



Annex

QUESTIONNAIRE FOR THE TESTING OF THE GUIDANCE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

GENERAL INFORMATION ABOUT THE TESTING	
Q1. These results are being submitted on behalf of a:	Party. Country: Cuba
Q2. When was the testing of the Guidance conducted?	November 25th, 2011
Q3. Type of event where the testing of the Guidance was conducted:	Group event: Meeting of experts on Risk assessment. Organizer: Dr. Leticia Pastor Chirino. Authorization Department of the National Center for Biosafety. Type of meeting: Face to face
Q4. Which sections of the Guidance were tested?	Part I: The Roadmap for assessment of LMOs. (7 experts)
	Part II: Specific types of LMOs or Traits: Risk Assessment of LMOs with staked genes or traits. (4 experts) Risk assessment of LM crops with tolerance to abiotic stress. (4) Risk assessment of LM mosquitoes.(3 experts)

OVERALL EVALUATION					
	Very poor	Poor	Neutral	Good	Very good
Q5. How do you evaluate the level of the Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?				2	5
Q6. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessment of LMOs in a scientifically sound and case by case manner?				4	3
Q7. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessment of LMOs introduced into various receiving environments?				3	4



PART I: ROADMAP FOR RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS				
	YES		NO	
	No. Experts	%	No. Experts	%
Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?	7	100%	0	0%
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	5	72%	2	28%
Q10. Is the Roadmap organized in a logic and structured manner?	7	100%	0	0%
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	7	100%	0	0%
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	5	72%	2	28%
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)?	7	100%	0	0%
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	0	0%	7	100%
Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?	5	72%	2	28%



PART II: SPECIFIC TYPES OF LIVING MODIFIED ORGANISMS OR TRAITS

Risk assessment of living modified organisms with stacked genes or traits

	YES		NO	
	No. Experts	%	No. Experts	%
Q16. Does this section provide useful guidance when conducting risk assessments of LMOs with stacked genes or traits in accordance with the Protocol?	4	100%	0	100%
Q17. Is this section of the Guidance useful to risk assessors who have limited experience with risk assessments of LMOs with stacked genes or traits?	1	25%	3	75%
Q18. Is this section of the Guidance organized in a logic and structured manner?	4	100%	0	100%
Q19. Is this section of the Guidance user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	4	100%	0	100%
Q20. Is there any other issue or concept that you would like to see included in this section of the Guidance?	4	100%	0	100%

Risk assessment of living modified crops with tolerance to abiotic stress

	YES		NO	
	No. Experts	%	No. Experts	%
Q21. Does this section provide useful guidance when conducting risk assessments of LM crops with tolerance to abiotic stress(es) in accordance with the Protocol?	4	100%	0	0%
Q22. Is this section of the Guidance useful to risk assessors who have limited experience with risk assessments of LM crops with tolerance to abiotic stress(es)?	1	25%	3	75%
Q23. Is this section of the Guidance organized in a logic and structured manner?	4	100%	0	0%
Q24. Is this section of the Guidance user-friendly taking into account that risk	4	100%	0	0%



assessment is a complex scientific and multidisciplinary activity?				
Q25. Is there any other issue or concept that you would like to see included in this section of the Guidance?	0	0%	4	100%
Risk assessment of living modified mosquitoes				
	YES		NO	
	No. Experts	%	No. Experts	%
Q26. Does this section provide useful guidance when conducting risk assessments of LM mosquitoes in accordance with the Protocol?	3	100%	0	0%
Q27. Is this section of the Guidance useful to risk assessors who have limited experience with risk assessments of LM mosquitoes?	0	0%	3	100%
Q28. Is this section of the Guidance organized in a logic and structured manner?	3	100%	0	0%
Q29. Is this section of the Guidance user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	3	100%	0	100%
Q30. Is there any other issue or concept that you would like to see included in this section of the Guidance?	0	100%	3	100%
ADDITIONAL COMMENTS				
<p>Q31. The guidance was studied and revised by 7 experts separately , all of them closely linked to the risk assessment of GMOs in Cuba. Once this first phase was finished, the guidance was applied to two cases study, the release of a genetically modified plant and confined trials with transgenic animals. This work was conducted by two teams and once finished, the final considerations were analyzed and discussed by the whole group (7 experts) which proposes the following suggestions to be addressed:</p> <ol style="list-style-type: none"> 1. In the Overarching Issues Section, regarding the identification and consideration of uncertainties, it is proposed to distinguish the uncertainties associated to the information, from those derived from the experimental systems. 2. In Related issues we propose to include the cost-benefit analysis. 				



3. We think that the importance of the selection of comparators should be addressed largely.
4. The "(near-)isogenic" term should be defined.
5. The experts suggested to include the analysis of individual risks for each adverse effect identified, prior to the overall estimate of risk.
6. In step 1, specifically at the points to consider about adverse effects, we proposed to be more specific about the potential effects on human health (toxicity and allergenicity).
7. In the same step, it is important to consider agricultural practices used in the trial, type of irrigation, number and doses of herbicide applications and the used method for harvesting and waste disposal.
8. From line 334 to 343, in the Receiving Environment topic, it is necessary to incorporate the aspects exposed in the example to facilitate the work of assessor (paragraph 20 at the end of the page).
9. In step 3, points to consider, subsection a) (i) and (ii), add soil microorganisms.
10. The roadmap is applicable to all LMOs in general, but very enclosed to plants and does not reflect the specifications of other cases.
11. It is suggested the use of examples that are not circumscribed only to plants but also to microorganisms and animals.
12. Previous experiences are required for the understanding and use of the guidance.
13. In the Roadmap, specifically into the strategies of risk management, the monitoring plans should be expressly mentioned.
14. The guidance on risk assessment of genetically modified mosquitoes should be a little more illustrative due to the complexity of the case and the uncertainties related to the topic.