Third World Network Briefing Note for CP-MOP 12 (October 2026)

Risk assessment and risk management of living modified organisms

Summary of key recommendations for the draft decision:

- Support the AHTEG recommendation to develop additional voluntary guidance materials for the proposed topics, due to the novel risks and uncertainties raised by their applications, target species and engineering tools.

- Support the conclusions of the AHTEG that the **precautionary approach is integral to the objective and scope of the Protocol** and further, that **Annex III is foundational to risk assessment**, including for related capacity building activities.

- Reject proposals for the submission of information on 'data transportability' to apply data from one region to another for risk assessments, as this would not be consistent with Annex III, which specifies the need to assess potential adverse impacts on the receiving environment.

- Reject proposals for the submission of information on experiences with the implementation of the 'simplified procedure' provided in Article 13, and of bilateral, regional and multilateral agreements and arrangements provided in Article 14. It is clear that these Articles already provide the necessary guidance, including to ensure "safe intentional transboundary movement" of LMOs "in accordance with the objective of this Protocol", and to be "consistent with the objective of this Protocol" and not result in a "lower level of protection than that provided for by the Protocol."

- Avoid specifically referring to the voluntary risk assessment guidance materials on LMOs containing engineered gene drives (*Biosafety Technical Series 07*), including in relation to capacity building, as the risk assessment approach therein is narrow and not appropriate for the proposed topics.

Introduction

The last 30 years of commercialisation of living modified organisms (LMOs) have thus far been restricted to a limited number of species and traits – a handful of commodity crop varieties carrying herbicide-tolerant, and to a lesser extent, insect-resistant traits. As such risk assessment experiences are generally limited to a narrow set of species, and traits and applications.

However, developers are broadening proposed environmental release applications to new spheres e.g. conservation, public health, 'defence', 'biomining' and/or bioremediation. Moreover, previous biosafety norms, such as not releasing LM microbes into the environment, are being eroded, and moving beyond current risk assessment experiences to date. The advancing technical ease and reduced costs of genetic engineering techniques such as genome editing, and supportive techniques within genomics and computational biology/AI, are further fuelling developments.

At the same time, LMO crops have been linked to numerous adverse impacts including increased herbicide and pesticide use, impacts on non-target organisms, crop failures linked to secondary pest infestations or insect/weed resistance, and genetic contamination including in centres of origin.

The huge range of proposals challenge current risk assessment methods. Such concerns relate to expansion into new species, traits, types of application as well as techniques deployed. The emerging

developments demand updates in regulatory oversight to stay abreast of novel risks and uncertainties, that are rooted in the precautionary approach.

Background to the risk assessment discussions

In decision CP-11/7, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP) established an Ad Hoc Technical Expert Group (AHTEG) to prepare a list of prioritized topics on which further guidance materials on risk assessment may be needed, including a rationale following the criteria set out in Annex I to decision CP-9/13. This was based on information submitted by Parties on national needs and priorities regarding the need for further risk assessment guidance on specific topics of LMOs.

The AHTEG concluded that seven topics fulfilled all the criteria set out in Annex I of decision CP-9/13 to warrant further guidance on risk assessment. Four topics were prioritised for risk assessment guidance materials[1]:

1) LM fish;
2) LM microorganisms;
3) LM algae; and
4) LMOs expressing genome editing machinery for pest or pathogen control.

Three topics were prioritised for the development of 'technical notes', as supplements to support more specific risk assessment considerations:

1) Long-term and cumulative effects of genetic constructs and LMOs;
2) Use of LMOs in centres of origin and in traditional agricultural systems; and
3) Operationalising protection goals into relevant risk assessment endpoints.

SBSTTA-27 discussions illustrated support for further guidance from many Parties, but there was a divergence of views regarding which topics to cover, how many to cover, and whether or not to develop 'technical notes' as opposed to full guidance materials for certain topics. As such, all topics remain on the table for consideration.

Cross-cutting risk considerations and challenges of new and emerging LMO applications

The four topics recommended by the AHTEG for further guidance illustrate numerous cross-cutting biosafety considerations that directly challenge existing risk assessment frameworks, guidance and methodologies. Applications are already advancing across the different topics, and in some cases already approved for release. The requests from Parties for guidance in these areas are testament to the continued need for the Cartagena Protocol to stay abreast of new developments, to ensure that releases into the environment do not undermine its objectives.

Current risk assessment experience is lacking for all four topics, with current methods and experiences largely catered to terrestrial species, and most commonly applied to annually-cultivated crop species.

[1] Other topics were considered as partially meeting the criteria. For example, the topic of genome-edited mammals was considered to meet all the criteria, except for criterion (b) on whether or not genome editing falls within the scope of the Cartagena Protocol. Due to a divergence of views on the issue, questions of scope were not discussed and thus the topic was unable to be recommended for full guidance. Similarly, the topic of LMOs produced with new biotechnologies was considered too broad to easily fulfil the criteria.

All four topics pose fundamental challenges to risk assessment. Microorganisms, including microalgae and bacteria expressing genome editing machinery, raise significant concerns regarding their high levels of spread, dispersal and persistence capabilities and the lack of ability to control, recall or monitor these. Microorganisms are known to be capable of long-distance dispersal such as through rain, wind, pollen, leaf litter, waterways, soils, and via human and animal microbiomes. This expands the potential routes and capacity for transboundary movement, which could be by natural or human-assisted dispersal.

Proposed 'safety' features such as genetic firewalls designed to control spread and persistence remain in development, unproven, and importantly, lag behind deployment. In contrast, some of the more aggressive applications are indeed explicitly designed for spread, for example LM viruses for use as self-spreading vaccines in wild populations.

For LMOs expressing genome edited machinery, there is another layer of complexity. Such products can be described as intentionally self-spreading. They encompass the release, not just of an LMO, but of one that is designed to spread genetic engineering machinery to other organisms directly in the open environment, with no apparent control over spread to non-target organisms.

Similarly, aquatic species such as fish have high levels of dispersal capacity across long distances. Such characteristics make the task of assessing impacts on all potential receiving environments, as well as controlling transboundary movements, challenging. Nonetheless, transgenic and genome edited fish are already on the market for environmental release. LM fish developed for aquarium use as pets have also been found to have been inadvertently released into the environment.

The rapid reproductive rates and evolutionary potential of microorganisms (including microalgae and those expressing genome editing machinery) also challenge the ability to predict outcomes, for example, due to evolutionary changes that change host specificity and increase spillover risks. Similar challenges apply to fish with their ability to adapt, and their sensitivity to environmental interactions. This raises significant uncertainties regarding the ability to assess unintended effects.

Another major concern spanning the four topics is the risk of gene flow. In particular, gene flow via horizontal gene transfer in microbial species including bacteria, is a central evolutionary mechanism, making the ability to control the spread of engineered traits in such species extremely difficult, if not impossible.

Finally, there are fundamental knowledge gaps on all the topics, including the lack of available baseline data on the biology of these organisms and the ecosystems they occupy, again increasing uncertainties.

The need for holistic and contextualised assessments

Two of the topics recommended are particularly urgent and should be prioritised: the "use of living modified organisms in centres of origin and in traditional agricultural systems and "long-term and cumulative effects".

The Cartagena Protocol recognizes the crucial importance to humankind of centres of origin and genetic diversity. LMOs represent direct and immediate biodiversity risks when released in their centres of origin, particularly in light of the ongoing biodiversity crisis, warranting further guidance on this issue.

Current guidance does not yet provide for contextualised risk assessments that incorporate local contexts and traditional agricultural systems where there may be high levels of biodiversity of wild relatives, traditional variety counterparts and non-target organisms. Special considerations are needed to assess the risks of gene flow in such contexts, and the potential impacts on genomic diversity and plasticity, as well as the impacts on diverse agricultural, ancestral and indigenous knowledges and practices. Informal or remote markets and seed exchanges may also challenge the ability to control gene flow, unintended spread and unauthorised uses.

Requests for further guidance on "long-term and cumulative effects" reflect ongoing concerns regarding the potential harms of LMOs to people and the environment, which may not be immediately realised. This is becoming increasingly relevant and urgent as "stacked" traits and multiple events are simultaneously entering the market, complexifying the potential adverse effects and the assessment thereof. The predominance of herbicide-tolerant varieties making up the vast majority of LM crops to date also raises immediate concerns regarding the gaps in assessment of the impacts of herbicides on the LM crop as well as on those consuming or exposed to them.

A recent study on Mexican cotton[2] illustrates clearly these gaps in risk assessment: noting high levels of genetic contamination of native cotton species, and further, evidence of recombination events, where transgenes segregate during breeding to result in the next generation carrying novel genetic configurations that were not previously evaluated during risk assessment, and segregation of stacked events. Ecological impacts were also documented. Of immediate concern is the 'self-sustaining' dynamic of contaminated individuals becoming a secondary source of unintended gene flow, including of novel combinations not approved before original release. This is an issue exclusive to centres of origin where crop-wild compatibility is complete and is further a relevant example of potential long-term and cumulative impacts.

The issues of data transportability, Articles 13 and 14

The complexities raised above highlight the importance of environmental contexts. They also expose the limitations of using 'data transportability' to apply data from one region to another so as to streamline risk assessment processes.

While data from one region can be used to inform the risk assessment in another region, the idea that the impacts on the receiving environment in one location will be similar and directly relevant in a different location, which may have different biodiversity and environmental conditions (e.g. endemic species, rare species or a unique habitat or ecosystem), lacks scientific basis.

The proposal in the draft decision for the submission of information on experiences on the transportability of data for risk assessment should therefore be rejected. Annex III of the Cartagena Protocol clearly specifies the need to assess potential adverse impacts on the receiving environment.

The draft decision also contains a proposal for the submission of information on experiences with the implementation of the simplified procedure provided in Article 13 of the Cartagena Protocol, and bilateral, regional and multilateral agreements and arrangements provided in Article 14.

Article 13 provides that Parties of import may apply a simplified procedure in two scenarios – where intentional transboundary movement may take place at the same time as the movement is notified to it, and where imports of LMOs to it may be exempted from the AIA procedure.

[2] Transgene introgression into wild cotton populations generates long-term genetic and ecological effects in a center of origin. Vázquez-Barrios, Ian A.E. Butler, Patricia Rojas, Ana Wegier, https://doi.org/10.1016/j.envpol.2026.128502

In both cases, this can only happen if the Party of import applies adequate measures "to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of this Protocol". Further, for the first case, the information provided in the notification "shall be the information specified in Annex I" – which in turn requires "a previous and existing risk assessment report consistent with Annex III".

The second case only affects proposed imports of a specific LMO to the Party of import. Transboundary movements of the same LMO to all other Parties remain subject to the Protocol's advance informed agreement procedure, which requires adherence to Annex I and Annex III. Article 13's simplified procedure should not be regarded as a procedure for simplified risk assessment.

Article 14 provides that Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of LMOs. This has to be "consistent with the objective of this Protocol and provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol." Article 14 should not be regarded as a means by which to circumvent the Protocol's risk assessment obligations.

Further guidance should be precautionary and rooted in Annex III

The risks and uncertainties associated with the topics recommended for further guidance warrant a precautionary approach, as recommended by the AHTEG. The AHTEG further recommended that any new guidance materials or technical notes need to align with Annex III of the Protocol. This recommendation is relevant to all related activities under the Protocol, including for capacity-building activities.

These factors are key in the ability to detect the full range of potential unintended effects that may arise, with aspects including, but not limited to:

1) Assessing potential impacts of any changes occurring within an LMO, arising from all intended and unintended changes.
2) Adhering to a science-based assessment that assesses *all* and not just *selective* risk hypotheses.
3) Maintaining the precautionary approach, anchored in the burden of proof resting on proponents to prove safety, rather than on others to prove harm.
4) Sufficiently addressing uncertainties and knowledge gaps to operationalise the precautionary approach.

Unfortunately, the 'pathways to harm' approach that was included in the recently developed voluntary guidance materials on LMOs containing engineered gene drives (*Biosafety Technical Series 07*) does not address the above. Crucially, it narrows the framing and scope of assessments, requires assessment of only select hypotheses, and reverses the burden of proof. It is actually a decades-old industry-devised method, that works to 'streamline and 'modernise' risk assessments.

Accordingly, further guidance materials should forward approaches that are fully rooted in, and aligned with, Annex III of the Protocol in order to operationalise a precautionary approach that is sufficiently robust to address novel risks and uncertainties raised by new topics.