

Post-2020 process for the Cartagena Protocol on Biosafety

Submission from Third World Network on:

- 1. Structure and content of the Implementation Plan for the Cartagena Protocol on Biosafety post-2020*
- 2. Possible elements of a specific action plan for capacity-building on biosafety, covering the Cartagena Protocol and its Supplementary Protocol*
- 3. Relevant elements of the biosafety component of the post-2020 global biodiversity framework*

(a) The **inclusion of biosafety in the post-2020 global biodiversity framework** is critical to the achievement of the CBD's objectives, in particular for the conservation of biological diversity and the sustainable use of its components. The Cartagena Protocol on Biosafety has operationalised the CBD's provisions on living modified organisms (LMOs) resulting from biotechnology. Additionally, the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety was adopted to deal with potential damage from LMOs in order to contribute to the conservation and sustainable use of biological diversity. These legal instruments are part of the CBD's scope of work and the issues safeguarded by them should remain central to the negotiations and outcomes of the post-2020 global biodiversity framework.

The full and effective implementation of the provisions of the Cartagena Protocol and the Supplementary Protocol is necessary for the operationalisation of the biosafety component of a post-2020 global biodiversity framework that meets the objectives of the CBD. Accordingly, continued biosafety capacity building is central to this goal.

The elements of the Strategic Plan for the Cartagena Protocol for the period 2011-2020 will continue to remain relevant in the post 2020 period. In particular, key substantive issues under the Cartagena Protocol will require continued and additional focus. These include the continuation of ongoing work on **risk assessment and risk management** (Articles 15 and 16), including in the context of synthetic biology and LMOs containing engineered gene drives, and **socio-economic considerations** (Article 26).

There are other provisions that are crucial to the implementation of the Protocol, including on **unintentional transboundary movements and emergency measures** (Article 17), **illegal transboundary movements** (Article 25), **public awareness and participation** (Article 23) and **handling, transport, packaging and identification** (Article 18), as well as on **monitoring and detection**; these need to also be prioritised in order to ensure that these biosafety functions are fulfilled.

The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress has recently entered into force. The **implementation of liability and redress provisions** at the national level is therefore an important biosafety component of the post-2020 framework. Under the Supplementary Protocol, there is urgent work that needs to be carried out, including the comprehensive study on financial security for consideration at its COP-MOP 2 in 2020, in accordance with the provision on financial security (Article 10 and COP-MOP Decision 9/15). Furthermore, the Decision adopted at COP-MOP 5 on liability and redress states that where the costs of response measures have not been covered, such a situation may be addressed by additional and supplementary compensation measures. These may include

arrangements to be addressed by the COP-MOP in the future. The issue of **financial security** in the context of liability and redress should therefore be another key element of the biosafety component of the post-2020 framework.

Moreover, the first review of the Supplementary Protocol, five years after entry into force (in 2023), includes a review of the effectiveness of the provisions on financial security and civil liability (Article 12). These provisions are critical to the implementation of the Supplementary Protocol and preparation needs to occur in advance of the review, making **financial security and civil liability implementation** important to the work of the post-2020 framework.

(b) There is a need to include **new developments relevant to biosafety that are raised by new modern biotechnologies** such as genome editing, genetically engineered gene drives and synthetic biology.

In this regard, the horizon scanning process envisaged in COP Decision 14/19 is an important tool by which to identify the impacts of synthetic biology and other new technologies on the three objectives of the Convention and its Protocols. Clear modalities need to be established for how to compile relevant information, evaluate the information in order to flag technological developments that may have potential risks to the conservation and sustainable use of biological diversity, taking into account risks to human health and to ensure that the information that is collected by a horizon scanning process is reported back to Parties in a timely manner. The issue of **horizon scanning for new developments in modern biotechnology and synthetic biology** should be an integral part of the post-2020 framework, allowing for flexibility and responsiveness to new challenges.

(c) In the specific case of **LMOs containing engineered gene drives** or gene drive organisms (GDOs), there is an urgent need for enhanced governance arrangements. Existing biosafety rules, established under the Cartagena Protocol for ‘conventional’ LMOs, are not fully equipped to manage the unique risks of GDOs. GDOs pose different legal and regulatory challenges because of their high potential to spread beyond national borders, particularly in the case of those organisms containing ‘global’ gene drives.

The following elements are necessary in a legal and regulatory regime for GDOs:

- Strict contained use standards specific to GDOs to regulate its laboratory research, as well as strict containment measures for transport
- Joint-decision making, in terms of operationalizing prior informed consent for all potentially affected countries of a particular environmental release
- Effective measures for dealing with unintentional transboundary movements
- Genuine public participation and obtaining the free, prior and informed consent of indigenous peoples and local communities
- Adapted risk assessment and risk management approaches for GDOs, including acknowledgment when such approaches are not possible
- Full assessment of socio-economic impacts including ethical concerns
- A technology assessment approach, including consideration of alternatives
- Rigorous monitoring and detection
- Stringent liability and redress rules

This requires further work under the CBD and its Protocols, and should be prioritised in the post-2020 framework.