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AFRICAN REGIONAL WORKSHOP ON CAPACITY- BUILDING
AND EXCHANGE OF EXPERIENCES ON RISK ASSESSMENT
AND RISK MANAGEMENT OF LIVING MODIFIED ORGANISMS
Addis Ababa, 23-25 August 2007

ANNOTATIONS TO THE PROVISIONAL AGENDA

INTRODUCTION

1. At its second meeting held in Montreal in June 2005, the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) requested, in paragraph 2 of decision BS-II/9, 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 the workshop, the Executive Secretary was requested to take into account the results of the meeting of the Ad Hoc Technical Expert Group on Risk Assessment, which was held from 15 to 18 November 2005 in Rome, Italy, and experience and expertise in the context of relevant international agreements and bodies.

2. At its third meeting held from 13 to 17 March 2006 in Curitiba, Brazil, the Conference of the Parties serving as the meeting of the Parties to the Protocol called, in paragraph 10 of decision BS-III/11, upon Parties, other Governments and donor organizations to make funds available for organization of the regional workshops. It also invited those with relevant experience in risk assessment and risk management to offer to share their experiences and expertise at the workshops.

3. Following the generous financial contribution by the Government of the Netherlands and the offer of logistical support by the African Union (AU) Commission, the regional workshop for Africa will be held in Addis Ababa, Ethiopia, from 23 to 25 August 2007, back-to-back with the AU Experts Meeting on the Revised African Model Law on Safety in Biotechnology. The workshop will bring together more than 50 participants, including research scientists, regulators and decision-makers involved in risk assessment and risk management of living modified organisms.

4. The workshop is intended to enable participants:

(a) To learn about risk assessment and risk management in the context of the Biosafety Protocol and to review the general concepts, principles and methodologies;

(b) To exchange practical experiences and lessons learned in conducting/reviewing risk assessments and implementing risk management measures in Africa;

(c) To review existing guidance materials on risk assessment and risk management and consider the need for further guidance;

(d) To review the format and key elements of risk assessment reports/dossiers and summaries for living modified organisms;

(e) To identify tools and mechanisms for promoting cooperation and networking between experts and agencies involved in risk assessment and risk management at the regional level, including the exchange of information, expertise, training materials and risk assessment tools.

ITEM 1. OPENING OF THE WORKSHOP

5. The workshop will be opened by a representative of the CBD Secretariat at 9 a.m. on Thursday, 23 August 2007. A representative of the African Union Commission will also give opening remarks. The representative of the Secretariat will give a brief background to the workshop, its objectives and expected outcomes.

ITEM 2. ORGANIZATIONAL MATTERS

2.1. Election of officers

6. Workshop participants will elect a chairperson and a rapporteur from among themselves.

2.2. Adoption of the agenda

7. Workshop participants will be invited to adopt the agenda on the basis of the provisional agenda circulated as document UNEP/CBD/BS/RW-RA&RM/Afr/1/1.

2.3. Organization of work

8. The workshop may wish to consider the proposed organization and programme of its work as contained in annex II below. It may also wish to conduct all of its deliberations in plenary, and establish focus discussion groups, as appropriate, to consider specific issues.

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

10. The workshop will be conducted in English and French only.

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

11. The Biosafety Protocol requires Parties to make decisions regarding the import of living modified organisms for intentional introduction into the environment in accordance with scientifically sound risk assessments. Article 15 establishes the basic requirements and annex III sets out the general principles, methodological steps and points to consider in the conduct of risk assessments. Article 16 of the Protocol 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 risk assessment and risk management provisions of the Protocol (Articles 15 and 16 and annex III) and the decisions taken by the Conference of the Parties serving as the meeting of the Parties to the Protocol in this regard. Participants will review the role and importance of risk assessment in the decision-making process regarding the import or release of living modified organisms 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 REGIONAL 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 its decision BS-III/11, paragraph 10, the Conference of the Parties serving as the meeting of 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 (Articles 15 and 16 and annex III), including the challenges encountered and how they 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 status and experiences in their respective countries, challenges encountered and country capacity needs with regard to risk assessment and risk management. Participants will also hear detailed case study presentations by representatives from the different sub-regions (i.e. North Africa, West Africa, Central Africa, Eastern Africa and Southern Africa). The presentations will include experiences of countries that have conducted and/or reviewed risk assessments for living modified organisms. Participants will have the opportunity to discuss the emerging issues and lessons, 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 living modified organisms have been developed over the years by different governments and organizations. At its second meeting, the Conference of the Parties serving as the meeting of the Parties to the Protocol took note of the review of the existing guidance materials prepared by the Executive Secretary for the second meeting (UNEP/CBD/BS/COP-MOP/2/9). 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 focused on: (i) particular types of living modified organisms; (ii) particular intended uses of living modified organisms; (iii) particular types of risks; (iv) particular receiving environments; or (v) long-term monitoring of living modified organisms released into the environment.

17. In paragraph 9 of decision BS-III/11, the Conference of the Parties serving as the meeting of the Parties to the Protocol decided to consider, at its fourth meeting, the need for further guidance on specific aspects of risk assessment and risk management, and the appropriate modalities for development of any such guidance, taking into account, *inter alia*, the results of the regional workshops on capacity-building and exchange of experiences on risk assessment and risk management.

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 living modified organisms. A report of the Norway-Canada Expert Workshop on Risk Assessment for Future Applications of Modern Biotechnology, held from 4 to 6 June 2007 in Montreal, will also be presented at the workshop. Participants will be invited to share their experiences in using existing guidance materials and to exchange views on the need for additional guidance and make recommendations to the Conference of the Parties serving as the meeting of the Parties to the Protocol.

ITEM 6. KEY CONSIDERATIONS IN THE PREPARATION AND/OR REVIEW OF REPORTS ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

19. Under Article 20, paragraph 3, Parties are required to, *inter alia*, make available to the Biosafety Clearing-House summaries of risk assessments or environmental reviews of living modified organisms generated by its regulatory process and carried out in accordance with Article 15. To date, only a few

countries have submitted risk assessment summaries to the Biosafety Clearing-House. Furthermore, the information contained in the risk assessment summaries currently available in the Biosafety Clearing-House varies widely according to requirements in the national regulatory frameworks of different countries. The summaries do not follow a common format. Without common formats and standards for reporting, such information can sometimes be difficult to use or understand. Comparison 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 of the Protocol.

20. The Ad Hoc Technical Expert Group on Risk Assessment, which met from 15 to 18 November 2005 in Rome, made a recommendation that Governments should be encouraged to submit risk assessment summaries to the Biosafety Clearing-House in the standardized format, giving attention, as appropriate, to how existing information is used to support risk assessments. In its decision BS-III/11, paragraph 4, the Conference of the Parties serving as the meeting of the Parties to the Protocol encouraged Parties and other Governments, in submitting risk assessment summaries to the Biosafety Clearing-House in accordance with Article 20 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, *inter alia*, in knowledge management relating to risk assessment and risk management, including: how to find, use and interpret existing information; how to identify and address need-to-know gaps in information; and how to present risk assessments.

22. Under this item, participants will review key elements of existing risk assessment dossiers and risk assessment summaries for living modified organisms, including those submitted to the Biosafety Clearing-House in accordance with Article 20 of the Protocol. They will also review key considerations and steps involved in evaluating data presented in living modified organism release or import applications and risk assessment summaries. Furthermore, participants will be invited to discuss the need to develop a common format for presenting risk assessment summaries and, if necessary, identify the core elements of such a format and make recommendations to the Conference of the Parties serving as the meeting of the Parties to the Protocol.

ITEM 7. REGIONAL COOPERATION AND SHARING OF INFORMATION AND EXPERTISE ON RISK ASSESSMENT AND RISK MANAGEMENT

23. In its decision BS-III/11, paragraph 13, the Conference of the Parties serving as the meeting of the Parties to the Protocol urged Parties, other Governments and relevant organizations to promote South-South and North-South partnerships as a means to increase the capacity available to Parties to implement the risk assessment and risk management provisions of the Protocol. In paragraphs 5 and 20, 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 of the same decision, the Executive Secretary was requested to collaborate with relevant organizations, in order to promote networking and inter-linkages between experts in risk assessment of living modified organisms and experts in other relevant fields of risk assessment and risk management.

24. Under this agenda item, participants will discuss ways to strengthen scientific cooperation in the risk assessment and risk management of living modified organisms. Furthermore, participants will be invited to identify existing opportunities for cooperation and discuss a possible framework/mechanism for networking between experts and agencies involved in risk assessment and risk management at the regional level, including exchange of information, expertise, training materials and risk assessment tools.

ITEM 8. CONCLUSIONS AND RECOMMENDATIONS

25. The workshop will be invited to consider the conclusions and recommendations to be submitted to the fourth meeting of the Conference of the Parties 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 be closed at 4 p.m. on Saturday, 25 August 2007.

Annex I

PROPOSED ORGANIZATION OF WORK

	Plenary
Thursday ***23 August 2007*** 9 a.m. – 9.30 a.m.	*Agenda item*: 1. Opening of the workshop.
9.30 a.m. – 10.15 a.m.	*Agenda items*: 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 living modified organisms 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.	*Agenda items*: 4. National and regional experiences and lessons learned: • Short presentations by participants. • Detailed case study presentations (4).
1 p.m .– 2 p.m.	**Lunch Break**
2 p.m. – 3.30 p.m.	*Agenda item 4* (*continued*)
3.30 p.m. – 4 p.m.	**Coffee/ Tea Break**
4 p.m. – 5.30 p.m.	*Agenda items*: 5. Guidance materials for risk assessment and risk management of living modified organisms: 5.1. Overview of the nature, scope and applicability of existing guidance materials;
Friday ***24 August 2007*** 9 a.m. – 10.30 a.m.	*Agenda item*: 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.	*Agenda items*: 6. Key considerations in the preparation and/or review of reports on risk assessment of living modified organisms: 6.1. Core elements and format of risk assessment reports/dossiers;
1 p.m. – 2 p.m.	**Lunch**

	Plenary
2 p.m. – 3.30 p.m.	*Agenda item*: 6.2. Format for risk assessment summaries.
3.30 p.m. – 4 p.m.	**Coffee/Tea Break**
4 p.m. – 5.30 p.m.	*Agenda item*: 7. Regional cooperation and sharing of information and expertise on risk assessment and risk management.
Saturday ***25 August 2007*** 9 a.m. – 10.30 a.m.	*Agenda items*: *Agenda item 7 (continued)* 8. Conclusions and recommendations.
10.30 a.m. – 11.00 a.m.	**Tea/Coffee Break**
11 a.m. – 1.00 p.m.	*Agenda items*: *Agenda item 8 (continued)* 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:

Symbol	*Title*
UNEP/CBD/BS/RW-RA&RM/Afr./1/1	Provisional agenda
UNEP/CBD/BS/RW-RA&RM/Afr./1/1/Add.1	Annotations to the provisional agenda
UNEP/CBD/BS/RW-RA&RM/Afr./1/2	Overview of the nature, scope and applicability of existing guidance materials for risk assessment and risk management of living modified organisms
UNEP/CBD/BS/COP-MOP/3/INF/1	Report of the Norway-Canada Expert Workshop Risk Assessment for Future Applications of Modern Biotechnology, held 4-6 June 2007 in Montreal
UNEP/CBD/BS/COP-MOP/3/INF/2	Report of the Ad Hoc Technical Expert Group on Risk Assessment (held 15 to 18 November 2005 in Rome, Italy)
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

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