Testing of the Guidance on Risk Assessment of Living Modified Organisms

#42

COMPLETE

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Q1: **Type of submission:**	Party

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Q2: **Name of the Party:**	Brazil
Q3: **Person submitting this questionnaire:**	
Full Name:	Davi de Oliveira Paiva Bonavides
Email Address:	dema@itamaraty.gov.br
Q4: **Institution(s) or organization(s) that participated in the testing:**	Government authority(ies)
Q5: **Context in which the testing was conducted**	Individual exercise(s)
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:	https://bch.cbd.int/database/record.shtml?documentid=104627
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:

The practicality of the Guidance could be improved. There is a lack of clarity on how to relate the different steps of the assessment. It is also important to consider the nature of the potential damage and to compare it with common practices of agricultural production, as well as those associated to human and animal health. There is also a need to avoid considering the gene flow for every LMO as damage, when this is a common phenomenon in nature. The Guidance should avoid prescriptive approaches and provide the necessary flexibility for the development of biotechnology.
More specifically:
- Step 1 is not well explained: is that a identification of potential adverse effects step (where the question "What could go wrong" could be applied) or a "what, why and how" step (line 398)? This step should be better explained as critical to the success of RA. An inappropriate risk hypothesis may misdirect the whole risk analysis process and lead to the imposition of unnecessary controls to manage risk. Although all the necessary information is listed in the Step 1, there is a lacking of clarity about how to link this information in a logical way to define a causal pathway.
- There are some sentences in the rationale of the text that creates complexities instead of explaining the purpose of each step. For example the sentence 'These includes any changes in the LMO, ranging from nucleic acid (including any deletions) to gene expression level to morphological changes' (lines 426 - 427) does not help to explain the step 1 of RA and the idea of this sentence is already covered in the 'points to consider' section. Also most of the examples in the text are not explained well enough to be used as practical examples (eg. lines 429-431; lines 513-514).
- To be a 'scientifically plausible scenario' (line 407) is there is a need to have a concrete pathway linking the proposed dealings with potential adverse effect. Only these scenarios should be considered in detail in risk assessment.
- The step 1 is based on the scope and context established in the planning phase so the ´points to consider´ section are the detailing of factors considered in this context to identify possible adverse effects. The way 'points to consider' are presented in the Guidance is therefore confusing due to: some information required are part of the previous step 'establishing the context' (line 458-450 and line 460-461); some information are being redundant (line 453-456 and 473-475) ; some information requirements are presented in the context of many factors (like type of irrigation, amount of herbicide applications, methods for harvesting and disposal etc. - line 493 and 494) and some information are required in a context using vague concepts (like cumulative effects – line 495). The entire 'points to consider' section could benefit from a simplification.
- In the step 3 there are many ´points to consider´ that are part of the ´establishing the context ´section like line 600, line 601-603 and line 604. Those factors are out of place and can make more difficult to follow a logical pathway in the process.

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

(no label)	Disagree

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:

One useful measure adopted by several regulatory agencies is the establishment of communications mechanisms that risk assessors might use in order to ask for additional information. The Guidance could be improved by the inclusion of such mechanisms.

- The 'Quality and relevance of information' (line 222) section does not allow an evaluation on how much and which type of data are needed in different cases of risk assessment (eg. field trial x commercial release). It also does not allow the establishment of the relative value of different types of information (eg. an opinion of an expert with the parent organism can be less reliable or relevant than a validated study conducted in accordance with international protocols). Some orientation in this sense would be useful.
- The 'Identification and Consideration of Uncertainty' (line 266) section does not present different approaches to deal with different kinds of uncertainty (eg. expert opinion, clear definition of key words etc). The approaches presented are only additional data and risk management measures that can make the process of risk analysis more complex without giving the necessary confidence for the risk assessor to reach a conclusion.
- The ´Establishing the context and scope´ section (line 300) should be more straight related with the context as the necessary information to sets the criteria against which risk will be evaluated (eg. genetic modification, parent organism, receiving environment, proposed activities with GMO and previous releases). In the Guidance there are some points listed that are vague (eg. line 329-332) and the introduction of broad parameters (eg. ecological function).
- The iterative nature of risk assessment process is mentioned in line 373, but the concept of iterative should be better exploited due to its importance to the process. Iterative means, for example, the result of ongoing accumulation of information (data from applicant, expert advice, literature search) where any step during risk assessment can be reviewed.
- The RoadMap is difficult to be applied in the RA process, for the information required are presented as a check list and is difficult to select which information are important or not for the case being evaluated and there are no suitable examples presented.
- In the step 2 the way likelihood is expressed is not well addressed. Although quantitative and qualitatively expression is mentioned there is no explanation in the proposed Guidance why for biological systems qualitative terms are used and neither the assessment scale used for this terms, making more difficult to understand this step.
- In the step 3 there is also an description of qualitative terms without any explanation on the importance of the definition of these terms in the context of a LMO risk assessment. 'Major', 'intermediate', 'minor' or 'marginal' consequences are not clear enough to help the evaluation. There is also a recommendation 'Parties may consider describing these terms and their uses in risk assessment guidelines published or adopted by them' but will be more useful if there is an example of how this terms may be used in the context of RA.
- In the step 4 the terms 'high', 'medium', 'low', 'negligible' and 'indeterminate' are mentioned in the text without definitions or the presentation of a risk matrix that can be used to estimate the level of risk, making more difficult to understand this step. In the 'points to consider' section there is also a mention of 'broader ecosystem and landscape consideration...' (lines 635-636) that should be considered in the step 1 and not in the last step of RA.

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

(no label) Strongly 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 Guidance must be focused specifically on risk assessments. Decision BS-VI/12 instructed Parties to test the document in "actual cases of risk assessment and in the context of the Cartagena Protocol on Biosafety". Therefore, it is clear that the Guidance must not go beyond the scope of the Protocol. Nonetheless, the section "Related Issues" is dedicated not to risk assessment in itself, but to "other issues that may be part of the decision-making process" (lines 714-715). Furthermore, the section also addresses "a number of other issues, which are not mentioned in the Protocol (e.g., co-existence, ethical issues)" (line 721)
In this topic, the work of the AHTEG goes beyond what Parties asked it and, for this reason, section the section "Related Issues" must be removed from the Guidance.

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

(no label) Neutral

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 institution responsible for risk assessments under the Brazilian law (the National Technical Commission for Biosafety – CTNBio) considers that the national legislation is more advanced than the Guidance. Therefore, testing the Guidance was not particularly beneficial for knowledge development.

According to CTNBio the Brazilian legislation allows risk assessments in independent sections that enables a particular approach to each of risk assessments area, according to scientific progress, considering the objectives of protection (invasiveness, non-target organisms). Each of these sections comprise a risk rating, which is characterized as a hazard exposure, where the problem in question is clearly defined. Another relevant aspect is that the national legislation allows the consideration of the available scientific information. In addition, the Brazilian law facilitates the communication between the risk assessor (CTNBio) and the risk managers (CTNBio and bodies of supervision and registration) which unfortunately is still a gap in the Guidance.

The Ministry of Agriculture, Livestock and Supply presented the following considerations:

"In the section ´Establishing the context and scope´ (line 300) the previous risk assessments (in different levels of appropriateness - with related surrogate systems, modified traits in other organisms, GMO or parent organisms overseas or the GMO/parent organism in the receiving environment) should be included as it can also be important to set up the context of the actual risk assessment. Risk assessment should be carried out on case-by-case basis and the required information may vary in the nature and level of detail (Annex III of the Protocol). However the fact that the information required can be simplified in some cases in not mentioned along any document. For instance, for ´RA of LMO plants with stacked genes or traits´ guidance there is no mention along the text of the possibility to reduce the information requirement in case the RA of stacked genes if individual events were already approved and if the evidences are showing that there is no interaction between the genes/proteins expressed (lines 759 - 952)".

Q29: **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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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** Yes

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Q31: **This section of the Guidance is practical.1**

(no label) Disagree

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:

The present study was based in a test of a bean genetically modified for disease resistance. This trait is produced with a different technology from the one considered by the guide. Thus, the Guidance was not helpful in this point, since it lacks the necessary flexibility to cover all the new techniques of genetic modification and new traits. The Guidance should be improved in order to be more useful in different situations, regardless of the methodology of modification or inserted phenotype.

Q33: This section of the Guidance is useful or has utility.2

(no label) Disagree

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:

The Guidance does not cover the type of technology applied to the test.

Q35: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3

(no label) Disagree

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:

Annex III of the Protocol covers the information that needs to be considered in a risk assessment in a flexible way. The Guidance, being a non-binding document, must reflect the same non-prescriptive approach.

Q37: This section of the Guidance takes into account past and present experiences with LMOs.4

(no label) Disagree

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:

The Guidance does not cover the type of technology applied to the test.

Q39: Here you may provide further details to explain your answers in evaluating this section of the Guidance:

The Guidance does not cover the type of technology applied to the test.

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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**	Yes

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Q51: **This section of the Guidance is practical.1**

(no label)	Neutral
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**

(no label)	Neutral
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**

(no label)	Neutral
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**

(no label)	Neutral
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:**

Although the Guidance does not cover the type of technology applied to the test, the National Health Surveillance Agency considers that, "in addition to environmental concerns, risk assessments on LM mosquitoes should also taking into account risks to human health", in accordance with articles 1 and 4 of the Protocol.

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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**	Yes

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Q61: **This section of the Guidance is practical.1**

(no label)	Neutral
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**

(no label)	Neutral
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**

(no label)	Neutral
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**

(no label)	Neutral
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:

Although the Guidance does not cover the type of technology applied to the test, the Ministry of Agriculture, Livestock and Supply presented the following considerations on the risk assessment of LM trees:
"There is no practicality or utility of having a separate guidance for LM trees: for field trials or commercial release the RA of LM trees will take into consideration the information about the genetic modification, the biology of parental organism, the receiving environment, the proposed activity with the LM tree and previous risk assessment as much as is considered for LM crop. The fact that 'Because of their perennial growth and, in many cases, long lifespan and large size, trees may develop complex and multi-level ecological interactions with other organisms' (lines 1189 e 1190) does not creates any additional risks that can be not evaluated using the five steps approach described in the Road Map as noticed in the present test.
The Guidance does not adequately address questions that could be inherent for LM trees and neither presents new specific 'points to consider', that could lead to different outcomes than those listed in the Road Map (part 1) : For instance, in the case of a confinement release the main point should be how the introduced trait might alter the biology of the tree regarding its ability to keep confined and the adequate measures for this confinement. Information from laboratory, green house or experience with similar genes introduced into crop plants or traits developed by traditional breeding could be used as source of information. If there is still a lack of information about the phenotype of a LM tree in the environment, measures to reproductively isolate the confinement could be adopted. In the case of a field trial, not all information is available yet as this is still a research step and the field data is necessary to assess the risks of a commercial release, however these factors are not clear in the Guidance leading to an endless looping.
In the 'points to consider' questions related with presence of genetic elements and propagation methods, long life span, phenotypic characterization and stability of the modified genetic elements, dispersal mechanisms, exposure of the ecosystem to LM trees and potential consequences are listed but they are nothing else than further elaboration of steps 1, 2 and 3 applied to LM trees, including a lot of redundancy among the listed topics".

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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)	Neutral

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:

Brazil follows its national legislation on monitoring both for the experimental stage and for commercial use. The legislation considers the national protection goals.

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:

Each country should consider its methodologies for monitoring and protection.

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:

It is important to bear in mind that article 33 of the Protocol provides the necessary flexibility for Parties to adopt its own methodologies for monitoring and protection. Therefore, the Guidance must adopt the same approach.

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:

Each country should consider its methodologies for monitoring and protection.

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 Yes

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Q81: This section of the Guidance is practical.1

(no label) Disagree

Q82: This section of the Guidance is useful or has utility.2

(no label) Disagree

Q83: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3

(no label) Neutral

Q84: This section of the Guidance takes into account past and present experiences with LMOs.4

(no label) Disagree

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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:

The Guidance on Risk Assessment of LMOs might be helpful for countries that do not have a legal framework for biosafety and biotechnology or do not have experience in the area.

For countries that already have a legal framework in place, as it is the case of Brazil, the Guidance is not very practical and could be improved. In this sense, some measures could be useful, such as: the establishment of communications mechanisms that risk assessors might use in order to ask for additional information; further explanation on how to relate the different steps of the risk assessment; provide flexible orientation on how to consider new technologies and new generations of LMOs. As biotechnology advances quickly, it is important that any regulatory strategy for this area of knowledge be flexible and scientifically grounded.