Testing of the Guidance on Risk Assessment of Living Modified Organisms

#28

COMPLETE

Collector: BCH website (Website Survey)
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Q1: **Type of submission:**	Party

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Q2: **Name of the Party:**	South Africa
Q3: **Person submitting this questionnaire:**	
Full Name:	Wadzanayi Mandivenyi
Email Address:	w mandivenyi@environment.gov.za
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., w orkshop, 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=14750
Risk Assessment 2:	http://bch.cbd.int/database/record.shtml?documentid=14797
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)	Agree

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:**

It is important for the introduction (line 188) to already clearly make the distinction between the role of state party risk assessors (risk analysis undertaken by regulator) and the actual risk assessment conducted by the applicant.

Some useful overarching elements are introduced that are important and provide greater clarityfor countries wanting to undertaken risk assessments as contemplated by the Cartagena Protocol on Biosfaty. Of particular interest is the introduction of elements of the concept of Problem Formulation and Options Assessment (PFOA) without any explicit reference or clear explaination. As a result, the elements introduced are not integrated into the overall risk assessment framework.

Problem Formulation and Options Assessment can be used to simplify the risk assessment process and identify potential assessment endpoints.

The concepts of protection goals and assessment endpoints are introduced but not fully explained.

These tend to be sovereign in nature and it is important that these are not presecribed in any form.
Line 421 (iv) transfer genes to other organisms/populations - not necessarily a harm, but potentially a pathway to a harm It may therefore be useful to distinguish between harm and pathways to harm in this section..

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

(no label)	Agree

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:

The introduction of specific elements in the document under the heading Point's to consider is useful for providing greater context and clarity. However, the language then utilized in these sections is prescriptive. The headings should therefore be rephrased to "points that may be considered as appropriate"

The roadmap was reviewed in the context of 2 applications. It was found that in some instances the information required under points to consider was not available in the dossiers.In particular elements relating to:
- Horizontal gene flow
- cumulative impacts on other LMOs
- Multitrophic effects

In addition, it waas noted that the structure of the Guidance was not aligned with the structure followed in the risk assessments analysed which used the Annex III structure

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

(no label) Agree

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:

It was recognized that the guideline is consistent with the limited focus of the CPB and is therefore not encompassing issues that may not be biodiversity related.

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

(no label) Agree

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:

485 Horizontal gene transfer in plants remains on the list, although it has not been demonstrated>

460 Baseline data not always available for new or novel applications.

Unintended effects

All the elements listed in the points to consider under 471 to 495 were not covered in the applications that were assessed as part of this exercise.

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

Line 622 Risk matrices is a usefule, simple tool that is useful. It may be a good idea to include an example of a completed risk matrix as a reference

This document focuses on conservation and sustainable use of biodiversity as the scope of the CPB requires. It should be recognised, however, that the introduction of LMOs can have impacts beyond biodiversity effects which can be positive ror negative. For Example (i) risk benefit scenarios where there is clear benefit for society (ii) the development of resistance tand its impact on the sustainability of LMO crops .

There are differnce roles for the roleplayers (competent authority, regulatory authority, notifier etc) in implementing this guidance. There is a distinction to be made between the risk assessment conducted by the notifier and the risk analysis conducted by the competent authority or regulator. It is important to have greater clarity that different roles could be taken on by different roleplayers and this may differ from country to country. A section that provides this clarity may be useful. Different roleplayers will play a key role/assume responsibility for different stages of the risk assessment. At times, more than one role player may be responsible for generating data or contributing to the risk assessment process.
It is important to use the terms consistently. The terms competent authority and regulator are used interchangeably.

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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**	Yes

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Q71: **This section of the Guidance is practical.1**

(no label)	Agree

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:

A greater emhasis on the distinction betw een General monitoring and Case Specific monitoring to be a applied consistently w ithin the section.. Each time the concept of monitoring is mentioned it must be clear w hether its case specific or General monitoring being refered to.

1839 should refer to Case Specific monitoring plan
This is the only place in the document that the roleplayers are named - notifier, competent authority, regulators

There are significant costs associated w ith a comprehensive monitoring plan if all of these elements are incorporated.

Q73: This section of the Guidance is useful or has utility.2

(no label) Neutral

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:

n the context of monitoring, it must be clearly stated that the parameters outlined only refer to commercial/large scale environmental releases.

It w ould be useful to include a section that highlights how Problem Formulation and option assessment could be used to reduce the monitoring requirements and allow for a more focussed monitoring plan.

Q75: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3

(no label) Neutral

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:

The link betw een monitoring and risk management needs to be more clearly articulated. To this end, it w ould be helpful if the roadmap could incorporate monitoring as part of riak management and include it in the last phase.

Q77: This section of the Guidance takes into account past and present experiences with LMOs.4

(no label) Neutral

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:

This component w as not incorporated into the actual cases of risk assessment considered.

More thoroughly integrating the concept of Problem formulation and option assessment could be used to reduce the monitoring requirements and allow for a more focussed monitoring plan.

Q79: Here you may provide further details to explain your answers in evaluating this section of the Guidance:

The section w ould be greatly improved through a reorganization of the text, Sections 1829 to 1831 w ould provide greater clarity if they w ere incorporated after line 1792.

There is need to distinguish the various levels at w hich monitoring happens. There is monitoring in the context product development and that w hich is undertaken as part of validating a risk assessment and constitutes risk management. This input could provide greater clarity to the section on monitoring. It should be clear, that the the monitoring infered in this text is for commercial large scale releases.

There reference to best available science in line 1894 is unnecssary in the context of the prior principles articulated.

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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:**

A significant focus on risk monitoring is not expected in light of the title. The title should change to reflect the contents of the document, namely risk assessment and risk monitoring.

The inclusion of points to consider throughout the text may be misconstrued as prescriptive requirements for each section. The sections should be renamed "Points that MAY be considered"