



CONVENTION ON BIOLOGICAL DIVERSITY

Distr.
GENERAL

UNEP/CBD/BS/AHTEG-RA/1/1/Add.1
5 October 2005

ORIGINAL: ENGLISH

AD HOC TECHNICAL EXPERT GROUP ON RISK
ASSESSMENT UNDER THE CARTAGENA
PROTOCOL ON BIOSAFETY
Rome, 15-18 November 2005

ORGANIZATION OF WORK: ANNOTATIONS TO THE PROVISIONAL AGENDA

INTRODUCTION

1. At its second meeting in 2005, the Conference of the Parties serving as the meeting of the Parties to the Protocol, in paragraph 4 of decision BS-II/9, decided to establish an Ad Hoc Technical Expert Group on Risk Assessment, and welcomed the offer of the Government of Italy to provide the necessary financial support for a meeting of the Group prior to the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol;
2. Pursuant to the establishment of the Ad Hoc Technical Expert Group on Risk Assessment, the Executive Secretary is convening, with the generous support of the Government of Italy, a meeting of the Group, to be held in Rome from 15 to 18 November 2005. According to the terms of reference for the Group as contained in the annex to decision BS-II/9, the Ad Hoc Technical Expert Group shall:
 - (a) Consider the nature and scope of existing approaches to risk assessment based on national experiences and existing guidance materials;
 - (b) Evaluate the relevance of existing approaches and guidance materials to risk assessment under the Protocol, and identify gaps in those existing approaches and guidance materials;
 - (c) Identify specific areas where limitations in capacity may be an impediment to effective implementation of the risk assessment provisions of the Protocol at national level, and where capacity-building activities may be particularly important;
 - (d) Submit a report for consideration by the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol;
3. Also in the terms of reference contained in the annex to decision BS-II/9, the Conference of the Parties serving as the meeting of the Parties to the Protocol noted that the deliberations of the Ad Hoc Technical Expert Group shall be based primarily on:
 - (a) Information provided in the interim national reports referred to in paragraphs 3 and 5 of that decision;
 - (b) Guidance materials listed in the annex to the review of existing guidance material relevant to risk assessment and risk management (UNEP/CBD/BS/COP-MOP/2/9), which are now available through the Biosafety Information Resource Centre at <http://bch.biodiv.org/resources/resources.shtml>;
 - (c) Any other relevant materials made available by the Secretariat;

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4. Accordingly, a provisional list of documents and materials for the meeting is provided in annex I to this document.

ITEM 1. OPENING OF THE MEETING

5. The meeting will be opened by a representative of the Executive Secretary at 10 a.m. on Tuesday, 15 November 2005. A representative of the Government of Italy will welcome the participants. The representative of the Secretariat will then explain the purpose of the meeting, its mandate, and the expected outputs.

ITEM 2. ORGANIZATIONAL MATTERS

2.1. Election of officers

6. After introducing themselves, the Group will be invited to elect the chair of the meeting. It is usual practice for the host government to make a proposal in this regard. The Group may also wish to elect a Rapporteur.

2.2. Adoption of the agenda

7. The Group will be invited to adopt the agenda for the meeting on the basis of the provisional agenda (UNEP/CBD/BS/AHTEG-RA/1/1), prepared by the Executive Secretary in line with decision BS-II/9 of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

2.3. Organization of work

8. The language of the meeting will be English.
9. The Group may wish to consider the proposed organization of its work as contained in annex II below. The Group may wish to conduct all of its deliberations in plenary, or break into smaller groups for consideration of specific issues.

ITEM 3. SUBSTANTIVE ISSUES

3.1. Consideration of the nature and scope of existing approaches to risk assessment based on national experiences and existing guidance materials

10. Under this agenda item, experts will consider the nature and scope of existing approaches to risk assessment.

11. In order to assist the deliberations, the Group may wish to consider:

(a) A synthesis of the information related to risk assessment and risk management received in interim national reports on implementation of the Protocol (UNEP/CBD/BS/AHTEG-RA/1/2);

(b) Guidance materials annexed to the note by the Executive Secretary on risk assessment and risk management 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 Cartagena Protocol on Biosafety (UNEP/CBD/BS/COP-MOP/2/9) and the additional guidance materials listed in annex I below;

(c) The characterization of existing approaches to risk assessment contained in paragraphs 8 to 15 of the above-mentioned note by the Executive Secretary (UNEP/CBD/BS/COP-MOP/2/9).

3.2. Evaluation of the relevance of existing approaches and guidance materials to risk assessment under the Protocol, and identification of gaps in those existing approaches and guidance materials

12. Based on the outcome of discussions regarding the nature and scope of existing approaches to risk assessment, under agenda item 3.1, the Group will be expected to identify gaps in those approaches and guidance materials in relation to their relevance to risk assessment under the Protocol.

3.3 *Identification of specific areas where limitations in capacity may be an impediment to effective implementation of the risk assessment provisions of the Protocol at national level, and where capacity-building activities may be particularly important*

13. Under this agenda item, the Group will consider specific areas where limitations in capacity may be an impediment to effective implementation of the risk assessment provisions of the Protocol at national level, and specific areas where capacity-building activities may be particularly important.

3.4 *Preparation of a report for consideration by the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol*

14. Under this agenda item, the Group will formulate its findings in the form of a report for consideration by the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

ITEM 4. OTHER MATTERS

15. Under this item, participants will be invited to raise other matters related to the subject matter of the meeting for discussion.

ITEM 5. ADOPTION OF REPORT

16. The Group will consider and adopt its report on the basis of the draft report of the meeting to be prepared by the Rapporteur, with the assistance of the Secretariat and the Chair.

ITEM 6. CLOSURE OF THE MEETING

17. It is expected that the meeting will be closed by 5.30 p.m. on Friday, 18 November 2005.

*Annex I***PROVISIONAL LIST OF DOCUMENTS AND GUIDANCE MATERIALS FOR THE AD HOC TECHNICAL EXPERT GROUP ON RISK ASSESSMENT****DOCUMENTS:**

| <i>Symbol</i> | <i>Title</i> |
|--------------------------------|---|
| UNEP/CBD/BS/AHTEG-RA/1/1 | Provisional agenda |
| UNEP/CBD/BS/AHTEG-RA/1/1/Add.1 | Annotations to the provisional agenda |
| UNEP/CBD/BS/AHTEG-RA/1/2 | Synthesis of information related to risk assessment and risk management received in interim national reports on implementation of the Protocol |
| UNEP/CBD/BS/COP-MOP/2/9 | Risk assessment and risk management (Articles 15 and 16) – pre-session paper 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. |

GUIDANCE MATERIALS:

Guidance materials were summarized in the annex to document UNEP/CBD/BS/COP-MOP/2/9 and were subsequently made available through the Biosafety Information Resource Center at <http://bch.biodiv.org/resources/resources.shtml>. In addition, the Executive Secretary is pleased to provide reference to the following two additional guidance materials:

1. Hilbeck, Andow, and Fontes [Eds]. 2006. Environmental risk assessment of genetically modified organisms Volume 2: methodologies for assessing Bt cotton in Brazil [uncorrected proofs].

Key Characteristics:

- Detailed case-study development of the methodology for a risk assessment, focusing on a particular trait in a particular receiving environment
- This book is the second in the series – the first was reviewed as guidance material #24 in document UNEP/CBD/BS/COP-MOP/2/9.

2. Public Research and Regulation Initiative – Draft guide for notifications and risk assessments for releases into the environment of genetically modified organisms; module 1: genetically modified crop plants [draft]. Available at www.pubresreg.org.

Key Characteristics:

- Practical guidance for approaching risk assessment in response to receipt of a notification.
- Focuses on information requirements and the organization of information to facilitate risk assessment.

Annex II

**PROPOSED ORGANIZATION OF WORK FOR THE AD HOC TECHNICAL EXPERT GROUP
ON RISK ASSESSMENT**

| | Agenda items |
|---|--|
| Tuesday, 15 November 2005 10am to 1pm | 1 – Opening of the meeting 2.1 – Election of officers 2.2 – Adoption of the agenda 2.3 – Organization of work 3.1 – Consideration of the nature and scope of existing approaches to risk assessment based on national experiences and existing guidance materials 3.2 – Evaluation of the relevance of existing approaches and guidance materials to risk assessment under the Protocol, and identification of gaps in those existing approaches and guidance materials |
| Tuesday, 15 November 2005 2:30pm to 5:30pm | Continuation of agenda items 3.1 and 3.2 |
| Wednesday, 16 November 2005 10am to 1pm | Continuation of agenda items 3.1 and 3.2 |
| Wednesday, 16 November 2005 2:30pm to 5:30pm | 3.3 – Identification of specific areas where limitations in capacity may be an impediment to effective implementation of the risk assessment provisions of the Protocol at national level, and where capacity-building activities may be particularly important. |
| Thursday, 17 November 2005 10am to 1pm | Continuation of agenda item 3.3 |
| Thursday, 17 November 2005 2:30pm to 5:30pm | 3.4 – Preparation of a report for consideration by the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. |
| Friday, 18 November 2005 10am to 1pm | Continuation of agenda item 3.4 |
| Friday, 18 November 2005 2:30pm to 5:30pm | 4 – Other matters 5 – Adoption of the report 6 – Closure of the meeting |
