

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

According to notification Ref.: SCBD/SPS/DC/MPM/MW/86376

A. Country information

Country name:	Plurinational State of Bolivia
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B. Please indicate your country's needs and priorities for further guidance on specific topics of risk assessment of living modified organisms (LMOs)

	Needs and priorities for further guidance on risk assessment of LMOs	Notes
1	Co-existence between LMOs and non-LMOs in the context of small scale farming	A large proportion of Bolivian farming, and in many other countries from the Global South, takes place at the small scale. Consideration of small-scale farming, particularly ecological and socio-economic conditions, in a comprehensive manner will be very helpful in processes of risk assessment of LMOs.
2	Risk assessment of living modified microorganisms and viruses	LM microorganisms and viruses have already a significant trajectory of use, including environmental release. Based on that, countries urgently require guidance on risk assessment of LM microorganisms and viruses on biological diversity taking also into account human health.
3	Risk assessment of LM animals	Given the cases of approvals of environmental release of LM insects, LM salmon and others, it is urgent to countries to have access to guidance on risk assessment on LM animals.
4	Risk assessment of LMOs derived from synthetic biology	Since the new generation of LMOs involve applications of synthetic biology techniques, which are likely to lead to the development of organisms that will differ fundamentally from naturally occurring ones, with complex genetic changes and important levels of uncertainty, it is important to have available guidelines for an adequate risk assessment of them.

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

	Criteria for the selection of topics	Notes and technical justification
1	Complexity in the evaluation of possible impacts of LMOs	The more complex the LMO dynamics and possible adverse effects, the more relevant are the availability of agreed risk assessment guidelines under the Cartagena Protocol.

2	Status of approval of LMOs intended for environmental release	LMOs currently approved for environmental release require guidance on risk assessment under the framework of the Cartagena Protocol.
3	Trajectory of use	LMOs that are approved and that already have a trajectory of use, urgently require agreed guidance on risk assessment. This will contribute to improve the implementation of the Cartagena Protocol and the biosafety responsibilities of Parties.
4	Pipeline developments	Guidelines for risk assessment of LMOs in the pipeline will contribute to anticipatory capacity building and better consideration of relevant risk aspects in the process of decision-making.
5	Gaps in the current guidance	LMOs approved and in use, but for which there is no guidance on risk assessment under the Cartagena Protocol, or for which the existing Guidance on Risk Assessment of Living Modified Organisms does not adequately cover, require prioritization in the working process of Art. 15.

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

	Perceived gaps	Views
1	Consideration of human health aspects	The objective and scope of the Cartagena Protocol clearly indicate that in the process of risk assessment of LMOs on biological diversity, human health should also be taken into account. This consideration is minimal in current guidance materials.
2	Integration of socio-economic considerations	The scope of the Cartagena Protocol mentions that LMOs that may have adverse effects on the conservation and sustainable use of biodiversity are subject of the Protocol provisions. Sustainable use is closely related to socio-economic considerations. This needs to be reflected in the current guidance materials. In this line of thought, it is also important to make a special consideration to vulnerable groups, such as small-scale and family farming, indigenous people and local communities, undernourished people, groups located in marginalized and fragile ecosystems, among others.
3	Consideration of the value of biological diversity to indigenous peoples and local communities	The CBD and Art. 26 of the Cartagena Protocol emphasize the value of biological diversity to indigenous peoples and local communities (IPLCs). Potential adverse effects on the conservation and sustainable use of biological diversity taking also into account human health in relation to IPLCs, is not reflected in current guidance materials.
4	LMOs under current approval and use	LMOs under current approval and use (i.e. LM insects, LM animals, LM microorganisms and LM viruses) are not part of the current guidance materials.