



Convention on Biological Diversity

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

Kuala Lumpur, 7-9 April 2008
Item 2 of the provisional agenda*

ORGANIZATIONAL MATTERS

Annotations to the provisional agenda

INTRODUCTION

1. At its second meeting, the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) requested the Executive Secretary to convene, prior to its fourth meeting, regional workshops on capacity-building and exchange of experiences on risk assessment and risk management of living modified organisms (LMOs). In organizing these workshops, the Executive Secretary was requested to take into account the results of the meeting of the Ad Hoc Technical Expert Group on Risk Assessment, held 15 to 18 November 2005 in Rome, Italy, and experiences and expertise from relevant international agreements and bodies.
2. At its third meeting, the COP-MOP called upon Parties, other Governments and donor organizations to make funds available for the organization of regional workshops. It also invited Parties, other Governments and organizations with relevant experience in risk assessment and risk management to share their experiences and expertise at the workshops.
3. Following an offer from the Government of Malaysia to host such a workshop, and generous financial contributions from the Governments of Norway and Netherlands, the sub-regional workshop for Asia will be held, 7-9 April 2008, in Kuala Lumpur, Malaysia. This workshop will bring together scientists, regulators and decision-makers who are involved in risk assessment and risk management of LMOs.
4. The workshop will, among other things, enable participants to:
 - (a) Learn about risk assessment and risk management in the context of the Protocol including a review of general concepts, principles and methodologies;
 - (b) Exchange practical experiences and lessons learned in conducting and reviewing risk assessments and implementing risk management measures;
 - (c) Review existing guidance materials on risk assessment and risk management and consider the need for further guidance;

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(d) Review the format and key elements of risk assessment reports/dossiers and risk assessment summaries for LMOs; and

(e) Identify tools and mechanisms for promoting, at the regional level, cooperation and networking between experts and agencies involved in risk assessment and risk management.

ITEM 1. OPENING OF THE WORKSHOP

5. The Workshop will be opened by a representative of the Government of Malaysia at 9 a.m. on Monday, 7 April 2008. A representative of the Executive Secretary of the Convention on Biological Diversity will also make opening remarks and give a brief background to the workshop, including its objectives and expected outcomes.

ITEM 2. ORGANIZATIONAL MATTERS

2.1. Election of officers

6. Under this item, participants will be invited to elect a Chairperson and a Rapporteur for the Workshop.

2.2. Adoption of the agenda

7. Under this item, Workshop participants will be invited to adopt the agenda on the basis of the provisional agenda (UNEP/CBD/BS/RW-RA&RM/AS/1/1).

2.3. Organization of work

8. Participants may wish to consider the proposed organization and programme of work contained in annex I below. They may also wish to conduct all of their deliberations in plenary and establish discussion groups, as appropriate, to consider specific issues.

9. A list of documents for the Workshop is contained in annex II below. Additional documents, including presentations by resource persons, may be made available prior to or during the Workshop.

10. The Workshop will be conducted in English only.

ITEM 3. INTRODUCTION TO RISK ASSESSMENT AND RISK MANAGEMENT OF LIVING MODIFIED ORGANISMS (LMOs) IN THE CONTEXT OF THE CARTAGENA PROTOCOL ON BIOSAFETY

11. The Protocol requires Parties to make decisions regarding the import of LMOs for intentional introduction into the environment in accordance with scientifically sound risk assessments. Article 15 of the Protocol establishes the basic requirements and Annex III sets out the objective, use, general principles, methodology and points to consider in conducting risk assessments. Article 16 also requires Parties to establish and maintain appropriate mechanisms, measures and strategies to manage and control risks identified in the risk assessment.

12. Under this item, participants will be introduced to the provisions of the Protocol and the decisions taken by the Parties that address risk assessment and risk management. Participants will have the opportunity to review the role and importance of risk assessment in the decision-making process regarding the import or release of LMOs into the environment. Basic concepts, principles and general methodologies of risk assessment and risk management of LMOs will also be introduced.

**ITEM 4. NATIONAL AND SUBREGIONAL EXPERIENCES AND LESSONS
LEARNED IN THE IMPLEMENTATION OF THE RISK ASSESSMENT
AND RISK MANAGEMENT PROVISIONS OF THE PROTOCOL
(ARTICLES 15 AND 16 AND ANNEX III)**

13. In their decision BS-III/11, paragraph 10, the Parties to the Protocol invited Parties, other Governments and organizations with relevant experience in risk assessment and risk management to share their experiences and expertise at the regional workshops.

14. Under this item, workshop participants will share experiences and lessons learned in the implementation of the risk assessment and risk management provisions of the Protocol, including challenges encountered and how those challenges have been addressed. They will also share experiences on how existing information has been used to support risk assessments.

15. Participants will be invited to make short presentations about the status of implementation, experiences, challenges encountered and capacity needs in their respective countries with regard to risk assessment and risk management. The presentations will include the experiences of countries that have conducted and/or reviewed risk assessments for LMOs. Participants will have the opportunity to discuss the emerging issues and lessons learned and develop a set of conclusions and recommendations, as appropriate.

**ITEM 5. GUIDANCE MATERIALS FOR RISK ASSESSMENT AND RISK
MANAGEMENT OF LIVING MODIFIED ORGANISMS**

16. A wide range of guidance materials on risk assessment and risk management of LMOs have been developed over the years by different governments and organizations. At their second meeting, the Parties to the Protocol took note of the review of the existing guidance materials prepared by the Executive Secretary for the second meeting ^{1/}. Subsequently, in decision BS-III/11, paragraph 8, it was noted that additional guidance may be required on specific aspects of risk assessment and risk management. For example, guidance could focus on: (i) particular types of LMOs; (ii) particular intended uses of LMOs; (iii) particular types of risks; (iv) particular receiving environments; or (v) long-term monitoring of LMOs released into the environment.

17. In paragraph 9 of decision BS-III/11, the Parties decided to consider, at their fourth meeting, the need for further guidance on specific aspects of risk assessment and risk management as well as the appropriate modalities for the development of any such guidance. Among other things, the results of the regional workshops on capacity-building and exchange of experiences on risk assessment and risk management will be taken into account.

18. Under this item, a presentation will be made providing an overview of the nature, scope and applicability of existing guidance materials for risk assessment and risk management of LMOs. The report of the Canada-Norway Expert Workshop on Risk Assessment for Future Applications of Modern Biotechnology, ^{2/} held in Montreal from 4 to 6 June 2007, will also be presented. Participants will be invited to share their experiences in using existing guidance materials and to exchange their views on the need for additional guidance and make recommendations to the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol.

**ITEM 6. CONSIDERATIONS IN THE PREPARATION AND/OR REVIEW OF
RISK ASSESSMENTS OF LIVING MODIFIED ORGANISMS**

19. Under Article 20, paragraph 3, of the Protocol, Parties are required to, among other things, make available to the Biosafety Clearing-House (BCH) summaries of risk assessments or environmental reviews of LMOs generated by its regulatory process and carried out in accordance with Article 15. To date, only a small number of countries have submitted risk assessment summaries to the BCH.

^{1/} UNEP/CBD/BS/COP-MOP/2/9.

^{2/} UNEP/CBD/BS/COP-MOP/4/INF/13.

Furthermore, due to the requirements in the national regulatory frameworks of different countries, the information contained in the risk assessment summaries currently available in the BCH varies widely. The summaries do not follow a common format. Without common formats and standards for reporting, risk assessment summaries can sometimes be difficult to use or understand. Comparisons of related risk assessments can also be difficult. It is important to prepare and present risk assessment in a way that is consistent with Annex III to the Protocol.

20. The Ad Hoc Technical Expert Group on Risk Assessment, held in Rome from 15 to 18 November 2005, made a recommendation to encourage Governments to submit risk assessment summaries to the BCH in the standardized format paying attention, as appropriate, to how existing information is used to support risk assessments. In their decision BS-III/11, paragraph 4, the Parties encouraged Parties and other Governments, in submitting risk assessment summaries to the BCH (in accordance with Article 20, paragraph 3 (c) of the Protocol) to include details on how particular challenges have been addressed and how existing information has been used to support risk assessments.

21. In paragraph 18 of decision BS-III/11, Governments and organizations were also encouraged to support and/or develop practical training activities in, for example, knowledge management relating to risk assessment and risk management, including how to: (i) find, use and interpret existing information; (ii) identify and address need-to-know gaps in information and (iii) present risk assessments.

22. Under this item, participants will be introduced to the elements and key considerations in the preparation and/or review of environmental risk assessments of LMOs. They will also review the key scientific capacity and the information required to support risk assessment and risk management. Furthermore, participants will review the BCH common format of the risk assessment summaries submitted (in accordance with paragraph 3(c) of Article 20 of the Protocol), discuss the need for its further development and, if necessary, identify key elements that need to be added to the common format and make recommendations to the fourth meeting of the Conference of the Parties to the Convention serving as the meeting of the Parties to the Cartagena Protocol.

ITEM 7. SUBREGIONAL COOPERATION ON RISK ASSESSMENT AND RISK MANAGEMENT, INCLUDING THE SHARING OF INFORMATION AND EXPERTISE

23. In paragraph 13 of their decision BS-III/11, the Parties urged Parties, other Governments and relevant organizations to promote South-South and North-South partnerships as a means of increasing the capacity available to Parties to implement the risk assessment and risk management provisions of the Protocol. In paragraphs 5 and 20 of the same decision, Parties and other Governments were also encouraged to put in place mechanisms for ensuring the sharing of information among government agencies and other stakeholders at the national and regional level. Furthermore, in paragraph 15, the Executive Secretary was requested to collaborate with relevant organizations in order to promote networking and inter-linkages between experts in risk assessment of LMOs and experts in other relevant fields of risk assessment and risk management.

24. Under this agenda item, participants will identify opportunities and ways to strengthen scientific cooperation on risk assessment and risk management at the regional and sub-regional levels. Furthermore, participants will be invited to discuss possible frameworks/mechanisms for networking between experts and agencies involved in risk assessment and risk management and for the exchange of information, expertise, training materials and risk assessment tools.

ITEM 8. CONCLUSIONS AND RECOMMENDATIONS

25. Participants will be invited to consider the conclusions and recommendations to be submitted to the fourth meeting of the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol.

ITEM 9. OTHER MATTERS

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

ITEM 10. ADOPTION OF THE WORKSHOP REPORT

27. Under this item, participants will be invited to consider and adopt the report of the Workshop on the basis of the draft report to be prepared by the Rapporteur with the assistance of the Secretariat.

ITEM 11. CLOSURE OF THE WORKSHOP

28. The Workshop is expected to end at 4 p.m. on Wednesday, 9 April 2008.

Annex I

PROPOSED ORGANIZATION OF WORK

	Plenary
Monday 7 April 2008 9 a.m. – 9.30 a.m.	<i>Agenda item:</i> 1. Opening of the Workshop.
9.30 a.m. – 10.15 a.m.	<i>Agenda items:</i> 2. Organizational matters: 2.1. Election of officers; 2.2. Adoption of the agenda; 2.3. Organization of work. 3. Introduction to risk assessment and risk management of LMOs in the context of the Cartagena Protocol on Biosafety.
10.15 a.m. – 10.45 a.m.	Coffee/Tea Break
10.45 a.m. – 1 p.m.	<i>Agenda items:</i> 4. National and regional experiences and lessons learned: • Case-study presentations from different sub-regions. • Short presentations on national experiences by participants.
1 p.m. – 2 p.m.	Lunch Break
2 p.m. – 3.30 p.m.	Agenda item 4 (<i>continued</i>)
3.30 p.m. – 4 p.m.	Coffee/Tea Break
4 p.m. – 5.30 p.m.	<i>Agenda items:</i> 5. Guidance materials for risk assessment and risk management of LMOs: 5.1. Overview of the nature, scope and applicability of existing guidance materials.
Tuesday 8 April 2008 9 a.m. – 10.30 a.m.	<i>Agenda item:</i> 5.2. Consideration of the need for further harmonized guidance on specific aspects of risk assessment and risk management.
10.30 a.m. – 11 a.m.	Coffee/Tea Break
11 a.m. – 1 p.m.	<i>Agenda items:</i> 6. Key considerations in the preparation and/or review of risk assessments of LMOs: 6.1. Basic elements and considerations in the preparation and/or review of environmental risk assessments of LMOs and the key scientific capacity and information requirements.
1 p.m. – 2 p.m.	Lunch

	Plenary
2 p.m. – 3.30 p.m.	<i>Agenda item:</i> 6.2. Format for risk assessment summaries submitted to the BCH in accordance with paragraph 3(c) of Article 20 of the Protocol.
3.30 p.m. – 4 p.m.	Coffee/Tea Break
4 p.m. – 5.30 p.m.	<i>Agenda item:</i> 7. Regional and sub-regional cooperation on risk assessment and risk management, including the sharing of information and expertise.
Wednesday 9 April 2008	<i>Agenda items:</i>
9 a.m. – 10.30 a.m.	Agenda item 7 (<i>continued</i>) 8. Conclusions and recommendations.
10.30 a.m. – 11.00 a.m.	Coffee /Tea Break
11 a.m. – 1 p.m.	<i>Agenda items:</i> Agenda item 8 (<i>continued</i>) 9. Other matters.
1 p.m. – 2 p.m.	Lunch
2 p.m. – 4 p.m.	10. Adoption of the Workshop report. 11. Closure of the Workshop.

Annex II

PROVISIONAL LIST OF DOCUMENTS*

DOCUMENTS:

<i>Symbol</i>	<i>Title</i>
UNEP/CBD/BS/RW-RA&RM/AS/1/1	Provisional agenda
UNEP/CBD/BS/RW-RA&RM/AS/1/1/Add.1	Annotations to the provisional agenda
UNEP/CBD/BS/COP-MOP/4/INF/13	Report of the Canada-Norway Expert Workshop on Risk Assessment for Future Applications of Modern Biotechnology, held in Montreal from 4 to 6 June 2007
UNEP/CBD/BS/RW-RA&RM/1/INF/2	Overview of suggested additions to the common format for risk assessment summaries submitted to the Biosafety Clearing-House
UNEP/CBD/BS/COP-MOP/3/INF/2	Report of the Ad Hoc Technical Expert Group on Risk Assessment, held in Rome from 15 to 18 November 2005
UNEP/CBD/BS/COP-MOP/2/9	Risk assessment and risk management (Articles 15 and 16): A pre-session paper prepared for the second meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Protocol

* More documents may be made available by resource persons during or prior to the Workshop.