

**TEMPLATE FOR COMMENTS ON THE DRAFT REPORT OF
DISCUSSIONS OF THE ONLINE FORUM ON RISK ASSESSMENT AND
RISK MANAGEMENT
(29 JANUARY-12 FEBRUARY 2018)**

Paragraph ID #	Suggested change ¹	Explanation
0 (general comment)		The term used throughout the document ‘voluntary AHTEG Guidance’ is neither helpful nor accurate. The title in full should be used at first mention, i.e. ‘Guidance on Risk Assessment of Living Modified Organisms and Monitoring in the Context of Risk Assessment’, and where abbreviation is necessary, ‘the Guidance’ can be used. This would be in line with language used in previous COP-MOP Decisions. The term ‘voluntary’ is also not necessary as this is not part of the name of the Guidance. The nature of the document is already adequately dealt with in COP-MOP Decisions.
31	Several submitters noted that there are many guidance materials on risk assessment available worldwide in addition to the Guidance, only some of which are in accordance with Annex III of the Cartagena Protocol. The submissions echo those in Topic 1, stating that many of these guidance documents are readily found in the BCH.	While there are many guidance materials on risk assessment available worldwide, not all are in accordance with Annex III of the Cartagena Protocol. This is to be expected, as the bases of these materials could be different laws or policies, including those of non-Parties to the Protocol, or in relation to different international legal instruments that may have different scope and objectives to that of the Protocol. Whereas the Guidance, developed by processes established under the Protocol and sensitive to its objectives, is in accordance with Annex III and the Cartagena Protocol, as recognised in paragraph #30 above.
43	Many submitters suggested that existing guidance documents are more than sufficient for any currently conceivable risk assessment, and that there is no need for the development of new guidance, either generally, or for specific organisms or classifications of organisms. Other submitters disagreed, pointing to perceived assessment gaps within existing guidance, as discussed further under Topic 3, and the need to address these gaps, inter alia, through the development of further guidance on specific topics of risk assessment of living modified organisms.	It is clear from the submissions and discussions under Topic 3, particularly as indicated in paragraph #62 and subsequent paragraphs, that there are perceived gaps within existing guidance, and that these gaps may be met, inter alia, by the development of new and/or further guidance on specific topics of risk assessment. This point of view should also be reflected, to ensure a more balanced document.
44	A few interventions mentioned the need for a benefits assessment to be done in tandem with risk assessments to help define an acceptable risk endpoint in the assessment. Several others disagreed, stating that the assessment of any claimed benefits were not part of risk assessment. Like the perceived risk assessment gaps	It is clear from the submissions and discussions under Topic 3 that there was disagreement on this topic. This point of view should also be reflected, to ensure a more balanced document.

	discussed above, this idea is expanded upon substantially in Topic 3.	
47	One submitter suggested that the guidance document is too long, and Part II on specific types of LMOs and traits is confusing to new users of the document. The intervention suggests removing Part II of the document, retaining only Part I and III of the document as the general road map for risk assessment, risk management and monitoring.	This sentence should be deleted, as it is not the task of the Online Forum on Risk Assessment and Risk Management to make changes to the ‘Guidance on Risk Assessment of Living Modified Organisms and Monitoring in the Context of Risk Assessment’.
58	The Precautionary Principle was also identified by one submitter as a “flawed paradigm” of the Cartagena Protocol, in addition to the lack of benefits analysis. Another submitter considered that benefits should also be considered within the scope of the Protocol, because this is consistent with the dual purpose of the protocol, to provide ‘an enabling environment for the environmentally sound application of biotechnology, making it possible to derive maximum benefit from the potential that biotechnology has to offer, while minimizing the possible risks to the environment and human health.’ The submitter went on to suggest that “guidance on risk assessment under the Protocol should go beyond a strictly precautionary consideration of the risks to include some means by which to consider benefits in the decision-making process.”	This paragraph should be deleted. The precautionary approach underpins the Cartagena Protocol and is operationalized in its substantive legally binding provisions. The scope of the Protocol is likewise set out in its Article 4, focusing on LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health.
82, 83 (general comment)		While these paragraphs refer to the opinions of the submitters regarding the sufficiency of risk assessment methodologies when applied to organisms developed through synthetic biology, reference should be made to paragraph 6 of Decision XIII/17, where it is noted that risk assessment methodologies may need to be updated and adapted for current and future developments and applications of synthetic biology.
	Additional rows can be added to this table by selecting “Table” followed by “insert” and “rows below”	

1 Proposals to add, move or delete text in the draft document may be accompanied by a brief explanation.