# TESTING OF THE GUIDANCE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

# Latin America Training Course on Risk Assessment of LMOs, Havana, Cuba, 7-11 November 2011

OVERALL EVALUATION						
	Very poor	Poor	Neutral	Good	Very good	
Please indicate the level of agreement you attribute to ea	ch of the question	s in the left colu	ı <u>mn.</u>			
Q5. How do you evaluate the level of consistency of Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?	the			$\boxtimes$		
Q6. How do you evaluate the usefulness of the Guida as a tool to assist countries in conducting and reviewing assessments of LMOs in <u>a scientifically sound and case-case manner</u> ?	risk		$\boxtimes$			
Q7. How do you evaluate the usefulness of the Guida as a tool to assist countries in conducting and reviewing assessments of LMOs <u>introduced into various receiving environments</u> ?						
PART I: ROADMAP FOR RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS						
Please answer each of the questions in the left column with "yes" or "no" and add comments if needed.						
Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?	⊠ Yes □ No	Comments:				
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	☐ Yes ⊠ No	Comments:				
Q10. Is the Roadmap organized in a logic and structured manner?	⊠ Yes □ No	Comments:				
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	⊠ Yes □ No	Comments:				
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	☐ Yes ⊠ No	Comments:				
Q13. Is the Roadmap applicable to all types of introductions into the environment (e.g. small- and large-scale releases, placing on the market/commercialisation)?	⊠ Yes □ No	Comments:				
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	☐ Yes ⊠ No	Comments: N	Vo en este mor	iento.		

Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?

□ Yes □ No

Comments: Más o menos.

OVERALL EVALUATION						
		ery oor	Poor	Neutral	Good	Very good
Please indicate the level of agreement you attribute to each of the questions in the left column.						
Q5. How do you evaluate the level of consistency of Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?	the				$\boxtimes$	
Q6. How do you evaluate the usefulness of the Guida as a tool to assist countries in conducting and reviewing assessments of LMOs in <u>a scientifically sound and case-case manner</u> ?	risk _				$\boxtimes$	
Q7. How do you evaluate the usefulness of the Guida as a tool to assist countries in conducting and reviewing assessments of LMOs <u>introduced into various receiving environments</u> ?				$\boxtimes$		
PART I: ROADMAP FOR RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS						
Please answer each of the questions in the left column w	ith "yes" or "	no" ar	nd add comme	nts if needed.		
Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?	☐ Yes ⊠ No		Comments: H científica.	Es necesário una	a rigorosa rev	isíon
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	⊠ Yes □ No			Para países con alguna forma.	poca experier	icia podría
Q10. Is the Roadmap organized in a logic and structured manner?	☐ Yes ⊠ No			lay que reducir ijemplos. Es neo		
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	☐ Yes ⊠ No		Comments:			
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	☐ Yes ⊠ No		Comments: I	El texto no conte	empla novas t	ecnologías.
Q13. Is the Roadmap applicable to all types of introductions into the environment (e.g. small- and large-scale releases, placing on the market/commercialisation)?	☐ Yes ⊠ No			No, pero existe i leda impossible		
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	⊠ Yes □ No		Comments: S microRNA.	5í, nuevos avano	cos como vac	unas,

Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?

□ Yes ⊠ No

Comments: El flujo es diseñado para el texto.

#### ADDITIONAL COMMENTS

Please add any additional comment you may have regarding the "Guidance on Risk Assessment of Living Modified Organisms" below.

Q31. 1. Sugiro que se incluan términos sobre nuevos avancos como vacunas, microRNA, etc.

2. Además, hay mucho testo que puede hacer lio a las ideas principales de los par'agrafos.

3. Una mayor clarificatíon para "(near-)isogenic".

### PARTICIPANT 3

OVERALL EVALUATION					
	Very poor	Poor	Neutral	Good	Very good
Please indicate the level of agreement you attribute to each of the	e questions i	in the left col	umn.		
Q5. How do you evaluate the level of consistency of the Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?			$\boxtimes$		
Q6. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs in <u>a scientifically sound and case-by-case manner</u> ?					
Q7. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs <u>introduced into various receiving</u> <u>environments</u> ?			$\boxtimes$		

#### PART I: ROADMAP FOR RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?	⊠ Yes □ No	Comments: Pero deve ser mejorada.
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	⊠ Yes □ No	Comments:
Q10. Is the Roadmap organized in a logic and structured manner?	⊠ Yes □ No	Comments:
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	⊠ Yes □ No	Comments:

Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	☐ Yes ⊠ No	Comments:
Q13. Is the Roadmap applicable to all types of introductions into the environment (e.g. small- and large-scale releases, placing on the market/commercialisation)?	⊠ Yes □ No	Comments: Eso depende de las medidas de gestion.
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	⊠ Yes □ No	Comments: Desarollo de la interaccion con el sistema teniendo en cuenta manejo cultural y relaciones ecosistemicas.
Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?	⊠ Yes □ No	Comments:

Please add any additional comment you may have regarding the "Guidance on Risk Assessment of Living Modified Organisms" below.

Q31. 1. Para el caso de países en desarollo generalmente no contamos con una línea base, ni hemos identificado un punto final, ni tenemos una política ambiental respecto al uso de OVM. Por ende, podría la guía dar otra opcíon como puede ser.

2. Iniciar evaluaciones puntuales de acuerdo con el medio receptor.

## PARTICIPANT 4

OVERALL EVALUATION					
	Very poor	Poor	Neutral	Good	Very good
Please indicate the level of agreement you attribute to each of the	e questions	in the left colu	<u>ımn.</u>		
Q5. How do you evaluate the level of consistency of the Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?				$\boxtimes$	
Q6. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs in <u>a scientifically sound and case-by-case manner</u> ?					
Q7. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs <u>introduced into various receiving</u> <u>environments</u> ?					

#### PART I: ROADMAP FOR RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	⊠ Yes □ No	Comments:
Q10. Is the Roadmap organized in a logic and structured manner?	⊠ Yes □ No	Comments:
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	⊠ Yes □ No	Comments:
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	⊠ Yes □ No	Comments:
Q13. Is the Roadmap applicable to all types of introductions into the environment (e.g. small- and large-scale releases, placing on the market/commercialisation)?	⊠ Yes □ No	Comments:
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	☐ Yes ⊠ No	Comments:
Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?	⊠ Yes □ No	Comments:

### concordancia con el Protocolo de Cartagena.

OVERALL EVALUATION					
	Very poor	Poor	Neutral	Good	Very good
Please indicate the level of agreement you attribute to each of the	e questions i	in the left col	<u>umn.</u>		
Q5. How do you evaluate the level of consistency of the Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?					$\boxtimes$
Q6. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs in <u>a scientifically sound and case-by-case manner</u> ?				$\boxtimes$	
Q7. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs introduced into various receiving environments?				$\boxtimes$	

Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?	⊠ Yes □ No	Comments:
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	⊠ Yes □ No	Comments:
Q10. Is the Roadmap organized in a logic and structured manner?	⊠ Yes □ No	Comments:
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	⊠ Yes □ No	Comments:
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	⊠ Yes □ No	Comments:
Q13. Is the Roadmap applicable to all types of introductions into the environment (e.g. small- and large-scale releases, placing on the market/commercialisation)?	⊠ Yes □ No	Comments:
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	☐ Yes ⊠ No	Comments:
Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?	⊠ Yes □ No	Comments:

# Please answer each of the questions in the left column with "yes" or "no" and add comments if needed.

OVERALL EVALUATION					
	Very poor	Poor	Neutral	Good	Very good
Please indicate the level of agreement you attribute to each of the questions in the left column.					
Q5. How do you evaluate the level of consistency of the Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?					$\boxtimes$
Q6. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs in <u>a scientifically sound and case-by-case manner</u> ?					

Q7. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs <u>introduced into various receiving</u> <u>environments</u>?

#### PART I: ROADMAP FOR RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

 $\boxtimes$ 

Please answer each of the questions in the left column with "yes" or "no" and add comments if needed.

Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?	⊠ Yes □ No	Comments:
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	☐ Yes ⊠ No	Comments:
Q10. Is the Roadmap organized in a logic and structured manner?	⊠ Yes □ No	Comments:
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	⊠ Yes □ No	Comments:
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	⊠ Yes □ No	Comments:
Q13. Is the Roadmap applicable to all types of introductions into the environment (e.g. small- and large-scale releases, placing on the market/commercialisation)?	⊠ Yes □ No	Comments:
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	☐ Yes ⊠ No	Comments:
Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?	⊠ Yes □ No	Comments:

#### ADDITIONAL COMMENTS

Please add any additional comment you may have regarding the "Guidance on Risk Assessment of Living Modified Organisms" below.

Q31. Era necesario tener más tiempo para revisar más tranquilamente esta guía. Además hubiera sido adecuado poder revisar la parte 2 y parte 3.

OVERALL EVALUATION					
	Very poor	Poor	Neutral	Good	Very good
Please indicate the level of agreement you attribute to each of th	e questions i	n the left col	umn.		
Q5. How do you evaluate the level of consistency of the Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?					$\boxtimes$
Q6. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs in <u>a scientifically sound and case-by-case manner</u> ?					
Q7. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs <u>introduced into various receiving</u> <u>environments</u> ?					
PART I: ROADMAP FOR RISK ASSESSM	IENT OF L	IVING MOI	DIFIFD ORCA	NISMS	

#### SK ASSESSMENT OF 121/12

Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?	⊠ Yes □ No	Comments:
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	⊠ Yes □ No	Comments:
Q10. Is the Roadmap organized in a logic and structured manner?	⊠ Yes □ No	Comments:
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	⊠ Yes □ No	Comments:
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	⊠ Yes □ No	Comments:
Q13. Is the Roadmap applicable to all types of introductions into the environment (e.g. small- and large-scale releases, placing on the market/commercialisation)?	⊠ Yes □ No	Comments:
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	☐ Yes ⊠ No	Comments:
Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?	☐ Yes ⊠ No	Comments: El diagrama de flujo no explica claramente como proceder. Por ejemplo, debe ser un diseño vertical donde los "overarching issues" abarque o se entienda que se deben tener en cuenta en todo el proceso de evaluación de riesgo.

Please add any additional comment you may have regarding the "Guidance on Risk Assessment of Living Modified Organisms" below.

Q31. La guía ha sido muy útil porque explica mejor la práctica como proceder en el anexo 3 del Protocolo, te enfoca como empezar, que aspectos se deben tener en cuenta siempre y como concluir la evaluación de riesgo.

OVERALL EVALUATION						
		Very poor	Poor	Neutral	Good	Very good
Please indicate the level of agreement you attribute to ea	ach of the q	uestions	in the left colu	<u>mn.</u>		
Q5. How do you evaluate the level of consistency of Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?	f the					$\boxtimes$
Q6. How do you evaluate the usefulness of the Guid as a tool to assist countries in conducting and reviewing assessments of LMOs in <u>a scientifically sound and case-case manner</u> ?	; risk				$\boxtimes$	
Q7. How do you evaluate the usefulness of the Guid as a tool to assist countries in conducting and reviewing assessments of LMOs <u>introduced into various receiving</u> <u>environments</u> ?	; risk					
PART I: ROADMAP FOR RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS						
Please answer each of the questions in the left column w	vith "yes" of	r "no" a	nd add commer	nts if needed.		
Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?	⊠ Yes □ No		Comments:			
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	⊠ Yes □ No		Comments:			
Q10. Is the Roadmap organized in a logic and structured manner?	⊠ Yes □ No		Comments:			
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	⊠ Yes □ No		Comments:			
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	⊠ Yes □ No		Comments:			
Q13. Is the Roadmap applicable to all types of introductions into the environment (e.g. small- and large-scale releases, placing on the market/commercialisation)?	⊠ Yes □ No		Comments:			

Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	☐ Yes ⊠ No	Comments:
Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?	⊠ Yes □ No	Comments:

Please add any additional comment you may have regarding the "Guidance on Risk Assessment of Living Modified Organisms" below.

Q31. 1. Sobre las incertitumbres propongo diferenciar las asociadas a la información y las correspondientes a la variabilidad del sistema experimental.

2. Acerca del monitoreo, considero que se debe distinguir el monitoreo sobre: el OVM, especies no blanco y otros efectos adversos sobre el ecosistema.

3. En spectos relacionados con la toma de decisiones, se propone adicionar el análises de costos y beneficios.

4. Sobre la selección de comparadores, proponemos esclarecer cuales se consideran casi-isogénicos, los usos de los comparadores en general y proponer comparadores para los "stacks" obtenidos por cruzamiento de parentales que son OVMs.

OVERALL EVALUATION					
	Very poor	Poor	Neutral	Good	Very good
Please indicate the level of agreement you attribute to eac	h of the questions	in the left col	umn.		
Q5. How do you evaluate the level of consistency of the Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?	ne				$\boxtimes$
Q6. How do you evaluate the usefulness of the Guidar as a tool to assist countries in conducting and reviewing ri assessments of LMOs in <u>a scientifically sound and case-b</u> <u>case manner</u> ?	isk			$\boxtimes$	
Q7. How do you evaluate the usefulness of the Guidar as a tool to assist countries in conducting and reviewing re assessments of LMOs <u>introduced into various receiving</u> <u>environments</u> ?				$\boxtimes$	
PART I: ROADMAP FOR RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS					
Please answer each of the questions in the left column with "yes" or "no" and add comments if needed.					
Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?	⊠ Yes □ No	Comments:			
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	☐ Yes ⊠ No	Comments: 1 riesgos de O	Requiere experi VM.	encia en eval	uación de

Q10. Is the Roadmap organized in a logic and structured manner?	⊠ Yes □ No	Comments:
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	⊠ Yes □ No	Comments:
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	☐ Yes ⊠ No	Comments: Faltan ejemplos para microorganismos.
Q13. Is the Roadmap applicable to all types of introductions into the environment (e.g. small- and large-scale releases, placing on the market/commercialisation)?	⊠ Yes □ No	Comments:
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	☐ Yes ⊠ No	Comments:
Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?	⊠ Yes □ No	Comments: Debría reestructurar su formato.

OVERALL EVALUATION					
	Very poor	Poor	Neutral	Good	Very good
Please indicate the level of agreement you attribute to each of the questions in the left column.					
Q5. How do you evaluate the level of consistency of the Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?					$\boxtimes$
Q6. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs in <u>a scientifically sound and case-by-case manner</u> ?					
Q7. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs <u>introduced into various receiving</u> <u>environments</u> ?					

### PART I: ROADMAP FOR RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?	⊠ Yes □ No	Comments:
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	☐ Yes ⊠ No	Comments:

Q10. Is the Roadmap organized in a logic and structured manner?	⊠ Yes □ No	Comments:
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	☐ Yes ⊠ No	Comments:
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	⊠ Yes □ No	Comments:
Q13. Is the Roadmap applicable to all types of introductions into the environment (e.g. small- and large-scale releases, placing on the market/commercialisation)?	⊠ Yes □ No	Comments:
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	☐ Yes ⊠ No	Comments:
Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?	⊠ Yes □ No	Comments:

OVERALL EVALUATION					
	Very poor	Poor	Neutral	Good	Very good
Please indicate the level of agreement you attribute to ea	ch of the question	ns in the left col	<u>umn.</u>		
Q5. How do you evaluate the level of consistency of Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?	the			$\boxtimes$	
Q6. How do you evaluate the usefulness of the Guida as a tool to assist countries in conducting and reviewing assessments of LMOs in <u>a scientifically sound and case-case manner</u> ?	risk			$\boxtimes$	
Q7. How do you evaluate the usefulness of the Guida as a tool to assist countries in conducting and reviewing assessments of LMOs introduced into various receiving environments?					
PART I: ROADMAP FOR RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS					
Please answer each of the questions in the left column w	Please answer each of the questions in the left column with "yes" or "no" and add comments if needed.				
Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?	⊠ Yes □ No	Comments:			
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	☐ Yes ⊠ No	Comments: amplia para	Creo que hay qu aplicarlo.	ie tener exper	iencia

🛛 No

Q10. Is the Roadmap organized in a logic and structured manner?	⊠ Yes □ No	Comments:
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	⊠ Yes □ No	Comments: Queda muy claro que es complejo.
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	⊠ Yes □ No	Comments: Logicamente algunos casos son más complejos pero es válido.
Q13. Is the Roadmap applicable to all types of introductions into the environment (e.g. small- and large-scale releases, placing on the market/commercialisation)?	⊠ Yes □ No	Comments:
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	☐ Yes ⊠ No	Comments:
Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?	⊠ Yes □ No	Comments: Falta esclarecer algunos conceptos como monitoreo y incertidumbre.

Please add any additional comment you may have regarding the "Guidance on Risk Assessment of Living Modified Organisms" below.

Q31. Creo que para el análisis no existe ninguna receta "muy buena". Es un proceso demasiado complejo.

OVERALL EVALUATION					
	Very poor	Poor	Neutral	Good	Very good
Please indicate the level of agreement you attribute to each of the	e questions i	n the left col	umn.		
Q5. How do you evaluate the level of consistency of the Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?				$\boxtimes$	
Q6. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs in <u>a scientifically sound and case-by-case manner</u> ?			$\boxtimes$		
Q7. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs <u>introduced into various receiving environments</u> ?					

Please answer each of the questions in the left column with "yes" or "no" and add comments if needed.

Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?	☐ Yes ⊠ No	Comments: El Protocolo de Cartagena Anexo 3 8f es claro y refiere que la incertidumbre es algo transversal y est'a presente en todas las etapas y no se discuten este tema.
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	☐ Yes ⊠ No	Comments: Esta diseñado para personas con experiencia.
Q10. Is the Roadmap organized in a logic and structured manner?	⊠ Yes □ No	Comments: Mejorar su construcción.
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	☐ Yes ⊠ No	Comments: Los ejemplos.
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	☐ Yes ⊠ No	Comments: Microorganismos no estan muy claro.
Q13. Is the Roadmap applicable to all types of introductions into the environment (e.g. small- and large-scale releases, placing on the market/commercialisation)?	⊠ Yes □ No	Comments:
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	Yes No	Comments: Separar decisiones con evaluación de riesgo.
Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?	☐ Yes ⊠ No	Comments: Hay que separar toma de decisiones y la evaluación de riesgo. Estructurarlo más claro.

OVERALL EVALUATION					
	Very poor	Poor	Neutral	Good	Very good
Please indicate the level of agreement you attribute to each of the questions in the left column.					
Q5. How do you evaluate the level of consistency of the Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?				$\boxtimes$	
Q6. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs in <u>a scientifically sound and case-by-case manner</u> ?				$\boxtimes$	

Q7. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs <u>introduced into various receiving</u> <u>environments</u>?

### PART I: ROADMAP FOR RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

 $\boxtimes$ 

Please answer each of the questions in the left column with "yes" or "no" and add comments if needed.

Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?	⊠ Yes □ No	Comments: Sin embargo, hay algunas ideias que deben ser enriquecidas.
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	⊠ Yes □ No	Comments: En algunos casos suelen ser un poco complicada en cuanto a interpretación.
Q10. Is the Roadmap organized in a logic and structured manner?	⊠ Yes □ No	Comments: Me parece que debe ser revisada y mejorada.
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	⊠ Yes □ No	Comments: Sí, pero se necesitan esclarecer algunas ideias.
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	☐ Yes ⊠ No	Comments: Me parece que el enfoque se ha quedado un poco corto.
Q13. Is the Roadmap applicable to all types of introductions into the environment (e.g. small- and large-scale releases, placing on the market/commercialisation)?	☐ Yes ⊠ No	Comments: Aplica el comentario anterior.
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	⊠ Yes □ No	Comments: Hay que enriquecer y adicionar algunas definiciones.
Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?	⊠ Yes □ No	Comments: Me parece que es una muy buena herramienta.

OVERALL EVALUATION					
	Very poor	Poor	Neutral	Good	Very good
Please indicate the level of agreement you attribute to each of t	the questions i	in the left col	umn.		
Q5. How do you evaluate the level of consistency of the Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?				$\boxtimes$	

Q6. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs in <u>a scientifically sound and case-by-case manner</u> ?		$\boxtimes$	
Q7. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs <u>introduced into various receiving environments</u> ?		$\boxtimes$	

Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?	⊠ Yes □ No	Comments:
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	☐ Yes ⊠ No	Comments:
Q10. Is the Roadmap organized in a logic and structured manner?	⊠ Yes □ No	Comments:
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	☐ Yes ⊠ No	Comments:
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	⊠ Yes □ No	Comments:
Q13. Is the Roadmap applicable to all types of introductions into the environment (e.g. small- and large-scale releases, placing on the market/commercialisation)?	⊠ Yes □ No	Comments:
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	☐ Yes ⊠ No	Comments: Valdría la pena incluir de alguna manera la nesecidad de conocer aspectos relativos a agricultura tradicional. Estos aspectos son importantes an centros de origen. Además definir centros de origen y centros de diversidad.
Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?	□ Yes ⊠ No	Comments: Es necesario mostrar que los aspectos relevantes ("overarching issues") son transversales a todas las demás etapas del proceso.

OVERALL EVALUATION					
	Very poor	Poor	Neutral	Good	Very good
Please indicate the level of agreement you attribute to each	ch of the questior	ns in the left col	<u>umn.</u>		
Q5. How do you evaluate the level of consistency of t Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?	he				
Q6. How do you evaluate the usefulness of the Guida as a tool to assist countries in conducting and reviewing r assessments of LMOs in <u>a scientifically sound and case-to case manner</u> ?	isk 🔄				
Q7. How do you evaluate the usefulness of the Guida as a tool to assist countries in conducting and reviewing r assessments of LMOs <u>introduced into various receiving</u> <u>environments</u> ?					
PART I: ROADMAP FOR RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS					
Please answer each of the questions in the left column with "yes" or "no" and add comments if needed.					
Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?	⊠ Yes □ No	Comments:			
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	⊠ Yes □ No	Comments:			
Q10. Is the Roadmap organized in a logic and structured manner?	⊠ Yes □ No	Comments: I información	Pero le falta tod técnica.	avia organiza	ción y
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	⊠ Yes □ No	Comments:			
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	⊠ Yes □ No	Comments:			

Q13. Is the Roadmap applicable to all types of Xes Yes introductions into the environment (e.g. small- and Comments: large-scale releases, placing on the 🗌 No market/commercialisation)? 🛛 Yes Q14. Is there any other issue or concept that you would like to see included in the Roadmap? Comments: 🗌 No Q15. Does the flowchart provide a useful graphic Yes representation of the risk assessment process as Comments: Le falta mucho simplificarlo. 🛛 No described in the Roadmap?

Please add any additional comment you may have regarding the "Guidance on Risk Assessment of Living Modified Organisms" below.

Q31. Q6 & Q7. It still needs organization.

Q10. Is the Roadmap organized in a logic and

structured manner?

1. En el "Use of terms" poner una referencia describindo bien lo que es el "centro de origen" para evitar confusiones, especialmente en el contexto nacional.

2. Al momento de elaborar las traducciones, importante un buen editor técnico. Por ejemplo, las traducciones al español de "analysis", "evaluation" (evaluación??), assessment (evaluación??), "monitoring" (monitoreo? vigilancia??).

3. Tratar de colocar los ejemplos al pie de página, ya que se est'an incluídos dentro de todo el texto, distraen de la idea principal.

4. En la medida que sea possible, involucrar los expertos que enriquezcan las revisiones y el documento.

#### **PARTICIPANT 16**

OVERALL EVALUATION						
		Very poor	Poor	Neutral	Good	Very good
Please indicate the level of agreement you attribute to ea	ch of the qu	estions	in the left colu	<u>ımn.</u>		
Q5. How do you evaluate the level of consistency of Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?	the		$\boxtimes$			
Q6. How do you evaluate the usefulness of the Guida as a tool to assist countries in conducting and reviewing assessments of LMOs in <u>a scientifically sound and case-case manner</u> ?	risk			$\boxtimes$		
Q7. How do you evaluate the usefulness of the Guida as a tool to assist countries in conducting and reviewing assessments of LMOs <u>introduced into various receiving environments</u> ?						
PART I: ROADMAP FOR RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS						
Please answer each of the questions in the left column with "yes" or "no" and add comments if needed.						
Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?	☐ Yes ⊠ No	Comments: El Protocolo de Cartagena Anexo 3 pa 8f es claro la incertidumbre es "transversal" y no s discute ese tema. Se esto no se resuelvexxxxxx		ıl" y no se		
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	☐ Yes ⊠ No	Comments: Requiere de conoscimineto y "experiencia" para adivinar lo que se pretende a paso; demasiadas palabras para decir un tema.				
010 Is the Roadman organized in a logic and	🛛 Yes			Mejor consisten s ejemplos dist		vo de la

🗌 No

evaluación de riesgo. Llevar a pie de página los

b) Fondo: Evitar términos juridicos, o de acuerdo

ejemplos; revisar las definiciones de otras organizaciones e el flujo de la estructura.

entre decisión y evaluación de riesgo; Evitar direccionar en una o otra posición. Q11. Is the Roadmap user-friendly taking into Yes account that risk assessment is a complex scientific Comments: Los ejemplos. 🛛 No and multidisciplinary activity? Comments: Esta centrado en temas de "Bt" y "RR", Yes Q12. Is the Roadmap applicable to all types of la tecnologia avanza y nos enfrena a nuevos eventos LMOs (e.g. plants, animals, microorganisms)? 🛛 No como el frijol de Brasil. Q13. Is the Roadmap applicable to all types of Yes Yes introductions into the environment (e.g. small- and Comments: No considera aspectos de simplificación large-scale releases, placing on the cuando el OVM está en etapa experimental. 🗌 No market/commercialisation)? X Yes Q14. Is there any other issue or concept that you Comments: Diferenciar cuando termina la ER y la would like to see included in the Roadmap? Decisión empieza y clarificar el flujo. 🗌 No Q15. Does the flowchart provide a useful graphic Yes Comments: Establece las etapas; si mejora la representation of the risk assessment process as interpretación Q14 podria ser positiva. 🛛 No described in the Roadmap?

que restan; objetividad y realizar una separación

#### ADDITIONAL COMMENTS

Please add any additional comment you may have regarding the "Guidance on Risk Assessment of Living Modified Organisms" below.

Q31. 1. El objetivo de esta guía es exclusivamente de evaluación de riesgo cuando se discute o agrega en español el análisis de riesgo es el contexto de la decisión y el AHTEG debe realizar el esfuerzo científico para separar.

2. Una vez separado ER de Decisión se deberá clarificar esta etapa.

3. Revisar los titulos y el editor científico sea objetivo.

4. Considerar la experiencia de monitoreo de Brazil y Mexico.

OVERALL EVALUATION					
	Very poor	Poor	Neutral	Good	Very good
Please indicate the level of agreement you attribute to each of the questions in the left column.					
Q5. How do you evaluate the level of consistency of the Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?				$\boxtimes$	
Q6. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs in <u>a scientifically sound and case-by-case manner</u> ?					
Q7. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs <u>introduced into various receiving</u> <u>environments</u> ?					

Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?	⊠ Yes □ No	Comments:
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	⊠ Yes □ No	Comments:
Q10. Is the Roadmap organized in a logic and structured manner?	⊠ Yes □ No	Comments:
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	⊠ Yes □ No	Comments:
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	⊠ Yes □ No	Comments:
Q13. Is the Roadmap applicable to all types of introductions into the environment (e.g. small- and large-scale releases, placing on the market/commercialisation)?	⊠ Yes □ No	Comments:
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	⊠ Yes □ No	Comments: Estoy de acuerdo de incluir lo discutido en el taller; gen producto ampliado.
Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?	☐ Yes ⊠ No	Comments: Se podria hacer visual el flujo y tambien separando la evaluación de riesgo de la toma de decisiones.

Please answer each of the questions in the left column with "yes" or "no" and add comments if needed.

# ADDITIONAL COMMENTS

Please add any additional comment you may have regarding the "Guidance on Risk Assessment of Living Modified Organisms" below.

Q31. La importancia para nuestros países de definir centro de origen.

-----