UPDATED BRIEFING NOTE FOR CARTAGENA PROTOCOL COP-MOP 10
Third World Network, November 2022

Item 14: Risk Assessment and Risk Management (Articles 15 and 16)

Status

At the resumed SBSTTA-24 meeting in Geneva in March 2022, there was no time to discuss the L-doc on risk assessment and risk management, which arose from the first part of SBSTTA-24 held online. The SBSTTA recommendation for risk assessment and risk management (CBD/SBSTTA/REC/24/5) therefore was adopted with several square brackets (indicating disagreement) that will need to be resolved at COP-MOP 10 (see the draft decision in CBD/CP/MOP/10/1/Add.5). A Contact Group is expected to be established to further the discussions.

Key issues

1. *Whether guidance on risk assessment should be developed for living modified (LM) fish*

Current text (Para 4): *Notes* the range of perspectives on the need for the development of guidance on risk assessment of living modified fish, *decides* not to proceed, at this stage, with the development of additional voluntary guidance materials on risk assessment regarding living modified fish, and *encourages* Parties and *invites* other Governments and relevant organizations to promote international cooperation, information sharing and capacity-building on risk assessment of living modified fish, and to make use of existing guidance materials, [with a view to considering further guidance on living modified fish at its eleventh meeting;]

Proposal: **The square brackets should be removed and the text retained.**

Rationale:

- LM fish pose transboundary and other risks such as potential food web and next-generation effects, including socio-economic implications.
- Several Parties have called for developing guidance, consistent with the previous identification of LM fish as one of the areas of priority. However, there was no consensus on this issue and Parties decided not to proceed with developing such guidance materials "at this stage".
- Providing a time frame, i.e. to consider further the issue at COP-MOP 11, would commit Parties to do so, rather than risk the issue not being considered in the future.

2. *Who is tasked to produce a detailed outline and develop a first draft of guidance materials on LMOs containing engineered gene drives*

Current text (Para 6): [6. *Requests* a panel of 3 to 6 experts selected in a way to warrant the required scientific expertise to develop a detailed outline and first

draft of additional guidance materials on risk assessment of living modified organisms containing engineered gene drives to ensure a fast and efficient drafting process;]

Current text (Para 11a): [(a) To contract, subject to the availability of resources, a panel of three to six experts selected in a way to warrant the required scientific expertise to develop a detailed outline and first draft of additional guidance materials on risk assessment of living modified organisms containing engineered gene drives;]

Proposal: **The text should be deleted, thus mandating the AHTEG to develop the guidance materials. This is important given the lack of guidance specified for the selection of the small expert group. Among the key issues that require specification are:**

- **Ensuring multidisciplinary expertise**
- **Avoiding or managing conflicts of interest**
- **Ensuring AHTEG oversight**

Rationale:

- There was disquiet with this proposal for a small expert group to produce a detailed outline and first draft of the guidance materials, a task that would normally be given to the AHTEG. This unease was due to the lack of clarity on the composition of such a small expert group, the criteria for selection, where the experts should be drawn from and what range of expertise they would have.
- Whereas the AHTEG would be composed of experts selected in accordance with the SBSTTA consolidated modus operandi (ensuring geographical representation, gender balance and developing country needs, as well as from relevant organisations, including indigenous peoples and local communities) and subject to the procedure for avoiding or managing conflicts of interest in expert groups established by Decision 14/33.
- Given that LMOs containing engineered gene drives are still under development and any release could lead to potentially severe and irreversible harm at many levels, including human health, environmental and socioeconomic impacts, it is crucial to address their risks based on a broad spectrum of expertise, going far beyond that of those currently active in their development.
- A small expert drafting group would limit the range of expertise, areas and types of knowledge that are required to be able to fully assess the risks of LMOs containing engineered gene drives.

3. Focus of the guidance on LMOs containing engineered gene drives

Current text (Annex, para 1d): [(d) Develop additional voluntary guidance materials for conducting case-by-case risk assessments of living modified organisms containing engineered gene drives in accordance with annex III of the Protocol. A specific focus of this material should be engineered gene drive mosquitos [taking into account general considerations of living modified

organisms containing on gene drives,][challenges identified by the Ad Hoc Technical Expert Group on Risk Assessment[5] and process identified in annex 1 of decision CP-9/13] and existing national and regional risk assessment experiences. [taking into account human health, environmental and socioeconomic impacts as well as traditional knowledge and the value of biodiversity to indigenous peoples and local communities]]

Proposal: ~~[~~(d) Develop additional voluntary guidance materials for conducting case-by-case risk assessments of living modified organisms containing engineered gene drives in accordance with annex III of the Protocol. A specific focus of this material should be engineered gene drive mosquitos ~~[~~**taking into account general considerations of living modified organisms containing ~~on~~ gene drives,**~~]~~~~[~~**challenges identified by the Ad Hoc Technical Expert Group on Risk Assessment[5] and process identified in annex 1 of decision CP-9/13**~~]~~ and existing national and regional risk assessment experiences~~.~~**, ~~[~~taking into account human health, environmental and socioeconomic impacts as well as traditional knowledge and the value of biodiversity to indigenous peoples and local communities**~~]]~~

Rationale:

- It would be crucial for the AHTEG to be specifically tasked with developing the guidance material for LMOs containing engineered gene drives.
- There is a need to first address the full spectrum of potential negative impacts and risks of LMOs containing engineered gene drives, and address engineered gene drive mosquitoes in this context, rather than narrowing the focus solely to engineered gene drive mosquitoes.
- In addition, while gene drive mosquitoes are likely to be the first application for release, R&D on other LMOs containing engineered gene drives is progressing rapidly. It would be prudent to not narrow the focus of the guidance too much, so that it remains relevant and applicable to other LMOs containing engineered gene drives.
- As LMOs containing engineered gene drives could lead to potentially severe and irreversible harm at many levels, including human health, environmental and socioeconomic impacts, it is critical that these issues are fully taken into account. As LMOs containing engineered gene drives are being developed directly for public health applications, human health aspects such as the potential adverse impacts on the stated goal of modifying disease burden must be considered. Further, Article 26 of the Cartagena Protocol on Biosafety establishes the right of Parties to take socio-economic considerations into account, especially with regard to the value of biological diversity to indigenous peoples and local communities. The opportunity costs of focusing on technoscientific over primary health care development, may have important socio-economic implications including divestment from existing social/political determinants of health.