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ASIAN TRAINING COURSE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS
Siem Reap, Cambodia, 12-16 July 2010
Item 2 of the provisional agenda *

ORGANIZATIONAL MATTERS

Annotations to the provisional agenda

INTRODUCTION

1. At its fourth meeting, the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP), in its decision BS-IV/11 paragraph 13, requested the Executive Secretary, among other things:

(a) 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; and

(b) 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 such a training course, and financial contributions from the Governments of the Netherlands and Norway, the Asian Training Course on Risk Assessment of Living Modified Organisms (LMOs) will be held in Siem Reap, Cambodia from 12 to 16 July 2010.

3. This course will bring together regulators, risk assessors and scientists who will be introduced to the elements and key considerations for carrying out risk assessments of LMOs in accordance with the Protocol.

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ITEM 1. OPENING OF THE TRAINING COURSE

4. The training course will be opened by a representative of the Government of Cambodia at 9 a.m. on Monday, 12 July 2010. A representative of the Executive Secretary of the Convention on Biological Diversity will also make opening remarks and give a brief overview of the course, including its objectives and expected outcomes.

ITEM 2. ORGANIZATION OF WORK

5. An overview of the programme of work as contained in the annex to this document will be presented.

6. Documents for the training course, including presentations by the Secretariat and resource persons, training material and a case-study will be made available prior to or during the course.

7. The course will be conducted in English only.

ITEM 3. INTRODUCTION OF PARTICIPANTS

8. Participants to the training course will be invited to introduce themselves and give a short background of their experience and current activities in biosafety and risk assessment and their expectations of the training course.

ITEM 4. SUBSTANTIVE ISSUES

4.1 Overview of biosafety and the Cartagena Protocol on Biosafety

9. Under this agenda item, participants will review basic concepts in biosafety and will be introduced to the Cartagena Protocol on Biosafety and other international biosafety-related bodies and organizations.

10. An overview of modern biotechnology and its techniques will be presented, as well as a presentation on provisions of the Protocol that are relevant to the course, in particular its scope and objective, Article 15 and Annex III on risk assessment and the Biosafety Clearing-House.

11. The role of other international bodies involved in risk assessment in the context of biosafety, such as Food and Agriculture Organization of the United Nations, Codex Alimentarius, International Plant Protection Convention, World Organisation for Animal Health, World Trade Organization and Organisation for Economic Cooperation and Development will be discussed, as well as bilateral and multilateral agreements.

4.2 Introduction to risk assessment and preparatory work

12. Under this agenda item, participants will be introduced 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. Participants will also be presented with the steps of a risk assessment process including the concepts and terminology used.

13. In the overview of the preparatory work, 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 and general principles, and mandate of risk assessors that may influence the risk assessment process will be presented.

14. Participants will be invited to provide an overview of their biosafety frameworks including national experiences, challenges and capacity needs with regards to risk assessment. In presenting national experiences, participants may also include the experiences of other countries in the region that have conducted and/or reviewed risk assessments for LMOs.

15. During the workshop, participants will be offered the opportunity to discuss the emerging issues and identify opportunities for strengthening scientific cooperation in risk assessment at the regional and subregional levels. Furthermore, participants will be invited to discuss possible frameworks/mechanisms for networking among experts and agencies involved in risk assessment.

4.3 Conducting the risk assessment

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

17. Presentations under this agenda item will be structured into three parts:

(a) The first part will provide 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 will also be reviewed along with the usefulness of this information;

(b) The second part will explain some common actions that are undertaken when setting the context and scope of the risk assessment; and

(c) The final part will discuss the process of conducting the risk assessment *per se* following the methodology and steps of Annex III of the Protocol along with a short description on how risk assessors may proceed in each of these steps.

18. An overview of the scientific information that may be required to support each of the actions and steps in the risk assessment process will also be presented.

19. With the help of a case-study on risk assessment, participants will be invited to put into practical use the concepts explained in the process and to perform a risk assessment in accordance with the Protocol.

20. Participants will be offered the opportunity to discuss the emerging issues, identify information gaps, challenges encountered, and make recommendations for improving the training material.

4.4 Preparing a risk assessment report

21. Under this item, participants will be presented with an overview of how risk assessors may communicate the outcomes of a risk assessment in a report structured such 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) consideration of remaining uncertainty; and (v) recommendations as to whether or not the risks are acceptable or manageable.

22. With the help of a case-study on risk assessment, participants will be invited to consider and provide examples of parts of a risk assessment report including a recommendation as to whether or not the risks identified are acceptable or manageable and, if necessary, identification of strategies to manage these risks.

4.5 Testing the roadmap for risk assessment

23. Under this item, participants will be invited to evaluate the usefulness and completeness of the roadmap for risk assessment as developed by the *Ad Hoc* Technical Expert Group (AHTEG) on Risk Assessment and Risk Management by answering a questionnaire and reporting back on their testing experience.

24. The roadmap was developed in response to paragraphs 3 and 4 of decision BS-IV/11. In this decision, the Parties considered the need for further guidance on specific aspects of risk assessment and established a process comprising an open-ended online forum through the Biosafety Clearing-House (BCH) and an AHTEG on risk assessment and risk management with the terms of reference as annexed to the decision.

25. The Parties to the Protocol mandated these groups of experts to, among other things, develop and test a roadmap on the necessary steps to conduct a risk assessment in accordance with Annex III to the Protocol.

26. An outcome of this process is a document entitled "Guidance on Risk Assessment of Living Modified Organisms". The first part of this guidance contains the "Roadmap for Risk Assessment of Living Modified Organisms", which provides an overview of the process of environmental risk assessment for an LMO in accordance with Annex III and all other articles of the Protocol related to risk assessment.

27. The overall aim of the Roadmap is to facilitate and enhance the effective use of Annex III by elaborating the technical and scientific process of how to apply the steps and points to consider in the process of risk assessment.

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

28. Under this item, a presentation will be made providing an overview of the nature, scope and applicability of existing guidance materials for risk assessment of LMOs available in the Biosafety Information Resources Centre (BIRC) of the Biosafety Clearing-House.

29. Participants will be invited to share their experiences in using existing guidance materials and to exchange their views on the need for additional guidance.

4.7 Submitting risk assessment summaries to the Biosafety Clearing-House

30. Under paragraph 3, Article 20 of the Protocol, Parties are required to make available to the Biosafety Clearing-House summaries of risk assessments or environmental reviews of LMOs generated by its regulatory process and carried out in accordance with Article 15.

31. Participants will review the key elements of the Biosafety Clearing-House common format for submitting risk assessment summaries.

ITEM 5. CONCLUSIONS AND RECOMMENDATIONS

32. Participants will be invited to draw conclusions regarding the training course and make recommendations to be submitted to the fifth meeting of the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol.

ITEM 6. OTHER MATTERS

33. Under this item, participants may wish to raise any other matters relevant to the implementation of the risk assessment provisions of the Protocol.

ITEM 7. ADOPTION OF THE REPORT

34. Under this item, participants will be invited to consider and adopt the report of the training course on the basis of the draft report to be prepared by the Secretariat.

ITEM 8. CLOSURE OF THE TRAINING COURSE

35. The training course is expected to end at 5 p.m. on Friday, 16 July 2010.

Annex

PROVISIONAL PROGRAMME OF WORK

Monday, 12 July 2010

9 a.m.	Opening of the training course (agenda item 1)
Morning	Organization of work (agenda item 2),
	Introduction of participants (agenda item 3)
	Substantive issues: Overview of biosafety and the Cartagena Protocol on Biosafety (agenda item 4.1)
Afternoon	Introduction to risk assessment and preparatory work (agenda item 4.2)

Tuesday, 13 July 2010

Morning	Conducting the risk assessment (agenda item 4.3)
Afternoon	Conducting the risk assessment (agenda item 4.3) (*continued*)

Wednesday, 14 July 2010

Morning	Preparing a risk assessment report (agenda item 4.4)
Afternoon	Preparing a risk assessment report (agenda item 4.4) (*continued*)

Thursday, 15 July 2010

Morning	Testing the roadmap for risk assessment (agenda item 4.5)
Afternoon	Testing the roadmap for risk assessment (agenda item 4.5) (*continued*)

Friday, 16 July 2010

Morning	Guidance materials in the Biosafety Information Resource Centre of the Biosafety Clearing-House (agenda item 4.6),
	Submitting risk assessment summaries to the Biosafety Clearing-House (agenda item 4.7)
	Conclusions and recommendations (agenda item 5)
Afternoon	Other matters (agenda item 6)
	Adoption of the report (agenda item 7)
5 p.m.	Closure of the training course (agenda item 8)
