



Cartagena Protocol on Biosafety  
**Risk Assessment and Management**



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**Risk Assessment and Management**



## Overview

- Risk Assessment – Article 15 of the CPB
- Background
- Formation of The AHTEG
- Processes involved in the preparation of the Guidance Documents
- Guidance on Risk Assessment Of Living Modified Organisms
- Roadmap




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**Article 15 of the CPB**  
Risk Assessment shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognised risk assessment techniques.

The Cartagena Protocol on Biosafety requires countries to carry out risk assessments to identify and evaluate the potential adverse effects of living modified organisms (LMOs) on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Risk assessment should be conducted in a scientifically sound and transparent manner and on a case-by-case basis.

Countries should take appropriate measures to manage the risks identified during the risk assessment and to prevent unintentional movements of LMOs from country to country.




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**Second meeting (MOP 2, 30 May-3 June 2005, Montreal, Canada)**

Established an **Ad Hoc Technical Expert Group on Risk Assessment (AGTEG)**;


- Review a synthesis report on RARM submitted by Parties in their interim national reports;
- Consider the nature and scope of existing approaches to RA based on national experiences and existing guidance materials;
- Evaluate the relevance and identify gaps in the existing approaches and guidance materials;
- Identify specific areas where capacity-building activities may be particularly important;



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**Third Meeting (MOP 3, 13-17 March 2006, Curitiba, Brazil )**

- Additional guidance may be required on specific aspects of RARM
  - on particular types of LMOs ,
  - particular intended uses of LMOs,
  - particular types of risks,
  - particular receiving environments,
  - long-term monitoring of LMOs released into the environment,
- Consider at its fourth meeting the appropriate modalities for development of any such guidance.





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**Fourth Meeting (MOP 4, 12-16 May 2008, Bonn, Germany)**


**Mandate**

- ❖ Develop a "roadmap" on the necessary steps to conduct a RA in accordance with **Annex III to the Protocol** ;
- ❖ Prioritize the need for further guidance on specific aspects of RA;
- ❖ Define an action plan for development of the guidance documents that were identified as priorities and for testing of the roadmap.
- Took note of the report of the Norway-Canada Workshop on RA for emerging appl;
- Established through the Biosafety Clearing-House an **open-ended online forum on RA**;
- Established an **AHTEG on RARM**

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**Open-ended Online Expert Forum on RARM**  
 8 ad hoc online discussion groups on specific topics of RARM (Nov – Dec, 2008)

- Fish
- trees,
- microorganisms and viruses,
- pharmaplants,
- stacked genes or traits,
- Post-release monitoring and long-term effects of LMOs released into the environment,
- RARM of specific receiving environments and
- Roadmap for RA

4 Regional (Europe, Africa, Asia and Latin America) Real-Time Online Conferences (Jan –Feb 2009)

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**First Meeting of the AHTEG (20 -24 April 2009, Montreal)**


**Members of the AHTEG**

**I. Eighteen participants from seventeen Parties** (Austria, Belize, Brazil, China, Croatia, Cuba, Egypt, Germany, Japan, Malaysia, Mexico, Netherlands, Niger, Nigeria, Norway, Republic of Moldova and Slovenia),

**II. Eight observers from three non-Parties** (Australia, Canada, United States of America) and **Five organizations** (Bayer CropScience, Federation of German Scientists, Monsanto Company, PRRI and University of Canterbury)

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**First Meeting of the AHTEG (20 -24 April 2009, Montreal) cont.....**

- Roadmap accordance with paragraphs 8 and 9 of **Annex III of the Protocol (Steps and Points to consider)**
- Example provided during the Open-ended Online Forum as basis for a working document
- An advance draft of a roadmap was produced for further work and testing
- Development of guidance documents on RARM (i) **LM Crops Tolerant or Resistant to Abiotic Stress**; (ii) **LM Mosquitoes**; and (iii) **LMOs with Stacked Genes or Traits** and
- Established four sub-working groups and using the Open Ended On-line Expert Forum





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**Activities Prior to the Second AHTEG Meeting**

- ❖ Online discussions within the AHTEG Sub-working Groups for further drafting of the guidance documents (May- June 2009, August – October 2009)
- ❖ Face to Face Meeting of the AHTEG Sub-working Group on the Roadmap and AHTEG Bureau (12 – 14 October 2009, The Hague, Netherlands)
- ❖ Online discussions within the AHTEG Sub-working Groups for further drafting of the guidance documents and testing of the Roadmap (November 2009- March 2010)



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**Second AHTEG Meeting (20-23 April 2010, Ljubljana, Slovenia)**

- Revised and finalised the "Roadmap" for the effective use of guidance documents on RA;
- Made recommendations on how to integrate the "Roadmap" and tools for retrieval of guidance materials available in the BIRC of the BCH relevant at the different stages of RA;
- Guidance on Risk Assessment of Living Modified Organisms** - divided into two main sections entitled **"Part I: Roadmap for RA of LMOs"** and **"Part II: Specific Types of LMOs and Traits"**.


**Several recommendations were made to COP-MOP 5**

- ❖ Publish and distribute in all UN languages
- ❖ Further testing
- ❖ Should be revisited within 2 years
- ❖ Develop additional guidance documents



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**Fifth Meeting (MOP 5, 11-15 October, Nagoya, Japan)**

Decided to extend the current open-ended online forum and the AHTEG on RARM

- Revise and test the first version of the Guidance;**
- Assess the overall applicability and utility of the Guidance;**


**To have the following outcomes:**

- ❖ A revised version of the **"Guidance on Risk Assessment of Living Modified Organisms"**;
- ❖ A mechanism, including criteria, for future updates of the lists of background materials;
- ❖ Further guidance on new specific topics of RA,




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**Activities Prior to the Third AHTEG**

- ❖ Scientific review between 4 February and 15 March 2011 (18 Parties, two other Governments and 12 organizations)
- ❖ Online discussion groups under the Open-ended Online Forum (28 March -18 April 2011)
- ❖ Chair prepared a draft revised text based on comments resulting from on-line discussions and the scientific reviews



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**Third AHTEG Meeting (Mexico City ,30 May - 3 June 2011)**

- ✓ Revised Draft -basis for further work through the Open-ended Online Forum
- ✓ Two additional guidance documents to be developed:
  - **Post-Release Monitoring and Long-Term Effects** of LMOs released into the environment; and
  - Risk assessment of **Living Modified Trees**


**Fourth AHTEG to be held before COP-MOP 6**





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**PART I Roadmap For RISK ASSESSMENT of Living Modified Organisms**

Background , Introduction , Overarching Issues in the Risk Assessment Process, Planning Phase of the Risk Assessment; and

**Conducting the Risk Assessment**

- **Step 1** An identification of any novel characteristics that may have adverse effects
- **Step 2** An evaluation of the likelihood of adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the LMO
- **Step 3** An evaluation of the consequences should these adverse effects be realized
- **Step 4** An estimation of the overall risk posed by the LMO based on the evaluation of the likelihood and consequences of the identified adverse effects being realized
- **Step 5** A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks



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**ACTIVITIES TO LOOK OUT FOR:**


- 23 January – 3 February 2012:** Online discussion of Guidance documents after consolidation of comments and scientific editing
- 27 February – 30 March 2012:** Real-time online regional conferences
- 7-11 May :** 4<sup>th</sup> Meeting of AHTEG
- 1-5 October:** Sixth meeting of the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (MOP 6)- Hydrebad, India.





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**12 Sept- 15 Dec 2011 – Testing of the Draft Revised Guidance on RA of LMO**


**CBD Workshops On Risk Assessment of LMOs**

- 12 - 16 July 2010, Siem Reap, Cambodia
- 26 - 30 September 2011, Belize City, Belize
- 7 - 11 November 2011, Havana, Cuba
- 12-16 December 2011, Accra,



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**Guidance On Risk Assessment Of Living Modified Organisms**

- “RA should be carried out in a scientifically sound and transparent manner, take into account expert advice of & guidelines developed by relevant Int. Orgs”
- RA should be carried out on a case-by-case basis.
- The required information may vary in nature and level of detail depending on the LMO

**IT IS INTENDED TO BE A “LIVING DOCUMENT” THAT WILL BE AND MUST BE MODIFIED AND IMPROVED AS AND WHEN MANDATED BY THE PARTIES TO THE CPB. PARTIES SHOULD ENSURE THAT THESE DOCUMENTS ARE “USER-FRIENDLY” AND GUIDANCE SHOULD BE RELEVANT TO THE SAFETY ASSESSMENT OF THE PARTICULAR LMO.**



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**THANK YOU**