

Risk Assessment and Risk Management under the Cartagena Protocol on Biosafety

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Abstract. The Biosafety Protocol requires Parties to make decisions on import of Living Modified Organisms (LMOs) for intentional introduction into the environment based on scientifically sound risk assessments (Article 15, Cartagena Protocol on Biosafety to the Convention on Biological Diversity). It sets out, in Annexe III of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, general principles, methodological steps, and points to consider in the conduct of risk assessment. The general principles include, among others, the following concepts: risk assessment should be carried out in a scientifically sound and transparent manner; lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk; risks should be considered in the context of risks posed by the non-modified recipients or parental organisms; and that risks should be assessed on a case-by-case basis.

The methodology described in Annex III of the Biosafety Protocol follows the conventional risk assessment paradigm, beginning with identification of a potential hazard, such as characteristics of an LMO, which may have an adverse effect on biodiversity. Risks are then characterized based on combined evaluation of the likelihood of adverse effects, and the consequences should those effects be realized.

The Protocol, in Article 16 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, requires Parties to adopt measures and strategies for preventing adverse effects and for managing and controlling risks identified by risk assessments (Articles 16.1 and 16.2 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity). Parties are also required to take measures to prevent unintentional transboundary movements (Article 16.3 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity), to ensure that LMOs undergo appropriate periods of observation prior to use (Article 16.4), and to cooperate in identifying LMOs and their traits that may pose risks, and in taking appropriate management measures (Article 16.5 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity).

At its second meeting, the Conference of the Parties to the Convention on Biological Diversity serving as the meet-

ing of the Parties to the Protocol (COP-MOP, the governing body of the Cartagena Protocol on Biosafety) considered risk assessment and risk management for the first time and adopted decision BS-II/9. In that decision, the Executive Secretary was requested to convene, prior to the fourth meeting of the COP-MOP and subject to availability of financial resources, regional workshops on capacity-building and exchange of experiences on risk assessment and risk management of LMOs. In addition, the COP-MOP decided to establish an Ad Hoc Technical Group on Risk Assessment (AHTEG) to further consider the nature and scope of existing approaches to risk assessment, evaluate such approaches and identify any gaps, and identify capacity-building needs.

At its third meeting, COP-MOP further considered risk assessment and risk management on the basis of the report of the expert group, information received in interim national reports under the Protocol, and submissions and guidance materials that were compiled in advance of the second meeting of the COP-MOP. In decision BS-III/11, COP-MOP examined further measures for enhancing

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capacity-building in risk assessment and risk management and outlined the process for collecting and sharing available information and guidance documents in order to facilitate the consideration, at the fourth meeting, of the need for further guidance on specific aspects of risk assessment and risk management.

At its fourth meeting, the COP-MOP, in decision BS-IV/11, established and mandated an AHTEG on Risk Assessment and Risk Management to, inter alia, (i) prepare a "roadmap", e.g. a flowchart, on steps for conducting a risk assessment in accordance with Annex III to the Protocol with examples of existing guidance documents for each of step; (ii) prioritize the identified needs for further guidance; (iii) define an action plan to produce modalities for developing guidance documents on specific aspects of risk assessment and risk management identified as priorities; and (iv) consider possible modalities for cooperation in identifying living modified organisms or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, also taking into account risks to human health. An open-ended online forum on specific aspects of risk assessment was also established, through the Biosafety Clearing House (BCH), to provide input into the work of the AHTEG. Furthermore, COP-MOP requested the Executive Secretary to organize training activities on risk assessment and risk management, including hands-on regional or subregional training courses.

The Ad hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management held its first meeting from 20 to 24 April 2009 in Montreal, Canada. The group discussed the development of guidance documents with the view to further support countries in conducting risk assessment of LMOs in the context of the Protocol. The participants produced a draft text for a roadmap on the steps in risk assessment and established four sub-working groups to further undertake the development of the roadmap and guidance documents on specific aspects of risk assessment and risk management prior to the Group's second meeting, scheduled to be held in April 2010 in Ljubljana, Slovenia. The following topics should be addressed first: (i) living modified crops tolerant or resistant to abiotic stress; (ii) living modified mosquitoes; and (iii) LMOs with stacked genes or traits.

A sub-working group on LM Mosquitoes was formed to produce modalities for development of guidance documents on risk assessment and risk management. In the context of the steps contained in paragraph 8 of Annex III of the Protocol, the general structure of these guidance documents should be organized by providing: (i) points to consider; (ii) rationales for the points to consider; and (iii) relevant bibliographies and supporting documents. Participants to the Open-ended Online Forum will be involved in the work of the sub-working groups through ad hoc online discussion groups and real-time online conferences. The outcomes of the sub-working group will serve as basis for informed discussion during the regional real-time online conferences (tentatively scheduled to take place in February

2010). For details see the report of the meeting in document UNEP/CBD/BS/AHTEG-RA&RM/1/3.

REFERENCES

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Articles 16.1, 16.2, 16.3, 16.4, 16.5. *In: Cartagena Protocol on Biosafety to the Convention on Biological Diversity* pp12. Montreal 2000, ISBN:92-807-1924-6.

MOP 2 decision BS-II/9 on risk assessment and risk management <<http://www.cbd.int/decision/mop/?id=10787>>.

MOP 3 decision BS-III/11 on risk assessment and risk management <<http://www.cbd.int/decision/mop/?id=11067>>.

MOP 4 decision BS-IV/11 on risk assessment and risk management <<http://www.cbd.int/decisions/?id=11067%20>>.

Report of the first meeting of the Ad Hoc Technical Expert Group on risk assessment and risk management under the Cartagena Protocol on Biosafety <<http://www.cbd.int/doc/meetings/bs/bsrarm-01/official/bsrarm-01-03-en.pdf>>.