ADDITIONAL VOLUNTARY GUIDANCE MATERIALS ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS CONTAINING ENGINEERED GENE DRIVES

DRAFT OF OUTLINE

PART A: RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS CONTAINING ENGINEERED GENE DRIVES (EGD-LMO)

1. Objective and scope of these additional voluntary guidance materials
   - Decision CP-10/10
2. Introduction
   - Annex III of Cartagena Protocol on Biosafety
   - Previous guidance under the Cartagena Protocol
   - Relevant guidance from other processes
3. Overarching issues in the risk assessment process on EGD-LMOs
   - Engineered gene drive terminology, types and general characteristics

   3.1. Protection goals, assessment endpoints and measurement endpoints
   - Descriptions of these relevant concepts

   3.2. Quality and relevance of information
   - Criteria for the quality of scientific information
   - Sources and relevance of information for the risk assessment

   3.3. Identification and consideration of uncertainty
   - Categories of uncertainty
   - Consideration and treatment of uncertainty
   - Uncertainty and the potential use and role of modelling
4. Planning phase of the risk assessment of EGD-LMOs

   4.1. Establishing the context and scope
   - Relevant considerations (e.g. legislation, guidelines, national requirements, protection goals, experience, available information)
   - Stakeholder engagement

   4.2. Problem formulation
   - Pathways to harm
   - Analysis plan

4.3. The choice of comparators

- Selection of appropriate comparators
- Alternative approaches

5. Conducting the risk assessment

- Annex III of the Cartagena Protocol on Biosafety
- Application of the Roadmap for risk assessment of living modified organisms[1]

5.1. Step 1. Identification of any novel genotypic and phenotypic characteristics associated with the EGD-LMO that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health

- Identification of plausible risk hypotheses and clear pathways to harm
- Elements for consideration of the EGD-LMO (e.g. non-modified/parental organism, characteristics of the donor organism, transformation method, molecular characteristics of the engineered gene drive, genotypic and phenotypic changes in the LMO)
- Elements for consideration for the intended use and in the receiving environment (e.g. availability of data on the receiving environment, spatial scale, duration, containment, characteristics of the receiving environment, pests of pathogen resistance)
- Elements for consideration regarding potential adverse effects resulting from the interaction between EGD-LMO and the receiving environment (e.g. characteristics of the EGD-LMO in the receiving environment, considerations for unmanaged and managed ecosystems, dispersal of EGD-LMO, potential for outcrossing, horizontal gene transfer, effects on non-target organisms, cumulative effects with other EGD-LMOs in the environment)
- Illustrative examples

5.2. Step 2. Evaluation of the likelihood of adverse effects being realised, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism

- Risk, likelihood and exposure characterization
- Elements for consideration (e.g. relevant characteristics in the receiving environment, expression in the EGD-LMO and persistence and accumulation in the environment, geographic and biogeographic information on the location of release, factors affecting spread of the EGD-LMO, likelihood of outcrossing, persistence of transgene in the environment, expected type and level of exposure)
- Illustrative examples

5.3. Step 3. Evaluation of the consequences should these adverse effects be realised

[1] Found in the Guidance on risk assessment for living modified organisms and monitoring in the context of risk assessment (UNEP/CBD/BS/COP-MOP/8/8/Add.1)

- Hazard characterization
- Evaluation of consequences
- Elements for consideration (e.g. pathways for dissemination, potential adverse effects from combinatorial or cumulative effects in the receiving environment, relevant knowledge and experience with LMOs or organisms with similar traits, results from laboratory experiments, results from field trials, potential adverse effects from outcrossing)
- Illustrative examples

5.4. Step 4. Estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realised

- Risk characterization
- Elements for consideration (e.g. individual risk and possible interactions between them, risk management, broader considerations based on ecosystems services approach)

5.5. Step 5. Recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks

- Acceptability of risks
- Monitoring
- Recommendations
- Elements for consideration related to risk management (e.g. existing management practices, methods to detect and identify EGD-LMO, management options and their feasibility, methods for evaluating proposed risk management and monitoring strategies)
- Elements for consideration related to acceptability of risks (e.g. established criteria, protection goals, assessment endpoints, relevant experience with non-modified recipient organisms, benefit analysis, ability to manage adverse effects)

6. Related issues

- Socioeconomic considerations (e.g. voluntary Guidance on the Assessment of Socio-Economic Considerations in the Context of Article 26 of the Cartagena Protocol on Biosafety)
- Issues related to Indigenous peoples and local communities
- Risks vs. benefits
- Sources and nature of uncertainty that could not be previously addressed

PART B: RISK ASSESSMENT OF LIVING MODIFIED ANOPHELES CONTAINING AN ENGINEERED GENE DRIVE FOR MALARIA CONTROL

7. Introduction

- Case study of an Anopheles mosquito

8. Objective and scope