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MEETING OF THE PARTIES TO THE CARTAGENA
PROTOCOL ON BIOSAFETY
Fifth meeting
Nagoya, Japan, 11-15 October 2010
Item 13 of the provisional agenda*

REPORT OF THE PACIFIC SUBREGIONAL WORKSHOP ON CAPACITY-BUILDING AND EXCHANGE OF EXPERIENCES ON RISK ASSESSMENT AND RISK MANAGEMENT OF LIVING MODIFIED ORGANISMS

INTRODUCTION

1. At its fourth meeting, the Conference of the Parties serving as the meeting of the Parties to the Protocol, in paragraphs 12 and 13 of its decision BS-IV/11, requested the Executive Secretary:

"(a) To convene, in cooperation with relevant regional organizations, at the earliest convenient date and subject to the availability of financial resources, a subregional workshop on capacity-building and exchange of experiences on risk assessment and risk management of living modified organisms in the Pacific subregion; and

"(b) To coordinate and facilitate, along with other relevant United Nations bodies and other international organizations, the development of training on risk assessment and risk management in relation to living modified organisms (LMOs), and to convene prior to the fifth meeting of the Conference of the Parties serving as the meeting of the Parties, regional or subregional training courses to enable countries to gain hands-on experience in preparing and evaluating risk assessment reports in accordance to the articles and Annex III of the Protocol."

2. Following an offer from the Government of Fiji to host the workshop and the generous financial contributions from the Governments of the Netherlands, Norway and Spain, the Pacific Subregional Workshop on Capacity-building and Exchange of Experiences on Risk Assessment and Risk Management of Living Modified Organisms was held in Nadi, Fiji, from 5 to 7 July 2010.

3. Twelve participants nominated by six Parties to the Protocol (Fiji, Kiribati, Niue, Samoa, Solomon Islands and Tonga), two non-Party countries (Cook Islands and Vanuatu) and one organization (University of Canterbury, New Zealand) attended the workshop. The complete list of participants is attached as annex I below.

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ITEM 1. OPENING OF THE WORKSHOP

4. The workshop was opened on behalf of the Government of Fiji at 9 a.m. on Monday, 5 July 2010 by Mr. Jope Davetanivalu, Director of Environment, Ministry of Local Government, Urban Development, Housing and Environment.

5. In his opening remarks, Mr. Davetanivalu welcomed participants to Fiji and noted the need for capacity-building in biosafety in the Pacific subregion as an important prerequisite to the implementation of the Cartagena Protocol on Biosafety. He further noted that the subregion welcomed this particularly workshop since risk assessment is an important cornerstone for informed decision-making on LMOs.

6. Speaking on behalf of Mr. Ahmed Djoghlaf, Executive Secretary of the Convention on Biological Diversity, Mr. Charles Gbedemah, Senior Programme Officer, Biosafety Division, welcomed participants to the workshop and expressed the appreciation of Secretariat to the Government of Fiji for hosting the workshop and the Governments of the Netherlands, Norway and Spain for their financial support. Mr. Gbedemah also gave a brief overview on the objectives and expected outcomes of the workshop.

ITEM 2. ORGANIZATION OF WORK

7. The following agenda was adopted on the basis of the provisional agenda (UNEP/CBD/BS/RWCBPAC/1/1) circulated by the Executive Secretary:

1. Opening of the workshop.
2. Organization of work.
3. Introduction of participants.
4. Substantive issues:
    - 4.1. Overview of biosafety and the Cartagena Protocol on Biosafety;
    - 4.2. Introduction to risk assessment and preparatory work;
    - 4.3. Conducting the risk assessment;
    - 4.4. Preparing a risk assessment report;
    - 4.5. Guidance materials in the Biosafety Information Resource Centre of the Biosafety Clearing-House.
    - 4.6. Submitting risk assessment summaries to the Biosafety Clearing-House.
5. Conclusions and recommendations.
6. Other matters.
7. Adoption of the report.
8. Closure of the workshop.

8. The organization of work as contained in annex I to the annotations to the provisional agenda (UNEP/CBD/BS/RWCBPAC/1/1/Add.1) was introduced by the Secretariat and adopted by the participants.

9. A draft training material, prepared by the Secretariat, in collaboration with other relevant United Nations bodies and other international organizations was distributed to participants as the main training material for the workshop. It was noted that the training material is a work-in-progress and therefore needs feedback and inputs from participants for its improvement. A risk assessment case-study for hands-on exercises was also distributed.

ITEM 3. INTRODUCTION OF PARTICIPANTS

10. Participants to the workshop gave a brief background of themselves and relevant experience in their various fields with their expectations from the workshop.

11. Among the expectations noted were: (i) a better implementation of the provisions on risk assessment for the safe transfer and use of LMOs; (ii) learning and sharing experience from within and outside the region; and (iii) building networks for future collaboration.

ITEM 4. SUBSTANTIVE ISSUES

4.1 Overview of biosafety and the Cartagena Protocol on Biosafety

12. Under this agenda item, the basic concepts in biosafety, the Cartagena Protocol on Biosafety and other international biosafety-related bodies and organizations were introduced and reviewed.

13. The Secretariat gave presentations on the following: overview of modern biotechnology and its techniques; provisions of the Protocol relevant to the workshop, in particular its scope, objective, Article 15 and Annex III on risk assessment; and the Biosafety Clearing-House; and the role of other international bodies involved in risk assessment in the context of biosafety, such as the Food and Agriculture Organization of the United Nations (FAO), Codex Alimentarius, International Plant Protection Convention, the World Organisation for Animal Health, the World Trade Organization and the Organisation for Economic Cooperation and Development, as well as other bilateral and multilateral agreements.

14. The presentations were followed by exchanged views and experiences by participants with emphasis on the relevant risk assessment provisions of the Protocol.

4.2 Introduction to risk assessment and preparatory work

15. Under this agenda item, an introduction to environmental risk assessment and some elements and actions that may be needed in setting the stage for a risk assessment before an LMO application is received were made.

16. In reviewing the preparatory work for risk assessment, the Secretariat explained the importance of understanding the broad context of national policies and the structure of the national regulatory and administrative frameworks, including national risk assessment practices, general principles and mandate of risk assessors.

17. The workshop participants discussed the emerging issues on setting the scene for risk assessment and explained the stage of implementation of their respective national biosafety frameworks. Discussions also centred around opportunities for strengthening scientific cooperation in risk assessment at the Pacific subregional level.

4.3 Conducting the risk assessment

18. Under this agenda item, participants reviewed the key elements and steps of Annex III of the Protocol for conducting a risk assessment in a scientifically sound and case-by-case manner.

19. Presentations made under this agenda item were structured into three components:

(a) An overview of the elements that form the basis for a scientifically sound risk assessment conducted on a case-by-case basis. For each of these elements, the points to consider of Annex III of the Protocol were reviewed along with the usefulness of this information;

(b) Actions undertaken when setting the context and scope of the risk assessment, including the consideration of protection goals, assessment endpoints and the establishment of baseline information; and

(c) The risk assessment methodology and steps of Annex III of the Protocol along examples on how risk assessors may proceed in each of these steps.

20. The presentations were followed by discussions on the scientific information that may be needed to support each of the actions and steps in the risk assessment process and how to identify and address information gaps.

21. With the help of a case-study on risk assessment, participants took part in a hands-on group exercise to put into practice some of the concepts learnt. Participants identified the elements in the case-study needed for conducting a risk assessment on a case-by-case basis and identified gaps in the information. They also reviewed possible risk scenarios on the basis of the case-study and how risk could be characterized.

4.4 Preparing a risk assessment report

22. Under this item, participants discussed how risk assessors may communicate the outcomes of a risk assessment in a structured report so as to provide information on (i) background, context and scoping of the risk assessment; (ii) characterization and estimation of risks; (iii) identification of risk management and monitoring strategies; (iv) considerations of remaining uncertainties; and (v) recommendations as to whether or not the risks are acceptable or manageable.

4.5 Guidance materials in the Biosafety Information Resource Centre of the Biosafety Clearing-House

23. The Secretariat provided examples on how to search and retrieve guidance materials on risk assessment of LMOs that are available in the Biosafety Information Resources Centre (BIRC) of the Biosafety Clearing-House (BCH).

4.6 Submitting risk assessment summaries to the Biosafety Clearing-House

24. The Secretariat also explained how the risk assessment records are linked to decisions and LMO records in the BCH and provided an overview of the key information contained in the common format for submitting risk assessment summaries to the BCH.

ITEM 5. CONCLUSIONS AND RECOMMENDATIONS

25. Participants were invited to undertake an evaluation exercise of the workshop and its training material by completing a questionnaire. The results of the questionnaire are attached hereto as annex II.

26. Results of the questionnaire indicated that the majority of participants strongly agreed that the training material (i) comprises an adequate overview of the risk assessment process; and (ii) is a useful tool for training on risk assessment.

27. The majority of participants also strongly agreed that the workshop: (i) provided hands-on training in preparing and evaluating risk assessment reports in accordance with the articles and Annex III of the Protocol; and (ii) helped develop skills on how to use and interpret existing information, as well as identifying and addressing information gaps.

28. In providing inputs for improving the training material, participants recommended the inclusion of the following: a glossary of terms, list of acronyms, flowcharts, diagrams, photographs and examples on monitoring strategies including a form of monitoring criteria.

29. Participants also suggested that the following elements might be taken into account by the Conference of the Parties serving as the meeting of the Parties to the Protocol in its consideration of the risk assessment agenda item at its fifth meeting:

Capacity building on risk assessment:

(a) Further training courses on risk assessment with a minimum duration of 5 days using visual/video teaching tools and interactive use of the BCH;

(b) Follow-up and more advanced training in risk assessment;

(c) Short and dedicated training on how to write risk assessment reports;

(d) National level training on risk assessment with the participation of relevant national agencies;

(e) Further training on risk assessment in the Pacific subregion should include additional resource people from various expertise (genetic modification, ecologists, etc), possibly from the Pacific subregion or at least with expertise relevant to this subregion;

General capacity building on biosafety:

(f) A Pacific subregional training of border-officers on the identification of LMOs and

(g) Biosafety should be given a higher priority within biodiversity activities in the Pacific subregion, beginning with the development of a plan to address the gaps in capacity that were identified in the national reports from the National Capacity Self-assessment UNEP-GEF Project for the Pacific subregion.

30. In addition the following general recommendations were made:

(a) Drawing on experience from other regions, the Pacific subregion should develop a subregional project on biosafety.

(b) Each country should liaise with the Operational Focal Point for GEF to facilitate the development of the subregional biosafety project; and

(c) UNEP-GEF should be requested to help develop the subregional biosafety project through, for example, the establishment of a subregional laboratory.

ITEM 6. OTHER MATTERS

31. No other matters were discussed.

ITEM 7. ADOPTION OF THE REPORT

32. In the afternoon of the last day, the participants reviewed and adopted a draft report of the meeting prepared by the Secretariat.

ITEM 8. CLOSURE OF THE WORKSHOP

33. The workshop was closed at 6:00 p.m. on Wednesday, 7 July 2010.

Annex I

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Annex II

RESULTS OF THE WORKSHOP ASSESSMENT QUESTIONNAIRE

1. Participants were invited to undertake an exercise by completing a questionnaire to evaluate the workshop and its training material. Participants were instructed to select one of the boxes that best reflected their level of agreement with each of the statements.

2. Twelve participants took part in the exercise. The numbers below indicate the number of participants who have chosen each of the options.

A. Objectives of the workshop

Level of agreement	Strongly disagree	Slightly disagree	Neutral / Indifferent	Slightly agree	Strongly agree
The workshop:					
Provided hands-on training in preparing and evaluating risk assessment reports in accordance to the articles and Annex III of the Protocol.	-	-	-	5	7
Provided tools for understanding how an interdisciplinary team can be established in the context of risk assessment	-	-	1	6	5
Helped develop skills on how to use and interpret existing information, as well as identifying and addressing information gaps	-	-	-	5	7
Helped understand how to establish baseline information relevant for the risk assessment	-	-	-	7	5

B. Quality of the training material

Level of agreement	Strongly disagree	Slightly disagree	Neutral / Indifferent	Slightly agree	Strongly agree
The training material distributed at the beginning of the workshop:					
Is a useful tool for training on risk assessment	-	-	-	4	8
Is easy to understand and follow	-	-	2	6	4
Comprises an adequate overview of the risk assessment process	-	-	1	3	8
Is useful for a wide range of users	-	1	2	4	5

C. Quality of the training modules

Level of agreement	Strongly disagree	Slightly disagree	Neutral / Indifferent	Slightly agree	Strongly agree
The subjects of the modules listed below were covered adequately:					
Module 1 – Overview of Biosafety and the Cartagena Protocol on Biosafety					
What is biosafety?	-	-	-	2	10
What are living modified organisms?	-	-	-	1	11
History of the Cartagena Protocol on Biosafety	-	-	-	3	9
Objective and scope of the Cartagena Protocol on Biosafety	-	-	-	1	11
LMOs for intentional introduction into the environment - Advanced Informed Agreement (AIA)	-	-	2	1	9
LMOs for direct use as food, feed, or for processing (LMOs-FFP)	1	-	2	3	6
Competent National Authorities	-	-	-	3	9
Risk assessment (Article 15 and Annex III)	-	-	-	2	10
Biosafety Clearing-House	-	-	-	3	9
Other international biosafety-related bodies	-	-	2	3	7
Module 1 (as a whole)	**-**	**-**	**-**	**4**	**8**
Module 2 – Preparatory Work: Understanding the context in which a risk assessment is carried out					
National protection goals and assessment endpoints	-	-	1	3	8
National biosafety framework	-	-	-	4	8
Competent National Authorities	-	-	-	3	9
Scientific advisory body	-	-	1	4	7
Responsibilities of the risk assessor(s)	-	-	-	4	8
Roster of experts on biosafety	-	-	1	4	7
Stakeholder participation	-	1	2	2	7
Module 2 (as a whole)	**-**	**-**	**-**	**3**	**9**

Module 3 –Conducting the Risk Assessment					
Selecting relevant assessment endpoints or representative species	-	-	1	5	6
Establishing the baseline	-	-	-	5	7
Establishing the appropriate comparator(s)	-	1	1	6	4
Living modified organism	-	-	-	4	8
Likely potential receiving environment(s)	-	-	-	4	8
Intended use	-	-	-	5	7
Step 1 – Identification of any novel genotypic and phenotypic characteristics associated with the LMO that may have adverse effects	-	-	2	7	3
Step 2 – Evaluation of the likelihood	-	-	-	4	8
Step 3 – Evaluation of the consequences	-	-	-	5	7
Step 4 – Estimation of the overall risk	-	-	-	5	7
Step 5 – Identification of risk management and monitoring strategies	-	-	-	4	7
Module 3 (as a whole)	**-**	**-**	**-**	**5**	**7**
Module 4 – Preparing a Risk Assessment Report					
Background, context and scoping of the risk assessment	-	-	-	3	9
Characterization and estimation of risks	-	-	-	3	9
Description of risk management and monitoring strategies	-	-	-	3	9
Consideration of remaining uncertainty	-	-	-	5	7
Recommendations as to whether or not the risks are acceptable or manageable	-	-	-	5	7
Module 4 (as a whole)	**-**	**-**	**-**	**3**	**9**
