

Submission by Third World Network (TWN)

Information on the identification of living modified organisms that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health

1. The context: Article 7(4)

The request for information on the identification of living modified organisms (LMOs) that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, is made in the context of Article 7(4) of the Cartagena Protocol on Biosafety.

Article 7(4) states:

The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Based on the current knowledge and experience gained on biosafety of LMOs, TWN is of the opinion that it is not possible to identify LMOs that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. This is due to various reasons, the need for case-by-case risk assessment being the most obvious one (see the elaboration in Point 3 below). Notwithstanding this opinion, TWN would like to emphasize that any identification of such LMOs **is only relevant to the application (or not, as the case may be) of the advance informed agreement procedure.**

Thus, if any such identification is agreed to by a decision of the COP-MOP in accordance with its rules and procedures, this cannot be taken to imply a blanket assurance of 'safety', nor should it be extrapolated as such.

2. Other applicable and/or relevant provisions of the Cartagena Protocol

This also means that if any such identification is agreed to by a decision of the COP-MOP in accordance with its rules and procedures, the other obligations and rights in the provisions of the Cartagena Protocol still continue to apply and/or are relevant to LMOs that have been identified as not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

The applicable and/or relevant provisions of the Cartagena Protocol and the key elements include, *inter alia*:

- Article 1 - the precautionary approach

- Article 2(4) – the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in the Protocol
- Article 15 – the right of a Party to subject all LMOs to risk assessment prior to the making of decision on import
- Article 16 – the obligation of Parties to establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks
- Article 16(3) – the obligation of Parties to take appropriate measures to prevent unintentional transboundary movements of LMOs, including such measures as requiring a risk assessment to be carried out prior to the release of a LMO
- Article 18(1) – the obligation of Parties to take necessary measures to require that LMOs that are subject to intentional transboundary movement are handled, packaged and transported under conditions of safety
- Article 18(2)(c) – documentation requirements accompanying LMOs that are intended for intentional introduction into the environment of the Party of import and any other LMOs within the scope of the Protocol
- Article 20 – information sharing and the Biosafety Clearing House
- Article 23 – public awareness, education and participation, including access to information
- Article 25 – the obligation of Parties to prevent and, if appropriate, penalize illegal transboundary movements
- Article 26 – the right to take into account socio-economic considerations
- Article 27 and the provisions of the Nagoya- Kuala Lumpur Supplementary Protocol on Liability and Redress – the application of liability and redress rules and procedures in the event of damage caused by a LMO.

TWN also emphasizes that if there is damage caused by a LMO, liability and redress applies regardless of whether that LMO has been identified as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

3. The need for case-by-case risk assessments and consideration of the LMO concerned, its intended use and the likely potential receiving environment

Article 15 of the Cartagena Protocol requires risk assessments to be undertaken in accordance with Annex III (Risk assessment).

Paragraph 1 of Annex III states:

*The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the **likely potential receiving environment**, taking also into account risks to human health. (emphasis added)*

Paragraph 5 of Annex III states:

*Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the **likely potential receiving environment**.* (emphasis added)

Paragraph 6 of Annex III states:

*Risk assessment should be carried out on a **case-by-case** basis. The required information may vary in nature and level of detail from case to case, **depending on the living modified organism concerned, its intended use and the likely potential receiving environment**.* (emphasis added)

Paragraph 8(a), 8(b) and 8(f) of Annex III state:

To fulfil its objective, risk assessment entails, as appropriate, the following steps:

- (a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the **likely potential receiving environment**, taking also into account risks to human health;*
- (b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the **likely potential receiving environment** to the living modified organism;*
- (f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the **receiving environment**.* (emphasis added)

Paragraph 9(h) of Annex III states:

*9. **Depending on the case**, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:*

- (h) Receiving environment. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the **likely potential receiving environment**.* (emphasis added)

It is clear from the reading of the above provisions that the risk assessment process set out in the Cartagena Protocol on Biosafety should be carried out on a case-by-case basis and that the specific LMO concerned, its intended use and the likely potential receiving environment are all important considerations. The latter criteria mean that the potential adverse effects of a LMO are dependent on its specific characteristics, how it is used and where it is released. These will vary in different ways and would be influenced also by environmental, health and socio-economic factors.

Therefore, case-by-case risk assessments cannot be transferable to all potential receiving environments. It follows that any generic identification of LMOs that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, is not possible. In fact, such a move would seriously undermine the case-by-case principle of risk assessment that is enshrined in the Cartagena Protocol. Accordingly, the identification of any criteria for the identification of such LMOs is not possible.