biological Diversity organized a training course on risk assessment of living modified organisms for the Anglophone African region, which was held in Pretoria from 8 to 12 April 2019.

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) 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 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-2019-01.

6. In total, 37 participants attended the workshop in representation of 16 countries from the Anglophone African region (see annex I for the full list of participants).

ITEM 1. OPENING OF THE WORKSHOP

7. The course was opened by Ms. Wadzanayi Mandivenyi, Chief Director of the Biodiversity Specialist Monitoring and Services, Department of Environmental Affairs of the Government of South Africa, at 9 a.m. on Monday, 8 April 2019. She welcomed the participants to Pretoria and thanked the Secretariat for facilitating training in the field of risk assessment of LMOs.

8. Mr. Shonisani Munzhedzi, Deputy Director-General, Biodiversity and Conservation, Department of Environmental Affairs, also welcomed the participants and the Secretariat to South Africa. He stressed the importance of the Cartagena Protocol and of the actions taken to ensure the safe use of biotechnology, and praised the cross-sectoral cooperation within the national Executive Council for Genetically Modified Organisms. He invited the participants to take advantage of the knowledge that would be shared during the course to reinforce existing capacities in their countries and to trigger further regional cooperation in biosafety.

9. Mr. Julian Jaftha, Chairperson of the Executive Council for Genetically Modified Organisms, noted the role of the Department of Environmental Affairs in providing leadership in the field of science-based risk assessment of LMOs and expressed appreciation for the increasing regional cooperation in that regard.

10. Ms. Paola Scarone of the Secretariat of the Convention on Biological Diversity welcomed the participants to the course. She expressed gratitude to the Government of the Republic of Korea for its generous financial support and to the Government of South Africa for hosting the meeting.

11. Following the opening remarks, Ms. Scarone introduced the programme of work for the week and invited participants to introduce themselves.

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

2.1. History of the Protocol and main provisions

12. Under this agenda item, a presentation was given 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, 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.

2.2. Techniques used in modern biotechnology

13. Following the presentation on the Cartagena Protocol, an overview of the techniques used in modern biotechnology was presented to familiarize the participants with the way in which genetic modifications occur.

ITEM 3. RISK ASSESSMENT EXPERIENCES IN THE REGION

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

14. Under this agenda item, the South African national biosafety system was detailed, 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 on risk assessment and the application of the Cartagena Protocol

15. 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 to identify lessons learned from the various approached 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

16. 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 was covered under this session. The rationale behind this session was to provide participants with a better

[1] Presentations for items 4, 5, and 6 were provided by a team of three resource persons: Ms. Wendy Craig, Ms. Jana Collatz and Ms. Debora Glandorf.

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 risk assessors

17. The role of the regulators and scientific advisory bodies was presented, including such issues as the responsibilities of 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. Risk assessment methodology

18. This session covered an overview of the risk assessment methodology, including issues 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 considered when undertaking risk assessment.

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

19. 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. Also discussed were such topics 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.

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

20. This topic included 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 led them to the formulation of risk hypothesis that would eventually be tested during the following steps of the risk assessment.

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

21. Information key for conducting the risk assessment was offered under this item. Some of the issues included were: (a) identification of the novel characteristics of the LMOs, (b) how to evaluate the likelihood or occurrence of adverse effects and the possible consequences, and (c) the overall estimation of the risk. Such concepts as gene flow, allergenicity and receiving environment were part of this topic.

5.5. Preparing a risk assessment report and recommendation

22. This topic 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 form would 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.

ITEM 6. CASE STUDIES

6.1. Presentation of case study 1

23. A case study on insect-resistant, herbicide-tolerant maize was presented during the plenary session. The participants were divided into groups, each of which were guided by a resource person on how that particular case study could be assessed on the basis of the concepts and methodologies presented on preceding days. The intention of this exercise was to give the participants the opportunity to see how

the concepts are applied. At the end of the session, each group reported back to plenary, presenting their assessment, which led to a group discussion.

6.2. Presentation of case studies 2

24. An additional case study on engineered mosquitoes containing a gene drive was presented in plenary, and the participants were then divided into groups to undertake an assessment of the information presented on the case studies. Participants were requested to identify protection goals, formulate a hypothesis, identify the assessment end-point, and 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 plenary, presenting their assessment, which led to a group discussion.

ITEM 7. RESOURCE MOBILIZATION AND BIOSAFETY CLEARING HOUSE

7.1. Biosafety resource mobilization

25. A presentation was made on how to access funding from the Global Environment Facility for projects on biosafety. The presentation included a brief explanation of what the Global Environment Facility is, how it works and how counties could use their STAR resources towards, among other things, the development of biosafety projects.

7.2. Biosafety Clearing-House

26. 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, national and reference records, among others.

ITEM 8. CONCLUSIONS AND RECOMMENDATIONS OF THE COURSE

8.1. Evaluation of the workshop

27. Finally, participants undertook an evaluation of the workshop. The results are summarized in annex II below.

8.2. Closure of the workshop

28. During the closure ceremony, representatives of the Department of Environmental Affairs and the Secretariat of the Convention on Biological Diversity thanked the participants, the Government of the Republic of Korea, other donors and partners for the opportunity to host this activity. The workshop closed at 11 a.m. on Friday, 12 April 2019.

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 31 participants completed the questionnaire. The number of respondents for each option is shown below. Overall, the participants found the training course useful and well organized. They found the risk assessment methodology presented to be effective and the structure of the workshop conducive for learning. The case studies, particularly the mosquito containing an engineered gene drive, were well-received due to the quality and the technical challenge presented.

A. Overall assessment			
	Number of Yes	**Number of No**	**Percentage of Yes**
(1) During the workshop, were you able to acquire knowledge related to:			
The Cartagena Protocol and its approach towards risk assessment	31	0	100%
The steps to undertake risk assessment of LMOs	31	0	100%
Practical experience in assessing case studies	30	1	97%

	The workshop exceeded my expectations	**The workshop met my expectations**	**The workshop partly met my expectations**	**The workshop did not meet my expectations**	**Percentage exceeded**	**Percentage met**
(2) To what extent were your expectations regarding the workshop met?	6	21	4	0	19	68
	Very relevant	**Somewhat relevant**	**Not relevant**	**Percentage relevant**	**Percentage somewhat relevant**	
(3) How relevant was the subject matter of the course to your job activities?	27	4	0	87	13	

B. Content and facilitation of the workshop							
	Average rating	**Excellent**	**Good**	**Adequate**	**Poor**	**Very Poor**	**Not Applicable**
The objectives of the workshop were clear	4.4	13	17	1	0	0	0
Quality of the training material	4.2	12	14	4	1	0	0
Quality of presentations	4.3	15	11	5	0	0	0
Organization of the sessions	4.3	12	15	2	1	0	0
Balance and relevance of topics	4.1	10	17	3	0	0	0
Overall assessment of the facilitators	4.2	13	15	1	1	0	0
Overall clarity of the workshop	4.2	7	20	2	0	0	0
Usefulness of each topic							
Biosafety and the Cartagena Protocol	4.3	10	17	1	0	0	0
Risk assessment experiences in the region	4.0	8	15	6	1	0	1
Overview of the risk assessment methodology	4.3	14	13	2	1	0	0
Case studies	4.4	16	11	4	0	0	0
Resource mobilization and the Biosafety Clearing-House	4.1	8	18	4	1	0	0
Conclusions and recommendations	4.1	7	17	3	0	0	0

Note: Excellent = 5, Good = 4, Adequate = 3, Poor = 2, and Very Poor = 1

C. Logistics							
	Average rating	**Excellent**	**Good**	**Adequate**	**Poor**	**Very Poor**	**Not applicable**
Time for distributing the invitations, agenda, and relevant materials	4.3	16	8	4	1	0	1
Sufficient time for discussion and participation	4.1	11	12	7	0	0	0
Delivery time of travel arrangements and expenses	4.3	10	16	0	1	0	3
Duration of the workshop	3.9	7	13	6	2	0	0
Quality of the venue and facilities	4.6	19	8	1	1	0	0
Planning and overall organization	4.4	20	9	0	1	0	0

Note: Excellent = 5, Good = 4, Adequate = 3, Poor = 2, and Very Poor = 1