Testing of the Guidance on Risk Assessment of Living Modified Organisms

#30

COMPLETE

Collector: BCH website (Website Survey)
Started: Monday, March 31, 2014 8:58:19 AM
Last Modified: Monday, March 31, 2014 9:37:59 AM
Time Spent: 00:39:40

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Q1: **Type of submission:**	Party

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Q2: **Name of the Party:**	European Union
Q3: **Person submitting this questionnaire:**	
Full Name:	Ms Ella Strickland
Email Address:	ella.strickland@ec.europa.eu
Q4: **Institution(s) or organization(s) that participated in the testing:**	Government authority(ies)
Q5: **Context in which the testing was conducted**	Other (please specify) In consultation with EFSA
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:	see_note@end_of_questionnaire
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:**

The EU welcomes the endorsement of the risk assessment principles as demonstrated by the adoption of the case-by-case approach, comparative analysis with a selected comparator, 6-step approach to the risk assessment with an emphasis on the problem formulation, coverage of all areas of risk and the principles adopted in the monitoring post release.

However the EU considers that the requirement (line 290) for various forms of uncertainty to be considered and described in each step of the risk assessment could be considered burdensome and disproportionate. It would be acceptable for the uncertainty for each indentified risk to be described, where relevant, under step 4 "An estimation of overall risk …."

The EU would also like to note that, in the EU, the risk assessment of an LMO for experimental purposes (i.e. a field trial) is the responsibility of the Member State on whose territory the release is to take place, therefore the European Commission is not in a position to comment on the practicality or any other aspect of the guidance in this respect and relies here on the comments made by its Member States.

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:

Line 578 - It is not clear in the guidance if the reversibility of an effect is referring to an intentional or unintentional effect. For example, in the case of an LMO plant that has been modified to be resistant to a pest the overall effect may be a reduction in the pest poopulation in a region how ever there may also be an unintentional effect on a non target organism population. It should be described more clearly in this section exactly w hat is meant by reversibility of an effect and w hether the risk assessor should consider the intentional or unintentional effects or both. In some cases scientific data and evidence of the reversibility of an effect may not be readily available. It w ould be more practical to consider the "potential for recovery" rather than the reversibility of an adverse/unintentional effect.

Line 660 refers to the recommendation that acceptability of risk should take into account potential benefits for the environment, biodiversity and human life. The EU does not support an approach to risk assessment that balances risk acceptability w ith benefits. If this text is to remain "should" should be replaced w ith "may" to reflect the view that not all parties agree w ith this approach.

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:	*Respondent skipped this question*

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:

The EU w elcomes the clarity provided (line 645) w ith regard to the need, during the problem formulation, to identify protection goals, assessment endpoints and risk thresholds.

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

The guidance w as not tested using actual applications. The EC, as risk manager, has review ed the guidance in collaboration w ith EFSA and considered if follow ed, if it w ould provide sufficent information and data to enable risk assessors to make informed decisions. Therefore in the follow ing sections only the usefulness and the utility and comments under this section have been completed.

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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	*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

(no label)	Agree

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:

Line 788 It should be stated more clearly that re-transformation and co-transformation is not considered in this part of the document but that such applications should be covered on a case-by-case basis and that these LMOs may be considered to be and subsequently assessed as a single event.

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

(no label)	Agree

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:

Line 901 consideration of the segregation of transgenes warrants a more detailed explanation and discussion in the document.

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

(no label)	Neutral

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	Yes

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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

(no label)	Agree

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:

The EC is supportive of the approach adopted which resonates with that proposed in the EFSA guidance, for example, the need to assess the unintended effects, to test GM plants in representative receiving environments under representative stress conditions and the availability of appropriate non GM comparators.

Q45: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3

(no label)	Agree

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

(no label) Agree

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 *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

(no label) Agree

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:

The guidance should include the following

(1) Advice on the use of non-GM surrogates (i.e. sterile mosquitoes through radiation) to inform on interactions with biotic and abiotic environment(s), and;

(2) Further guidelines on selection of comparators including the possible need for alternative comparators (to non GM parental line).

Q55: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3

(no label) Agree

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: *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**	Yes

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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**

(no label)	Agree
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)	Agree
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:**

The lifespan of trees and the likelihood that such LMOs may be released in unmanaged ecosystems presents a challenge to risk assessors and risk managers when considering the monitoring requirements for these LMOs. These factors, among others related to LM trees, are the subject of ongoing discusions in the EU.

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:	*Respondent skipped this question*

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

(no label)	Agree

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:

The approach, case specific monitoring to confirm assumptions made during the risk assessment process and general monitoring to monitor for unanticipated adverse effects, is supported by the EU.

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

(no label)	Agree

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

(no label)	Agree

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:

As a risk manager the European Commission (EC) is not responsible for the environmental risk assesment (ERA) of individual LMOs, this is the remit of the European Food Safety Authority (EFSA).This exercise has thus been completed in collaboration with EFSA. Whilst no specific application was tested and no direct comparison has been made with the EFSA guidance, where there are similarities that we support, or gaps that we consider should be addressed, we have considered the usefulness and the utility of the guidance but have not commented on the practicality.

Some Member States have conducted a more detailed analysis using specific assessments.