

## Risk Assessment and the Cartagena Protocol on Biological Biosafety,

### Past, Present & Future

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For over 10 years, experts have debated widely divergent ideas on risk assessment for GMO's in various fora supported by the Secretariat of the Convention on Biological Diversity (CBD). Numerous versions of non-binding "guidance" and training materials have been drafted and "tested" multiple times without achieving consensus. This effort (and expense) will continue for the foreseeable future unless and until Contracting Parties decide otherwise.

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CPB) was finalized in Montreal on January 29, 2000 and entered into force September 11, 2003. It is a supplementary agreement to the CBD pursuant to Article 19, which called Contracting Parties to consider "*the need for and modalities of a protocol setting out appropriate procedures [...] in the field of the safe transfer, handing and use of living modified organisms resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.*" As of September 10, 2015, there are 170 Contracting Parties to the CPB, which is a large percentage of the Parties to the CBD (196). However, countries with significant research, development and commercial interest in living modified organisms i.e., GMO's are not Parties including Argentina, Australia, Canada and the United States.

The objective of the CPB is to "*ensure an adequate level of protection in the field of the safe transfer, handing and use of living modified organisms resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.*" (Article 1) In meeting this objective, Contracting Parties to the CPB must give proper attention to the precautionary approach as contained in Principle 15 of the Rio Declaration. They must also take care to account for risks to human health especially in the context of transboundary movements.

There are several subjects being negotiated under the CPB, but risk assessment (Art. 15) and risk management (Art. 16) are likely the most relevant to the ISBR. Negotiations on topics like risk assessment and risk management occurs through a process that has several components. First, the Meeting of the Parties (MOP) that meets approximately every two years develops a mandate based on a consensus of Contracting Parties present. This mandate is communicated in a MOP decision. In the case of risk assessment and risk management, the MOP has repeatedly called for ad hoc technical expert groups (AHTEG) to take up the subject in a combination of on line fora and (if budget allows) face-to-face meetings. The MOP provides guidance to the AHTEG in the form or terms of reference. In 2005, MOP2 decided to form an AHTEG "*to further consider the nature and scope of existing risk assessment, evaluate such approaches and identify any gaps, and identify capacity-building needs*" ([http://bch.cbd.int/protocol/cpb\\_art15\\_info.shtml](http://bch.cbd.int/protocol/cpb_art15_info.shtml)). This first AHTEG met in Rome and concluded that general guidance in accordance with Annex III of the CPB is not a priority, and that there is great deal of information on risk assessment; but there may be use in developing some specific guidance based on organism types.

Three years later MOP4 decided that a “roadmap” or flowchart to help people interpret Annex III of the CPB would be helpful (<http://bch.cbd.int/protocol/decisions/decision.shtml?decisionID=11690>) . Development of a roadmap began with the first meeting of the second AHTEG on risk assessment and risk management in 2009 in Montreal. At present (2015), a consensus roadmap has not been finalized nor does it appear to be close to completion. Subsequent MOPs (since MOP4) have reconvened and reformed AHTEG’s in the hope that this work could be realize some level of general agreement as recognized by a consensus among Parties. Efforts to improve the guidance took the form of multiple rounds of “testing” by Parties and other stakeholders. In the meantime and in addition to bringing the roadmap to some punctuated endpoint, recent MOP mandates have been interpreted as calling for additional work including the development of further guidance materials on special topics (listed below), prioritization of more future topics for guidance (listed below) as well as a mechanism to annotate guidance documents with relevant references and develop training materials based on the (uncompleted) guidance.

Further Guidance: (a) risk assessment of living modified plants with stacked genes for traits; (b) risk assessment of living modified plants with tolerance to abiotic stress; (c) risk assessment of living modified trees; and (d) risk assessment of living modified mosquitoes.

Future topics for Guidance: (a) post-release monitoring and long-term effects of LMOs released into the environment; (b) risk assessment of living modified trees; (c) risk assessment of living modified fish; (d) risk assessment of living modified microorganisms and viruses; and (c) risk assessment and risk management in specific receiving environments.

The current state of the development of risk assessment guidance under the CPB coming out of MOP7 is that another, but expanded, AHTEG has been formed. This AHTEG will operate under similar, but new, terms of reference (<http://bch.cbd.int/protocol/decisions/?decisionID=13359>) and will work through a combination of on line and a face-to-face exchanges. Perhaps the second greatest challenge this AHTEG will face (the first being achieving consensus) will be dealing with the numerous and disparate testing results received from 43 Parties, 3 non-Parties and 10 Organizations ([http://bch.cbd.int/protocol/testing\\_guidance\\_RA.shtml](http://bch.cbd.int/protocol/testing_guidance_RA.shtml)). Efforts are being made to create a process to manage this challenge. Nevertheless, the question remains whether and how contradictory suggestions can be reconciled, and in the end produce guidance that is useful and grounded in real-world experience.