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. Please specify: <Country's name> ☐ Other Government. Please specify: <Country's name> ☒ Organization: Please specify: Haut Conseil des biotechnologies
Q2. When was the testing of the Guidance conducted?	Please enter date: November 2011
Q3. Type of event where the testing of the Guidance was conducted?	☒ Group event (e.g., workshop, training course, meeting). Please provide the title of the event and name of organizer: Examen par le Comité scientifique du Haut Conseil des biotechnologies Type of meeting: ☐ Face-to-face ☒ Online ☐ Individual exercise. Please provide your name, occupation and affiliation: <Type here> ☐ Other: Please specify: <Type here>
Q4. Which sections of the Guidance were tested?	☒ Part I: The Roadmap for Risk assessment of LMOs Part II: Specific types of LMOs or Traits: ☒ Risk assessment of LMOs with stacked genes or traits ☒ Risk assessment of LM crops with tolerance to abiotic stress ☒ Risk assessment of LM mosquitoes

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.

	Very poor	Poor	Neutral	Good	Very good
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?	☐	☐	☒	☐	☐
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 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: Le texte a toutefois été jugé trop général dans l'ensemble. Points critiques soulevés par le CS du HCB: - Les exigences en termes d'analyses statistiques devraient être plus développées. - Il devrait être clarifié que les résultats bruts doivent pouvoir être obtenus sur demande s'ils ne sont pas inclus dans le dossier. - Problèmes éventuels liés aux pays non signataires du P de C (ex: obtention de données supplémentaires d'une société d'un pays non signataire? obtention de méthodes de détection / identification de LMO importé d'un pays non signataire?) à clarifier. - Définir "ecological function" (p. 6 l. 207). - La question des méthodes de détection/identification des LMOs devrait être développée.
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	☒ Yes ☐ No	Comments: Les commentaires exposés à la question précédente sont également valables ici. Définir "Party involved" (l. 187 et suivantes)
Q10. Is the Roadmap organized in a logic and structured manner?	☒ Yes ☐ No	Comments: <Type here>
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	☒ Yes ☐ No	Comments: <Type here>
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	☒ Yes ☐ No	Comments: <Type here>
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: Lacunes identifiées par le CS du HCB: - le cas des essais expérimentaux n'est pas abordé - la surveillance des points d'entrée et voies de transports lors d'introduction de LMO pour transformation et alimentation n'est pas développée - les cas particuliers de LMO destinés à des usages industriels spécifiques, des utilisations pharmaceutiques ou de la phytorémédiation, ne sont pas discutés.
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	☒ Yes ☐ No	Comments: Lacunes identifiées par le CS du HCB: les plans de surveillance post-commercialisation

| Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap? | ☒ Yes
☐ No | Comments: <Type here> |

PART II: SPECIFIC TYPES OF LIVING MODIFIED ORGANISMS OR TRAITS

Risk assessment of living modified organisms with stacked genes or traits

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

Q16. Does this section provide useful guidance when conducting risk assessments of LMOs with stacked genes or traits in accordance with the Protocol?	☒ Yes ☐ No	Comments: <Type here>
Q17. Is this section of the Guidance useful to risk assessors who have limited experience with risk assessments of LMOs with stacked genes of traits?	☒ Yes ☐ No	Comments: <Type here>
Q18. Is this section of the Guidance organized in a logic and structured manner?	☒ Yes ☐ No	Comments: <Type here>
Q19. Is this section of the Guidance user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	☒ Yes ☐ No	Comments: <Type here>
Q20. Is there any other issue or concept that you would like to see included in this section of the Guidance?	☐ Yes ☒ No	Comments: <Type here>

Risk assessment of living modified crops with tolerance to abiotic stress

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

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?	☒ Yes ☐ No	Comments: <Type here>
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)?	☒ Yes ☐ No	Comments: Il aurait toutefois été judicieux de ne pas limiter tous les exemples de stress abiotique à la tolérance à la sécheresse et à la salinité.
Q23. Is this section of the Guidance organized in a logic and structured manner?	☒ Yes ☐ No	Comments: <Type here>
Q24. Is this section of the Guidance user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	☒ Yes ☐ No	Comments: <Type here>
Q25. Is there any other issue or concept that you would like to see included in this section of the Guidance?	☐ Yes ☒ No	Comments:

Risk assessment of living modified mosquitoes

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

Q26. Does this section provide useful guidance when conducting risk assessments of LM mosquitoes in accordance with the Protocol?	☒ Yes ☐ No	Comments: Le terme de moustiques est vague. Culicidae serait plus approprié.
Q27. Is this section of the Guidance useful to risk assessors who have limited experience with risk assessments of LM mosquitoes?	☒ Yes ☐ No	Comments: Les Culicidae se nourrissent de nectar mais leur impact sur la pollinisation devrait être décrit avec plus de précision.
Q28. Is this section of the Guidance organized in a logic and structured manner?	☒ Yes ☐ No	Comments: Il est toutefois important de souligner le risque majeur de résistance aux insecticides dans la première partie du texte. Ce point n'est décrit que brièvement à la fin du paragraphe. Même remarque concernant le risque de dissémination par rapport au contexte environnemental (tout endroit où l'eau stagne suffisamment longtemps pour permettre le développement larvaire de l'insecte).
Q29. Is this section of the Guidance user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	☒ Yes ☐ No	Comments: La diversité des problèmes associés aux moustiques GM est bien décrite, mais il n'y a pas d'échelle des différents risques mentionnés. L'importance de la pollinisation devrait être mieux décrite (ex: limitée ou non).
Q30. Is there any other issue or concept that you would like to see included in this section of the Guidance?	☒ Yes ☐ No	Comments: L'importance de l'habitat dans la capacité des moustiques de se disperser et de se multiplier n'est pas suffisamment soulignée. L. 122: Dire qu'il y a peu d'études n'est pas totalement correct: plus de 200 articles ont été publiés sur la biologie des Culicidae.

ADDITIONAL COMMENTS

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

Q31.   Remarque annexe :

La question de la coexistence est mentionnée (p. 15 l. 590) comme un sujet pouvant être pris en compte dans le processus de prise de décision en plus de l'évaluation des risques. Le CS du HCB remarque que le sujet n'est pas abordé dans le Protocole.