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CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY SERVING AS THE MEETING OF THE PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY
Fifth meeting
Nagoya, 11-15 October 2010
Item 13 of the provisional agenda*

REPORT OF THE ASIAN TRAINING COURSE ON RISK ASSESSMENT 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 (COP-MOP), in paragraphs 12 and 13 of its decision BS-IV/11, requested the Executive Secretary, *inter alia*, 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 Cambodia to host the training course and the generous financial contributions from the Governments of the Netherlands, Norway and Spain, the Asian Training Course on Risk Assessment of Living Modified Organisms was held in Siem Reap, Cambodia, from 12 to 16 July 2010.

3. Twenty three participants attended the training course. They were nominated by fifteen Parties to the Protocol (Bhutan, Cambodia, India, Indonesia, Islamic Republic of Iran, Lao People's Democratic Republic, Malaysia, Mongolia, Myanmar, Pakistan, Syrian Arab Republic, Thailand, Turkmenistan, Viet Nam and Yemen), a non-governmental organization (Third World Network) and the United Nations Environment Programme (UNEP). One resource person from the Netherlands also took part in the training course. The complete list of participants is attached as annex I.

ITEM 1. OPENING OF THE TRAINING COURSE

4. The training course was opened at 9 a.m. on Monday, 12 July 2010, by Dr. Pisey Oum, Technical Advisor to the Ministry of Environment, on behalf of the Kingdom of Cambodia.

* UNEP/CBD/BS/COP-MOP/5/1.

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5. In his opening remarks, Dr. Oum welcomed participants to Cambodia and noted the importance of capacity building on risk assessment of LMOs for the Asian subregion towards the full implementation of the Cartagena Protocol on Biosafety.

6. Mr. Charles Gbedemah, Senior Programme Officer, Biosafety Division of the Secretariat of the Convention on Biological Diversity, speaking on behalf of Mr. Ahmed Djoghlaf, Executive Secretary of the Convention, welcomed participants to the training course and expressed the appreciation of Secretariat to the Kingdom of Cambodia for hosting the course 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 training course.

ITEM 2. ORGANIZATION OF WORK

7. The following agenda was adopted on the basis of the provisional agenda prepared by the Executive Secretary (UNEP/CBD/BS/RAT-AS/1/1)

1. Opening of the training course.
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 Testing the Roadmap for Risk Assessment of Living Modified Organisms;
    - 4.6 Guidance materials in the Biosafety Information Resource Centre of the Biosafety Clearing-House;
    - 4.7 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 training course.

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

9. 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 course. It was noted that the training material is work-in-progress and therefore needs feedback and inputs from participants for its improvement.

10. Participants also received a draft Roadmap for Risk Assessment of Living Modified Organisms prepared by the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management.

11. A risk assessment case-study for hands-on exercises was also distributed.

ITEM 3. INTRODUCTION OF PARTICIPANTS

12. Participants to the training course, in introducing themselves, gave a brief overview of their experience in their various fields relevant to biosafety and of their expectations from the course.

13. Among the expectations noted were: (i) a better implementation of the provisions of the Protocol; (ii) being able to better conduct risk assessment for the safe use of LMOs; and (iii) learning from others in the region and building networks for collaboration.

ITEM 4. SUBSTANTIVE ISSUES

4.1 Overview of biosafety and the Cartagena Protocol on Biosafety

14. 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.

15. The Secretariat gave presentations on the following: overview of modern biotechnology and its techniques; provisions of the Protocol relevant to the training course in particular its scope, objective, Article 15 and Annex III on risk assessment and the Biosafety Clearing-House.

16. The role of other international bodies involved in risk assessment in the context of biosafety was also presented, including the Food and Agriculture Organization of the United Nations, Codex Alimentarius, the International Plant Protection Convention, the World Organisation for Animal Health, the World Trade Organization, and the Organisation for Economic Co-operation and Development, and other bilateral and multilateral agreements.

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

4.2. Introduction to risk assessment and preparatory work

18. Under this agenda item, the Secretariat presented 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.

19. 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.

20. The course participants discussed the different phases of a risk assessment process and issues regarding setting the scene for a risk assessment and explained the stage of implementation of their respective National Biosafety Frameworks.

4.3. Conducting the risk assessment

21. Under this agenda item, participants reviewed the key elements and steps of Annex III of the Protocol for conducting a risk assessment.

22. The Secretariat presented an overview of elements that may be considered when setting the context and scope of the risk assessment, including protection goals, assessment endpoints and the establishment of baseline information.

23. The Secretariat also presented 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 an analysis as to when each of this information may be relevant.

24. 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.

25. The Secretariat introduced 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. Participants discussed these issues at length focusing 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.

26. Participants took part in a second hands-on group exercise using the case-study to put into practice the steps of the risk assessment in accordance with Annex III. Each group presented the results of the exercise, including their conclusions on the likelihood of the adverse effects occurring, the consequences should these adverse effects occur, considerations of uncertainties and identification of risk management and monitoring strategies.

4.4. Preparing a risk assessment report

27. 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. Testing the Roadmap for Risk Assessment of Living Modified Organisms

28. Mr. Hans Bergmans from the Netherlands made a presentation explaining how the "Roadmap for Risk Assessment of Living Modified Organisms" (hereinafter, "the Roadmap") was developed through a process established by the Parties to the Protocol comprising the Open-ended Online Forum and the AHTEG on Risk Assessment and Risk Management. He noted that a large number of experts in risk assessment took part in the development of the Roadmap, a process in which he facilitated as Chair of the AHTEG Sub-Working Group on the Roadmap.

29. Mr. Bergmans presented an overview of the Roadmap, its objectives and structure. He noted that, pending a decision by the Parties, the Roadmap may be revised in the future and invited the participants to evaluate the Roadmap and provide feedback for its improvement.

30. Participants took part in discussions and group exercises to evaluate the usefulness and completeness of the Roadmap as guidance to facilitating and enhancing the effective use of Annex III. The group exercises focused on each of the steps of the risk assessment process as well as on its overarching issues. Several suggestions for improvement were made and thoroughly discussed.

31. Participants welcomed the Roadmap and found it a useful tool for the implementation of Annex III to the Protocol.

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

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

4.7. Submitting risk assessment summaries to the Biosafety Clearing-House

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

ITEM 5. CONCLUSIONS AND RECOMMENDATIONS

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

35. Results of the questionnaire indicated a general agreement that, in accordance to its objectives, the training course (i) provided hands-on training in preparing and evaluating risk assessment reports in accordance to the articles and Annex III of the Protocol; (ii) helped develop skills on how to use and interpret existing information, as well as identifying and addressing information gaps; and (iii) helped understand how to establish baseline information relevant for the risk assessment.

36. Results of the questionnaire also indicated that the majority of participants agreed that the training material distributed at the beginning of the course (i) is a useful tool for training on risk assessment; (ii) is easy to understand and follow; (iii) comprises an adequate overview of the risk assessment process, and (iv) is useful for a wide range of users.

37. In providing further feedback, participants acknowledged the training material as a very good teaching tool that provides a well-structured and comprehensive introduction to the risk assessment process and is useful to Parties as well as to other countries and relevant organizations.

38. In suggesting improvements to the training material, participants recommended that the modules of the training material be further developed to include (i) a glossary; (ii) examples of recommendations from previous risk assessments; (iii) practical examples including examples from each region; (iv) elements from the "Guidance on Risk Assessment of Living Modified Organisms" developed by the AHTEG, namely from the Roadmap (e.g. flowchart) and from the guidance on the specific types of LMOs and traits (i.e. risk assessment of living modified mosquitoes, LMOs with stacked genes or traits and living modified crops with tolerance to abiotic stress); (v) examples on LMOs other than crop plants; (vi) an annex with information on genes and traits commonly used in genetic modifications; and (vii) information on current issues under the Protocol (e.g. liability and redress) that may be relevant to risk assessment.

39. Participants recommended that future training courses on risk assessment should include:

(a) Practical examples of risk assessments from the specific region;

(b) Additional hands-on group exercises; and

(c) Additional case-studies including incomplete dossiers that identify information gaps.

40. Participants drew attention to the following elements/activities that the Parties might wish to consider during their deliberations at their fifth meeting:

Capacity building on risk assessment

(a) Further development of the training material on risk assessment for its continued improvement by making it easily available (e.g. published as CD, online) and user-friendly (e.g., as an interactive software) and making it available all United Nations languages;

(b) Further training courses on risk assessment at the national level or for smaller geographical areas (e.g. around 5-7 countries) where the receiving environment is similar to allow the participation of a core team of country experts;

(c) Follow-up advance training in risk assessment focusing, for example, on different types of intended uses (i.e. introduction into the environment and LMOs for direct use as food, feed, or for processing) and different types of LMOs;

(d) Dedicated training courses on:

(i) Preparing risk assessment reports and recommendations;

(ii) Extracting relevant data from LMO applications;

(iii) Assessing the quality of data submitted the application; and

(iv) Establishing detailed baseline information;

(e) Training of trainers who can further build capacity at national level;

Guidance on risk assessment

(f) Publication and distribution of the AHTEG "Guidance on Risk Assessment of Living Modified Organisms", including an online version under the Biosafety Clearing-House (BCH), in all United Nations languages;

(g) Development of further guidance on risk assessment as recommended by the AHTEG;

General capacity-building on biosafety

(h) An Asian subregional training on the identification of LMOs; and

(i) Training of decision makers on evaluating the recommendations of the risk assessment and on the implementation of risk management strategies.

ITEM 6. OTHER MATTERS

41. Participants expressed their gratitude to the Kingdom of Cambodia and to the Governments of the Netherlands, Norway and Spain for hosting and funding the training course as well as to the Secretariat for its organization and to Mr. Hans Bergmans for assisting in the discussions.

ITEM 7. ADOPTION OF THE REPORT

42. In the afternoon of the last day, the participants reviewed and adopted a draft report as amended.

ITEM 8. CLOSURE OF THE TRAINING COURSE

43. The training course was closed at 5:40 p.m. on Friday, 16 July 2010.

Annex I

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Annex II

RESULTS OF THE TRAINING COURSE ASSESSMENT QUESTIONNAIRE

Participants were invited to undertake an exercise by completing a questionnaire to evaluate the training course 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.

Twenty one 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 training course

Level of agreement	Strongly disagree	Slightly disagree	Neutral / Indifferent	Slightly agree	Strongly agree
The training course:					
Provided hands-on training in preparing and evaluating risk assessment reports in accordance to the articles and Annex III of the Protocol.	0	0	0	10	11
Provided tools for understanding how an interdisciplinary team can be established in the context of risk assessment	0	1	2	8	10
Helped develop skills on how to use and interpret existing information, as well as identifying and addressing information gaps	0	0	0	9	12
Helped understand how to establish baseline information relevant for the risk assessment	0	0	0	10	11

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 training course:					
Is a useful tool for training on risk assessment	0	0	1	6	14
Is easy to understand and follow	0	0	3	5	13
Comprises an adequate overview of the risk assessment process	0	0	0	13	8
Is useful for a wide range of users	0	0	2	11	8

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?	0	0	1	4	16
What are living modified organisms?	0	0	0	5	16
History of the Cartagena Protocol on Biosafety	0	1	1	2	17
Objective and scope of the Cartagena Protocol on Biosafety	0	0	0	4	17
LMOs for intentional introduction into the environment - Advanced Informed Agreement (AIA)	0	0	1	4	16
LMOs for direct use as food, feed, or for processing (LMOs-FFP)	0	0	1	6	13
Competent national authorities	0	0	0	7	14
Risk assessment (Article 15 and Annex III)	0	0	0	7	14
Biosafety Clearing-House	0	0	1	7	13
Other international biosafety-related bodies	0	0	1	8	12
Module 1 (as a whole)	0	0	0	6	15
Module 2 – Preparatory Work: Understanding the context in which a risk assessment is carried out					
National protection goals and assessment endpoints	0	0	3	4	14
National biosafety framework	0	0	0	7	14
Competent national authorities	0	0	0	7	14
Scientific advisory body	0	0	0	6	15
Responsibilities of the risk assessor(s)	0	0	1	7	13
Roster of experts on biosafety	0	0	1	9	11
Stakeholder participation	0	0	1	8	12
Module 2 (as a whole)	0	0	0	8	13

Level of agreement	Strongly disagree	Slightly disagree	Neutral / indifferent	Slightly agree	Strongly agree
The subjects of the modules listed below were covered adequately:					
Module 3 –Conducting the risk assessment					
Selecting relevant assessment endpoints or representative species	0	0	1	6	14
Establishing the baseline	0	0	1	6	14
Establishing the appropriate comparator(s)	0	0	1	7	13
Living modified organism	0	0	0	5	16
Likely potential receiving environment(s)	0	0	2	8	11
Intended use	0	0	3	3	15
Step 1 – Identification of any novel genotypic and phenotypic characteristics associated with the LMO that may have adverse effects	0	0	1	10	10
Step 2 – Evaluation of the likelihood	0	0	1	9	11
Step 3 – Evaluation of the consequences	0	0	1	9	11
Step 4 – Estimation of the overall risk	0	0	1	10	10
Step 5 – Identification of risk management and monitoring strategies	0	0	1	11	9
Module 3 (as a whole)	0	0	1	8	11
Module 4 – Preparing a risk assessment report					
Background, context and scoping of the risk assessment	0	0	0	6	15
Characterization and estimation of risks	0	0	0	7	14
Description of risk management and monitoring strategies	0	0	0	9	12
Consideration of remaining uncertainty	0	0	1	7	13
Recommendations as to whether or not the risks are acceptable or manageable	0	0	1	7	13
Module 4 (as a whole)	0	0	0	7	14
