Ref.: SCBD/SPS/DC/MPM/MW/86376 12 April 2017

**N O T I F I C A T I O N**

**Submission of information requested in decision VIII/12   
on Risk Assessment and Risk Management**

Dear Madam/Sir,

In its decision VIII/12, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP) invited interested Parties, other Governments and relevant organizations to take the Guidance on Risk Assessment of Living Modified Organisms into account as a voluntary tool to assist in conducting risk assessment in accordance with the Cartagena Protocol while acknowledging that other guidance documents and national approaches can also assist in conducting risk assessment in accordance with the Protocol.

In the same decision, COP-MOP invited Parties to submit to the Executive Secretary:

(a) Information on their needs and priorities for further guidance on specific topics of risk assessment of living modified organisms;

(b) Proposals on criteria, including the technical justification, that may facilitate the selection of topics for the development of further guidance; and

(c) Views on perceived gaps in existing guidance materials.

COP-MOP requested the Executive Secretary to compile and submit the views submitted by Parties for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA).

Furthermore, COP-MOP requested SBSTTA to review the information provided and to recommend a way forward to address the needs, priorities and gaps identified by Parties for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its ninth meeting, including the possible establishment of a new ad hoc technical expert group, with the understanding that new guidance proposals should only be presented upon approval by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol.

Accordingly, I would kindly invite you to submit to the Secretariat the information referred to above as soon as possible but no later than **25 August 2017**. Late submissions will not be considered. Furthermore, Parties are kindly requested to make their submissions using the template annexed herewith. Submissions made in any other format will not be considered.

Parties may send submissions online through the Biosafety Clearing-House at <http://bch.cbd.int/managementcentre/edit/submission.shtml> or via e-mail to [secretariat@cbd.int](mailto:secretariat@cbd.int).

I appreciate your continued support towards the implementation of the Cartagena Protocol on Biosafety.

Please accept, Madam/Sir, the assurances of my highest consideration.

Cristiana Paşca Palmer, PhD

Executive Secretary

***Annex***

**FORM FOR THE SUBMISSION OF INFORMATION REQUESTED IN DECISION VIII/12 ON RISK ASSESSMENT AND RISK MANAGEMENT**

A. Country information

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| **Country name:** | **France\*** |

B. Please indicate your country’s needs and priorities for further guidance on specific topics of risk assessment of living modified organisms (LMOs)

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|  | **Needs and priorities for further guidance on risk assessment of LMOs** | **Notes** |
| 1 | LM fish, LMOs from sythetic biology including gene drive. | As previously submitted, these needs are related to the current development of new techniques likely to generate LMOs whose genomes differ substantially from those in existing organisms, such as LMOs with novel genes from multiple sources.  In particular, the detection and assessment of unintended off-target changes at the DNA level needs to be further examined, taking into account the specificity of the new techniques and their combinations.  The accessibility to synthetic biology techniques shall be further considered in the guidance, to avoid transboundary movements of LMOs that would not have been subject to an effective assessment.  The increasing use of mechanisms called “gene drives” to modify traits that are intended to be passed on to entire populations give rise to a need for adapted methodologies in order to fully assess the potential effects of such LMOs. |
| 2 | LMOs impact on the state and dynamics of biodiversity in interaction with agriculture | Current information is insufficient for assessing LMOs impact on the state and dynamics of biodiversity in interaction with agriculture (e.g. farmland birds…). There is a need to develop guidance on how to deal with incomplete data from monitoring, and how to draw lessons from the observations currently available, for example by the mean of modeling or developing experiments in mesocosms. |
| 3 | Impacts of acceleration and accumulation | According to the "red queen hypothesis" (Leigh Van Valen) regarding the principle of co-evolution of the species and their environment, an accelerated breeding might engender additional difficulties for biodiversity (see for example Devictor et al. 2012, Nature Climate Change). It might as well increase the difficulty to assess cumulative and delayed impacts on health. Case by case analysis should be completed by a more inclusive analysis, and better assess the possibility of pleiotropic effects due to cross-talk mechanisms. Experiments in mesocosms should be carried out. Further guidance is needed to implement such approach. |

***C. Please propose possible criteria that may facilitate the selection of topics for th***e development of further guidance on specific topics of risk assessment of LMOs, including a technical justification for each of the criterion proposed\*

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| --- | --- | --- |
|  | **Criteria for the selection of topics** | **Notes and technical justification** |
| 1 | Cf European Union submission |  |

D. Please share your views on perceived gaps in existing guidance materials

|  |  |  |
| --- | --- | --- |
|  | **Perceived gaps** | **Views** |
| 1 | Effects of LMOs on biodiversity involving micro-organisms (microbionts) | * Effects of LMOs on biodiversity should more clearly include effects through micro-organisms (microbionts, meaning all the microorganisms living in a specific environnment, or microbial community and parasitic system). * Guidance is needed to examine how LMOs, as holobionts (microbiont and its host), will interact with and impact on other holobionts (see Beckers et al., PNAs, 2016) : plants, predators, mutualists, competitors… |
| 2 | About biodiversity baseline | * Importance of developing biodiversity observation networks to get sufficient information (with decent statistical power). Develop in particular monitoring of the disregarded different EBV (essential biodiversity) classes (see Geo-Bon work). |
| 3 | Pleiotropic effects of the LMOs | * Plants tolerant to biotic stress : study the possibility of pleiotropic effects due to cross-talk mechanisms. This item is developed in the abiotic stress example but seems to be lacking in the other cases. * These are expected, especially when basic physiological mechanisms are altered. Which procedures and experimental procedures would be required to assess the unintended functional impacts of genes that differ substantially from those in existing organisms? * Mesocosms seem to offer a good possibility to examine these effects. * For these mesocosms, the spatial and temporal extents of the experiments should be examined: what size of mesocosms, which communities, types of microbionts…, for how long, several years (depending on the modified character concerned) ? |
| 4 | Consequences of the modified trait on the surrounding soils of LM trees | Trees have an important function on soil stabilization and contribute to their fertility, potentially impacting on soil ecosystem services.  Genes modifying root architecture, nutrition, root exudates, lignin content or composition, may have consequences on soils and associated microbiota. |

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