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LATIN AMERICAN TRAINING COURSE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS
Havana, 7-11 November 2011
Item 2 of the provisional agenda*

ORGANIZATIONAL MATTERS

Annotations to the provisional agenda

INTRODUCTION

1. In decisions BS-IV/11 and BS-V/12, the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol on Biosafety requested the Executive Secretary to convene regional or subregional training courses to enable countries gain hands-on experience in preparing and evaluating risk assessment reports in accordance with the Cartagena Protocol on Biosafety.

2. Following an offer from the Government of Cuba to host such a training course, and financial contribution from the Government of Spain, the Latin American Training Course on Risk Assessment of Living Modified Organisms (LMOs) will be held in Havana, from 7 to 11 November 2011.

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

ITEM 1. OPENING OF THE TRAINING COURSE

4. The training course will be opened by a representative of the Government of Cuba at 9 a.m. on Monday, 7 November 2011. 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. The material for the training course, including a training manual developed by the Secretariat in collaboration with international organizations,[1] will be made available prior to or during the course.

7. The course will be conducted in Spanish only.

* UNEP/CBD/BS/RAT-LA/1/1.

[1] UNEP/CBD/BS/COP-MOP/5/12 paras. 32-36.

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ITEM 3. INTRODUCTION OF PARTICIPANTS

8. Participants 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 the Food and Agriculture Organization of the United Nations (FAO), Codex Alimentarius, the International Plant Protection Convention (IPPC), the World Organisation for Animal Health (OiE), the World Trade Organization (WTO) and the Organisation for Economic Co-operation and Development (OECD) 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 a 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 regions that have conducted and/or reviewed risk assessments for LMOs.

15. During the training course, 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 to 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 to 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 to provide information such as: (i) background and setting the context and scope 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 Guidance for Risk Assessment of LMOs

23. Under this item, participants will be invited to evaluate the usefulness and completeness of the Guidance for Risk Assessment of LMOs, in particular its Roadmap for Risk Assessment,[2] as developed by the Open-ended Online Expert Forum and the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management[3] as mandated by the Parties in decisions BS-IV/11 and BS-V/12.

24. Participants will be invited to use the Guidance side-by-side with a case-study and to report back by answering a questionnaire and reporting back on their testing experience.

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

25. 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)[4] of the Biosafety Clearing-House.

26. 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

27. 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.

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[2] http://bch.cbd.int/onlineconferences/guidancedoc_ra_roadmap.shtml.

[3] http://bch.cbd.int/onlineconferences/ahteg_ra.shtml.

[4] http://bch.cbd.int/database/resources/.

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

ITEM 5. CONCLUSIONS AND RECOMMENDATIONS

29. Participants will be invited to draw conclusions regarding the training course and make recommendations to be submitted to the sixth meeting of the Parties to the Protocol.

ITEM 6. OTHER MATTERS

30. 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

31. 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

32. The training course is expected to end at 5 p.m. on Friday, 11 November 2011.

Annex

PROVISIONAL PROGRAMME OF WORK

Monday, 7 November 2011

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, 8 November 2011

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

Wednesday, 9 November 2011

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

Thursday, 10 November 2011

Morning	Testing the Guidance for Risk Assessment of LMOs (agenda item 4.5)
Afternoon	Testing the Guidance for Risk Assessment of LMOs (agenda item 4.5) (*continued*)

Friday, 11 November 2011

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)
