Testing of the Guidance on Risk Assessment of Living Modified Organisms

#50

COMPLETE

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Q1: **Type of submission:**	Party

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Q2: **Name of the Party:**	India
Q3: **Person submitting this questionnaire:**	
Full Name:	Dr Ranjini Warrier
Email Address:	warrier@nic.in
Q4: **Institution(s) or organization(s) that participated in the testing:**	Government authority(ies)
Q5: **Context in which the testing was conducted**	Group event(s) (e.g., workshop, training course, meeting)
Q6: **Actual case(s) of risk assessment used in the testing: Note: Please enter the hyperlinks of BCH Risk Assessment Records (e.g. http://bch.cbd.int/database/record.shtml?documentid=104904 and http://bch.cbd.int/database/record.shtml?documentid=104905) or other publicly accessible web pages containing the technical and scientific data of the actual cases of risk assessment used in the testing.**	
Risk Assessment 1:	http://bch.cbd.int/database/record.shtml?documentid=103020
Q7: **In what language was the Guidance tested?**	English

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Q8: Name of the other Government:	*Respondent skipped this question*
Q9: Person submitting this questionnaire:	*Respondent skipped this question*
Q10: Institution(s) or organization(s) that participated in the testing:	*Respondent skipped this question*
Q11: Context in which the testing was conducted	*Respondent skipped this question*
Q12: Actual case(s) of risk assessment used in the testing: Note: Please enter the hyperlinks of BCH Risk Assessment Records (e.g. http://bch.cbd.int/database/record.shtml?documentid=104904 and http://bch.cbd.int/database/record.shtml?documentid=104905) or other publicly accessible web pages containing the technical and scientific data of the actual cases of risk assessment used in the testing.	*Respondent skipped this question*
Q13: In what language was the Guidance tested?	*Respondent skipped this question*

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Q14: Name of the organization:	*Respondent skipped this question*
Q15: Person submitting this questionnaire:	*Respondent skipped this question*
Q16: Institution(s) or organization(s) that participated in the testing:	*Respondent skipped this question*
Q17: Context in which the testing was conducted	*Respondent skipped this question*
Q18: Actual case(s) of risk assessment used in the testing: Note: Please enter the hyperlinks of BCH Risk Assessment Records (e.g. http://bch.cbd.int/database/record.shtml?documentid=104904 and http://bch.cbd.int/database/record.shtml?documentid=104905) or other publicly accessible web pages containing the technical and scientific data of the actual cases of risk assessment used in the testing.	*Respondent skipped this question*
Q19: In what language was the Guidance tested?	*Respondent skipped this question*

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Q20: **Would you like to submit an evaluation of the following section of the Guidance: Part I: The Roadmap for Risk Assessment**	Yes

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Q21: **This section of the Guidance is practical.1**

(no label)	Disagree

Q22: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:

1. The pre-face and introduction section to the Road Map for risk assessment of LMOs is well drafted. However the explanatory text in the subsequent sections needs to be greatly simplified. The practicality of the document can be significantly improved by removing the overtly complex explanations and terminologies, as these could lead to different interpretations by countries/risk assessors.
2. 'Rationale' section under each of the five steps is written in a complex language and needs to be rewritten in a simple language (2-3 lines) and supported by links to explanatory resource materials or examples.
3. Some of the sentences in rationale are complex and also repetitive and do not explain the purpose of each step. Some examples are as under:
• Line 223 - the term 'sufficient' introduces subjectivity to a scientific risk assessment process
• Line 263-265 regarding the availability of independent experts is part of a regulatory process and does not fit within the overarching Principles of Scientific risk assessment.
• Line 278-283 deals with lack of information or knowledge due to experimental variability is an issue which relates to statistical validation of a study or faulty experimental design which is already covered in line 261-262 and does not fit under 'uncertainty'.
• The concept of 'uncertainty is captured in lines 267 to 277.
• Line 284-296 is a repetition of lines 267 -277 and may be deleted as it is superfluous. .
• Line 302, the term 'each' may be deleted
• Line 314 to 318; reference to protection goals and assessment end points is inclusive of national laws, guidelines, obligations under international agreements as indicated in line 200-203. The line 314 to 318 may be appropriately redrafted.
• Line 353 is stating the obvious.
• Line 319-320 lacks clarity and needs further explanation.
• Line 360-363 "When the likelihood ----------non-modified organisms" is superfluous and may be deleted.
• Lines 396-397 are repeated again in line 428-429.
• 394 – 431 – the language is too complex and needs to be greatly simplified to provide guidance on how to actually complete the process of Step 1. While dealing with Step 1, the utility of biology documents with respect to the non-modified or parental organisms needs to be introduced.
• LINE -402 – 404 -identification of "protection goals" and "hazard identification" are both part of problem formulation based on which "assessment ends points" are decided. Therefore this statement needs to be redrafted.
• Line 432 - the word ' Parental Organism' may be inserted after non-modified organism for the sake of uniformity.
• Line 460 – the word 'meaningful' may be changes to scientific or relevant
• Line 449 – 456 is prescriptive and not a guidance
• Line 469-470 relates to risk management and not part of Step 1
• Line 495 - Sentence is not complete.
• Line 502-504 needs more explanation on how evaluation of likelihood and consequences can be undertaken in the inverse order. It appears there is a mix up of risk hypothesis and risk assessment.
• Line 527 -553 is crop specific but guidance document is for all LMOs therefore it needs to be generalised in a simplistic manner.
• Line 554-557 is a management issue. Exposure due to gene flow and incidental exposure due to handling transport etc should be separated as impact due to gene flow is covered in other sections
• Line 595-597 needs more explanation with examples and reference to resource material.

• Line 601-603 - not part of ERA but food safety assessment.
• Line 635-636 should form part of Step 2 and is already covered in that section.
• Step 5 'Rationale' is too broad and there are sections here that go into realm of decision making process.
• Line 527-553, Line 684- -688 and Line 694 -696 - it is not clear if this is linked to confined field trials (CFT) or commercial releases.
• Line 713-723 on 'Related Issues' prescribes how a decision making process is to be followed by a Party which is outside the mandate and scope of this document and may be deleted.

Q23: This section of the Guidance is useful or has utility.2

(no label)	Neutral

Q24: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:

1. The Article 15, 16 and Annex III of the protocol are applicable to all types of environmental releases and the same has been reiterated in the roadmap (lines 184-185). However there is no distinction made between the risk assessment considerations for small scale experimental releases under confined conditions for the purpose of field trials or large scale/commercial releases under unconfined conditions in the roadmap. Therefore, it is difficult for risk assessor to select which information will be essential for either of the above two scenarios. It is important to recognize that confined field trials are needed to generate data for risk assessment and therefore the information requirements for the same are much different and limited as compared to large scale environmental releases.
2. Each of the step listed in the guidance requires consideration of various issues such as gene flow, effect on target/non-target organisms, changes in management practices etc. It is difficult to understand for risk assessors particularly who are doing it for the first time or having limited experience to establish links between area of assessment or issues under consideration.
3. Some of the text is also verbose, prescriptive and restrictive and can be modified / deleted to make the document more easy to understand. In step 3 several points in the points to consider are almost covered in the section on “establishing the context and scope” e.g., line 600, 601-603 and 604.
4. The case by case approach as indicated Annex III has been indicated at the beginning of introduction (line 190). In line 206 -208, the word ‘iterative’ introduces ambiguity to a scientific risk assessment process. Information requirement for a risk assessment is captured in the screening and scoping of impacts exercise in an Environmental Impact Assessment which is akin to identification of Protection Goal and Assessment End Points. The process of identifying the information requirements is country specific. Risk Assessment is based on available scientific information at the time of conducting the risk assessment.
5. In several places, the key terms have been introduced suddenly in the text, without providing a background. For example even the term “Protection goal” and its linkages to the concept of ‘Problem Formulation’ is not clearly understood in many countries and is not used presently in several regulatory systems.
6. The other terminologies which are not well explained and need further elaboration include
• Line 198 - unintended effects,
• Line 279 – lack of information and incomplete knowledge can be reconciled.
• Line 303 and 317 - Risk threshold
• Lines 396-397 - terms such as ‘direct’, ‘indirect’, and ‘immediate’, ‘delayed’ are not explained in the "Use of terms" on page 57. Further usage of these terms in the context of the Nagoya Kuala Lumpur Supplementary Protocol (NKLSP) on liability and Redress is not appropriate as definition of damage under Article 2 (b) is with reference to ‘response measures’ and therefore outside the scope of this guidance document. NKSLP is yet to come into force.
• Line 431 and 598 - ‘combinatorial effects’ and ‘cumulative impacts’
• Line 438 and 467 under the ‘points to consider’ regarding characters of LMOs, it has been mentioned to list characteristics such as ‘origin’ besides centres of origin and centres of genetic diversity. It is not clear in what context the word ‘origin’ has been used and introduces subjectivity to a scientific process which is avoidable.
• Line 435 ‘gene products’
• Line 524- highly likely, likely, unlikely highly unlikrly
• Line 541- ‘Anthropogenic mechanisms’
• Line 581 – ‘major’, ‘intermediate’, ‘minor’ or ‘marginal’
• Line 624 – ‘high’, ‘medium’, ‘low’, ‘negligible’ or ‘ intermediate’

Q25: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3

(no label)	Disagree

Q26: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:

The scope, mandate and understanding in developing this document were specifically to elaborate on Annex –III to the Cartagena Protocol on Biosafety. While the broad structure and the 5 steps outlined in the document are consistent with the steps in Anne III to the Protocol, the text of the document is not in conformity. The basic reason for the same is that Annex III is based on scientific considerations, whereas the guidance document extends into policy considerations and administrative issues. For example under the section on 'Overarching issues in the risk assessment' sub section ‘quality and relevance of information’, several points/terms being used are administrative in nature. The terms such as 'independent review', sufficient quality of information etc are administrative/operational procedures and subject to different interpretations. In addition there have been use of new terminologies as mentioned in the previous sections which is not consistent with the CPB .
As mentioned earlier, inclusion of the Section on ‘Related Issues’ extends beyond the realm of this exercise into decision making by a Party with respect to a LMO. Guidance for decision making is a process after completing the risk assessment process and therefore outside the scope. Relevance of including issues such as Socio-economic consideration which are still being discussed at the Cop-MoP level and the Nagoya Kuala Lumpur Supplementary Protocol on Liability and Redress in the context of Annex III is not Issues such as ethical issues, co-existence etc is outside the scope of the Protocol itself and introduces a high level of subjectivity to a scientific risk assessment process.

Q27: This section of the Guidance takes into account past and present experiences with LMOs.4

(no label)	Disagree

Q28: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:

The guidance document is envisaged to enhance the understanding of scientific risk assessment process for all LMOS but has been developed with focus on LM plants in view of the available experience (refer line 181-183) with LM plants. However this linkage has not been established in Part I and part II and needs to be reviewed. In fact the pattern followed in part II for Guidance on Stacked Events is pre-emptive and restrictive. It does not highlight / demonstrate (I) how a risk assessment is actually conducted (i) how the risk assessment process can be simplified using the available experience and (ii) risk assessment may not be applicable to all Protection Goals or end points . It is case /trait specific, nature of receiving environment and intended use.
The complexity further arises from the fact that experience in conduction risk assessment for chemical hazards has been extrapolated for assessing risks from biological material / LMOs.

Q29: Here you may provide further details to explain your answers in evaluating this section of the Guidance:

As the Guidance document is a negotiated text and not a consensus document, there are areas of policy, administration procedures appearing in the text leading to confusion in understanding the scientific considerations in the risk assessment process, which is the primary objective of the document. So much so that experienced risk assessors found it difficult to apply the document to real case scenarios.
2. Though the guidance does describe the main concepts within the methodology used in conducting a risk assessment, it use complex terminologies, which does not resemble the structure/terminology used in risk assessment in India as well as other regulatory authorities. It also does not resemble the procedures and protocols used by technology developers in generating safety data and in regulatory submissions.
3. Therefore placing relevant information in the context of the guidance document is complex and time consuming. In the present form the practical understanding of the risk assessment document shall be extremely limited, particularly to novice risk assessors in Parties which have never been involved in this process and may be applying it for the first time.
4. The questionnaire is not consistent to the purpose of titles generated for the purpose of purported comments on each section. Routine and repetitive queries may not elicit relevant response. In the current format, it is difficult to elucidate any original response.

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Q30: Would you like to submit an evaluation of the following section of the Guidance: Part II: Specific types of LMOs or Traits - Risk assessment of LMOs with stacked genes or traits	No

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Q31: This section of the Guidance is practical.1	*Respondent skipped this question*
Q32: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q33: This section of the Guidance is useful or has utility.2	*Respondent skipped this question*
Q34: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q35: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3	*Respondent skipped this question*
Q36: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q37: This section of the Guidance takes into account past and present experiences with LMOs.4	*Respondent skipped this question*

Q38: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q39: Here you may provide further details to explain your answers in evaluating this section of the Guidance:	*Respondent skipped this question*

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Q40: **Would you like to submit an evaluation of the following section of the Guidance: Part II: Specific types of LMOs or Traits - Risk assessment of LM crops with tolerance to abiotic stress**	No

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Q41: This section of the Guidance is practical.1	*Respondent skipped this question*
Q42: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q43: This section of the Guidance is useful or has utility.2	*Respondent skipped this question*
Q44: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q45: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3	*Respondent skipped this question*
Q46: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q47: This section of the Guidance takes into account past and present experiences with LMOs.4	*Respondent skipped this question*
Q48: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q49: Here you may provide further details to explain your answers in evaluating this section of the Guidance:	*Respondent skipped this question*

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Q50: **Would you like to submit an evaluation of the following section of the Guidance: Part II: Specific types of LMOs or Traits - Risk assessment of LM mosquitoes**	No

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Q51: This section of the Guidance is practical.1	*Respondent skipped this question*
Q52: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q53: This section of the Guidance is useful or has utility.2	*Respondent skipped this question*
Q54: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q55: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3	*Respondent skipped this question*
Q56: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q57: This section of the Guidance takes into account past and present experiences with LMOs.4	*Respondent skipped this question*
Q58: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q59: Here you may provide further details to explain your answers in evaluating this section of the Guidance:	*Respondent skipped this question*

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Q60: **Would you like to submit an evaluation of the following section of the Guidance: Part II: Specific types of LMOs or Traits - Risk assessment of LM trees**	No

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Q61: This section of the Guidance is practical.1	*Respondent skipped this question*
Q62: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q63: This section of the Guidance is useful or has utility.2	*Respondent skipped this question*
Q64: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q65: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3	*Respondent skipped this question*

Q66: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q67: This section of the Guidance takes into account past and present experiences with LMOs.4	*Respondent skipped this question*
Q68: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q69: Here you may provide further details to explain your answers in evaluating this section of the Guidance:	*Respondent skipped this question*

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Q70: **Would you like to submit an evaluation of the following section of the Guidance: Part III: Monitoring of LMOs Released into the Environment**	No

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Q71: This section of the Guidance is practical.1	*Respondent skipped this question*
Q72: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q73: This section of the Guidance is useful or has utility.2	*Respondent skipped this question*
Q74: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q75: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3	*Respondent skipped this question*
Q76: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q77: This section of the Guidance takes into account past and present experiences with LMOs.4	*Respondent skipped this question*
Q78: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q79: Here you may provide further details to explain your answers in evaluating this section of the Guidance:	*Respondent skipped this question*

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Q80: **Would you like to submit an evaluation of the following section of the Guidance: Background Documents**	No

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Q81: This section of the Guidance is practical.1	*Respondent skipped this question*
Q82: This section of the Guidance is useful or has utility.2	*Respondent skipped this question*
Q83: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3	*Respondent skipped this question*
Q84: This section of the Guidance takes into account past and present experiences with LMOs.4	*Respondent skipped this question*

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Q85: **Please use the space below if you wish to provide additional feedback regarding the testing of the Guidance on Risk Assessment of Living Modified Organisms:**

No comments can be made on Part II on specific types of LMOs and traits as the roadmap needs significant revisions and therefore its applicability to specific LMOs and traits cannot be tested or commented in the present form.
As per decision of COPMOP6, the guidance is to be tested using actual cases of risk assessment conducted in accordance with Annex III of the Cartagena Protocol. There are no risk assessment summaries/documents available for GM trees or GM mosquitoes as the risk assessment of these product groups has not yet been completed. No such risk assessment summaries are available for testing.
Annex III provides a well-structured approach to risk assessment, that needs to be applied on a case by case basis. Coupled with various resource documents available, it is sufficient to conduct risk assessment of specific product groups/traits and can be elaborated by Parties as per their regulatory requirements. It is strongly opined that development of specific guidance be left to Parties and not pursued.