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SYNTHESIS OF SUBMISSIONS BY PARTIES IN RESPONSE TO PARAGRAPH 6 OF DECISION CP-VIII/12

Note by the Executive Secretary

I. GAPS IN EXISTING GUIDANCE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

1. In their submissions, Parties identified a number of gaps in existing guidance documents, including the following:

(a) Austria noted that information is lacking on how to perform the assessment of certain LMOs when no appropriate comparators exist, or may be used for testing (e.g. pathogenic organisms, comparators which will not survive in the receiving environments) and "per se" risk assessment approaches have to be developed and implemented. Furthermore, Austria and Italy noted that even though "limits of concern" is an important element in the evaluation of the adversity of measured effects, specific "limits of concern" still need to be further elaborated for different areas of biosafety risks and measurement endpoints;

(b) Bolivia noted that human health is only marginally addressed on existing guidance on risk assessment of LMOs. It also noted that although the CBD and Article 26 of the Cartagena Protocol emphasize the value of biological diversity to indigenous peoples and local communities (IPLC), the potential adverse effects of LMOs in relation to IPLCs is not reflected in current guidance materials. In addition, Bolivia pointed out those socio-economic considerations needs to be reflected in the current guidance materials;

(c) Costa Rica and Honduras noted that existing guidance materials have been designed for experienced risk assessors, and putting them into practice is a challenge for countries without experience in risk assessment;

(d) France noted that current information is insufficient for assessing LMOs impact on the state and dynamics of biodiversity in interaction with agriculture (e.g. farmland birds) and knowledge gaps exist 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 modelling or developing experimental conditions that mimic the natural environment. France also noted the importance of developing biodiversity observation networks to obtain baseline information of sufficient quality and coverage;

(e) Italy noted that there is a need for further harmonization of terminology and its use in the different guidelines; as well as a need for updating of most of the existing guidelines;

* CBD/SBSTTA/22/1.

(f) Japan noted that there is no explanation on how scientific knowledge accumulated through previous environmental risk assessments can be efficiently used to further improve the risk assessment process;

(g) Mexico noted a lack of information, in existing guidance documents, on how to manage the risks identified during the risk assessment process. Mexico also emphasized the importance of carrying out activities for capacity development, on a regular basis, to enable regulators and risk assessors to keep pace with technological developments;

(h) South Africa noted the need for further examples on how to address uncertainty in the risk assessment of LMOs with complex traits.

II. NEEDS AND PRIORITIES FOR FURTHER GUIDANCE ON SPECIFIC TOPICS OF RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

2. Seven Parties (Brazil, Costa Rica, European Union, Honduras, Japan, Mexico and New Zealand) indicated that the existing guidance documents on specific topics of risk assessment of living modified organisms are sufficient and recommended that no new guidance should be developed for the time being. Among those submissions, New Zealand considered that these publicly available resources are more than adequate for Parties to conduct risk assessments of LMOs, and that many governmental and non-governmental bodies are available to assist Parties which require assistance. Honduras and Costa Rica recommended the sharing of experiences in actual cases of risk assessment, which were conducted in a case-by-case manner and in accordance with national risk assessment frameworks and the Guidance on Risk Assessment of Living Modified Organisms developed under the Cartagena Protocol. Furthermore, Brazil recommended that the need to develop guidance on new topics of risk assessment should be evaluated periodically, on the basis of Parties' priorities and taking into account scientific and technological progress.

3. Twelve Parties (Austria, Belarus, Bolivia, Bulgaria, Finland, France, Italy, Malaysia, Moldova, Nigeria, Norway and South Africa) recommended that new guidance should be developed on specific topics of risk assessment to provide additional assistance to the parties in addressing particular issues for which the already available guidelines may not be sufficient, in particular in relation to new developments which may pose new risk assessment challenges that may require different approaches.

4. Two priority topics were identified by to develop guidance on "risk assessment of organisms developed through synthetic biology, including organisms produced through genome editing and organisms containing engineered gene drives", and on "risk assessment of living modified fish".

5. A compilation of topics that were identified as needs and priorities by Parties is provided below.

Topic	**Proposed by**	**Notes / Justification**
Risk assessment of organisms developed through synthetic biology, including organisms produced through genome editing and organisms containing engineered gene drives	Austria, Belarus, Bolivia, Bulgaria, Finland, France, Malaysia, South Africa	The application of synthetic biology is evolving rapidly, and while existing risk assessment methodologies for LMO may be applicable, several developments pose new risk assessment challenges that may require different approaches from existing risk assessment methodologies. For example, the risk assessment of organisms that are substantially different from existing LMOs will be associated with high levels of uncertainty, and it may be difficult or impossible to find suitable comparators

		to conduct a comparative assessment. Techniques for genome editing have developed significantly and can rapidly lead to the development of new LMOs. This is further complicated by the fact that genome editing can edit the entire genome, instead of few genes at a time, and may give rise to complex new LMOs. 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 release of organisms containing engineered gene drive could rapidly change the genetic makeup of entire populations. Once released into the environment, it may be very difficult to control or remove such organisms from the environment, and they may affect biological diversity beyond national boundaries or the populations originally targeted.
Risk assessment of LM fish	Austria, Belarus, Finland, France, Italy, Moldova, Norway, South Africa	LM fish have several issues that are unique for them. Understanding possible adverse impacts of LM fish is vital because fish are highly mobile, have a long lifespan, and may affect wild populations in many ways (genetic diversity, changes in population dynamics and life cycle characteristics). New guidance should focus on the impacts of LM fish on wild species resulting from intentional release or escape into the environment, as well as on possible cumulative long-term effects, taking into account specific breeding strategies for fish that, for example, can affect the sex ratio of populations.
Risk assessment of living modified animals/mammals	Bolivia, Malaysia, Moldova, Norway	LM animals have been approved for environmental release, and it is urgent for countries to have access to guidance in order to be able to assess the risks of such releases.
Risk assessment of arthropods, including insects and molluscs.	Belarus, Malaysia, Moldova	Insects are the major player in the food chain, including pollination. And some

		can function as pest while others play the role of beneficial organisms. LM insects are expected to have significant impacts on ecosystems and food chain.
Risk assessment of living modified microorganisms and viruses	Bolivia, Malaysia, Moldova	LM microorganisms and viruses are been developed and some were already approved for environmental release. Countries urgently need guidance in order to assess the risks posed by such organisms on biodiversity and human health.
Co-existence between LMOs and non-LMOs in the context of small scale farming	Bolivia, Malaysia, Moldova	Consideration during the risk assessment process of environmental and socio-economic conditions of LMO cultivation in the context of small-scale farming is needed.
Risk assessment of living modified organisms on soil dwelling organisms	Finland, France, Italy	Soil habitats have several different taxa that can be utilized for improving the performance of crop plants either through better nutrient uptake or by protecting them from plant pathogens. LMOs (e.g. with modified root architecture, nutrition, root exudates) may have consequences on soils and associated microbiota. LM soil microbes may represent an important risk due to the potential for gene transfer to other organisms, and due to the potential to affect different trophic levels. The guidance could consider the effects of LMOs, in particular LM crops, trees and microorganisms, on soil biodiversity, soil fertility and plant health.
Post-release monitoring of LMOs	Belarus, Nigeria	The chapter on "Monitoring" of the Guidance on Risk Assessment should be revised to include examples from various well-established types of monitoring available in the literature.
Risk assessment of living modified organisms produced through cisgenetics	Malaysia, Moldova	Justification not provided
Risk assessment of LM algae	Austria	Scaled up production of LM algae will typically not be within contained systems, thus a risk assessment of

		effects due to exposure of the environment to LM algae will be required.
Risk assessment of LMOs involving paratransgenesis	Austria	Exposure of the environment to LM microorganisms associated with insects or other host organisms, may lead to risks for biodiversity and human health, the respective risk assessment will require specific considerations and is not adequately covered by existing guidance.
Risk assessment of living modified birds	Finland	LM birds have been developed for various applications. The mobility of birds, their migratory, courting and nesting behaviors as well as their important role as zoonosis carriers sets special challenges for their risk assessment.
Assessment of impacts due to the acceleration and accumulation of LMOs present in the environment	France	Further guidance is needed to assess cumulative and delayed impacts of LMOs, including case-by-case analysis completed by a more inclusive analysis, to better assess potential pleiotropic effects due to cross-talk mechanisms.
Risk assessment of living modified organisms created using RNAi technology	South Africa	In assessing potential adverse effects linked to RNAi-derived LMOs intended for release into the environment, risk assessment guidance is needed on characterizing potential exposure pathways and hazards, including off-target gene silencing, target gene silencing in non-target organisms, environmental persistence of small RNAs.

6. Process to facilitate the selection of topics for the development of further guidance on risk assessment of LMOs

7. Sixteen Parties provided views on the process for the selection of topics for the development of new guidance on risk assessment. Based on the submissions, specific topics, identified on the basis of Parties' needs, might be prioritized for the development of guidance if they relate to risk assessments that:

(a) Fall within the scope and objectives of the Cartagena Protocol;

(b) Cannot be performed by using existing guidance documents and pose new challenges to risk assessment frameworks and methodologies (for example, due to the complexity of the LMO in question, lack of suitable comparators, new and relevant ways of exposure of the environment and human beings);

(c) Involve technical knowledge and expertise which are available in the scientific community at large;

(d) Concern techniques with a high pace of scientific and technological advancement;

(e) Concern LMOs that have the potential to cause serious or irreversible adverse effects on biodiversity, taking into account the urgent need to protect specific aspects of biodiversity such as an endemic/rare species, or a unique habitat or ecosystem;

(f) Concern LMOs that may be introduced into the environment either deliberately or accidentally;

(g) Concern LMOs which have the potential to disseminate across territorial borders;

(h) Concern LMOs that are already, or are likely to be, commercialised or in use somewhere in the world.

8. The EU, its member states, and South Africa supported the undertaking of a structured analysis to apply the criteria above when considering possible topics for the development of new guidance. In addition, Brazil recommended looking whether guidance on similar topics have been developed by national, regional and international bodies and, if so, whether they can be revised or adapted to the objectives of the Protocol, as appropriate.

9. With regard to applying the criteria to the topic of risk assessment of organisms developed through synthetic biology, New Zealand considered that the lack of a comparator organism for risk assessment of organism developed through synthetic biology is insufficient as a technical criterion/justification for the selection of this topic, since such organisms fall within the LMO definition under the Cartagena Protocol, and numerous freely available risk assessment guidelines provide ample direction on the evaluation of scientific uncertainty in risk assessment and subsequent decision-making processes. On the other hand, Bulgaria noted that no guidance documents that specifically address risk assessment of organisms that contain gene drives are available, and that the necessity of broad (international) cooperation when assessing the risks for the environment from such organisms has been identified by the leading scientists in the field, learned societies, national political bodies and scientific advisory committees.

10. In order to ensure transparency and enable broader participation of experts in any future development of guidance, Japan further recommended that Parties should agree on the process to develop such guidance once a topic is selected

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