

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: Egypt

Other Government. Please specify: <Country's name>

Organization: Please specify: <Organization's name>

Q2. When was the testing of the Guidance conducted?

Please enter date: November 6-24, 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: "Testing the guidance document on RA of GMOs, multi-stakeholder consultative exercise ". Organized by the Ad Hoc Steering Committee for the national biosafety legislation implementation (RA/RM group)

Type of meeting: Face-to-face
 Online

Individual exercise. Please provide your name, occupation and affiliation: Analysis of interventions and responses and reflecting views and experiences in the response to the questionnaire. Dr. Ossama M. El-Tayeb, Professor of Biotechnology, Cairo University, Scientific Advisor to the Egyptian Environmental Affairs Agency and National Focal Point for Biosafety.

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
<i>Please indicate the level of agreement you attribute to each of the questions in the left column.</i>					
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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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-</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

case manner?

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?

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: <Type here>

Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?

Yes
 No

Comments: <Type here>

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: the rationale for emphasis on crop plants and managed ecosystems has been explained, but is not justified with present day developments of GMOs and worries about the integrity of ecosystems. See Q31 below.

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: there is need to place specific reference to the various types of releases.

Q14. Is there any other issue or concept that you would like to see included in the Roadmap?

Yes
 No

Comments: linkage of RA to decision making and the overall goal of the Protocol and the CBD needs to be more explicit. See Q31 below

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?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Comments: RA is not a simple exercise which could be carried out with low capacity.
Q18. Is this section of the Guidance organized in a logic and structured manner?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: linkage to the overall goals of the Protocol and the CBD needs to be reflected more explicitly. See Q31 below.

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?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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)?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Comments: See Q17 above. Implications for ecosystem integrity is an essential element of RA for this class of GMOs.
Q23. Is this section of the Guidance organized in a logic and structured manner?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: See Q14, Q20, Q22 above and Q31 below.

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: <Type here>

Q27. Is this section of the Guidance useful to risk assessors who have limited experience with risk assessments of LM mosquitoes? Yes No Comments: <Type here>

Q28. Is this section of the Guidance organized in a logic and structured manner? Yes No Comments: <Type here>

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: <Type here>

Q30. 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>

ADDITIONAL COMMENTS

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

Q31. The conclusion of this national testing exercise is that the document has been significantly improved since COP-MOP-5. The following further observations were made:

- 1- It is recognized that Annex III of the protocol was a "political" compromise on a highly dynamic technical issue, reached during a dynamic period for biotechnology development, which required continuous up-dating.
- 2- Reference to the Precautionary principle in the preface is highly commended, but this is not adequately reflected in the "points to consider" as closely linked to "uncertainties". Reference to the importance of RA in the "potential receiving environment", country policies and regulations, local practices and habits related to the handling and use of GMOs are also commendable and should be an explicit cardinal principle.
- 3- While "part II" touches rightly on 2 of the non-crop plants GMOs this does not clearly anticipate further developments in biotechnologies which would bring about new elements and approaches in RA. From an environmental perspective, the rationale for emphasis on crop plants and managed ecosystems may be a practical approach but lacks in scientific validity. Reference in "Background" of part I needs to be more explicit in considering need for RA methods in response to future developments in biotechnology, hence release of new GMOs in addition to mosquitos and plants with abiotic stress traits.
- 4- The section on "choice of protection goals" is too narrow and would not accommodate the environmental protection goals of the CBD and the Protocol, where decisions are based on RA and all articles of the Protocol. . It needs to be categorically broadened to include socio-economic, public perception, religious, spiritual, ethical and other considerations which vary from community to community.
- 5- In the "choice of comparators of Part I, reference needs to be made to all articles of the Protocol and the fundamental goal which the CBD targets, including: ecological functions and services and ecological balances in both managed and un-managed ecosystem. This is now restricted to the sections on LMO mosquitos and needs to cover the entire roadmap. While reference to "additional points not explicitly mentioned in Annex III" in the section on "conducting the RA" is commendable, the rationale should include phenomena such as: gene interactions, "gene scrambling" and the possibility that gene expression and the interactions of the gene product may be influenced by

environmental factors. Step 1 needs to include ecological services and balances, and "novel characteristics" needs to include certainty, accuracy and precision of the transformation event and interaction with other genetic constituents whether expressed naturally or not: this being reflected in several elements of the "points to consider regarding characterization of the LMO". In Step 2, the rationale needs to reflect the LMO and its products which may find its way into the environment. In Step 5, the recommendations need to take into consideration socio-economic, public perception, religious, spiritual, ethical and other considerations which vary from community to community. In the same Step, reference to "benefits" analysis is unscientifically suggestive and is best modified to "cost-benefit" analysis.

6- The "points to consider" section could benefit from reference to: in situ conservation goal of the CBD, Identity preservation, countries' capabilities and priorities and alternative options.

7- In the section of Effects on the abiotic environment and ecosystem, in "Risk Assessment of Living modified plants with tolerance to abiotic stress", the last paragraph would benefit from reference to "*cost in terms of ecological services?*"

8- The section on Risk assessment of living modified mosquitoes is more elaborate, balanced and "frank". It is an example showing that when a non-"trade related" GMO is considered, a more open, less restricted, scientifically sound and more ecologically-relevant RA becomes more likely. RA should not be unduly biased by trade-interests. Here, species, habitats, ecosystem function and services etc. are more prominent (see Steps 2 and 3 of the roadmap). Fish and other aquatic GMOs are not much different from mosquitoes but received less attention because of trade considerations.
