Estado Plurinacional de Bolivia

MMAyA Ministerio de Medio Ambiente y Agua

Bolivian Position on Identification of Living Modified Organisms that are not Likely to Have Adverse Effects In the Context of the Cartagena Protocol on Biosafety

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I BACKGROUND

The Cartagena Protocol on Biosafety (CPB) in its Article 7.4, under Article 7 on Application of the Advance Informed Agreement Procedure, states that: "*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*."

In relation to Article 7.4, the Executive Secretary of CPB through Notification SCBD/BS/MPDM/jh/6758 requested to submit: (i) information on risk assessments, carried out on a case-by-case basis with regards to the receiving environment of the living modified organism, that might assist Parties in 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, and (ii) the criteria that were considered for the identification of such living modified organisms.

The following is the position of the Plurinational State of Bolivia on the information requested above in light of the available knowledge, as well as the Bolivian experience on biosafety of living modified organisms (LMOs).

II BOLIVIAN POSITION ON ARTICLE 7.4

2.1 Restricted and conditioned application of Art. 7.4

In the context of the CPB, the consideration 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 applies solely to the Advance Informed Agreement (AIA) procedure, and it is subjected to:

- Implementation of the precautionary approach (according to Article 1).

- Analysis of the likelihood of adverse effects based on the risk assessment findings (according to Article 7.1 that relates to decision procedures and risk assessment).

- Decision of the Conference of the Parties (according to Article 7.4).

In other words, 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, cannot be identified *a priori*; but they must be subject of a precautionary-driven risk assessment. Moreover, the determination of such LMOs is not up to a single Party, non-Party or organization, but is to be determined by a decision of the Conference of the Parties.

Moreover, in the case that such a LMO would be identified by the Conference of the Parties, it would be only exempt from the AIA procedure if consistent with the domestic law of the Parties where its transboundary movement would take place. Meaning, that such LMOs will still be subject to other CPB provisions such as, *inter alia,* review and change decisions in light of new scientific information on potential adverse effects (Article 12), risk assessment (Article 15), risk management (Article 16), handling, transport, packing and identification (Article 18), illegal transboundary movements (Article 15), socioeconomic considerations (Article 26), and liability and redress (Article 27).

2.2 Inappropriateness of defining *a priori* LMOs that are not like have adverse effects

This points addresses: (i) information on risk assessments, carried out on a case-by-case basis with regards to the receiving environment of the living modified organism, that might assist Parties in 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.

Any potential identification by the Conference of the Parties 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, will imply an *a priori* determination of absence of potential adverse effects related to the LMO in question. This is not only erroneous; but also not precautionary.

Current knowledge on biosafety of LMOs clearly points out unforeseen adverse effects on different component of biological diversity (for instance, adverse effects in the equilibrium among insect populations[1,2], the natural pollination dynamics[3], and soil biology[4,5] - just to mention some - related to insect resistant (*Bt*) crops), as well as potential adverse effects in human health (e.g. Dona and Arvonitoyannis, 2009[6]; Domingo, 2007[7]; Malatesta et al.,

1 Hilbeck A. 2002. Transgenic host plant resistance and non-target effects. In Genetically Engineered Organisms. Assessing Environmental and Human Health Effects. D.K. Letourneau, B.E. Burrows, eds. (Boca Raton, CRC Press), pp. 167-185.

2 Schmidt J.E.; Braun C.U.; Whitehouse L.P.; Hilbeck A. (2009). Effects of Activated Bt Transgene Products (Cry1Ab, Cry3Bb) on Immature Stages of the Ladybird Adalia bipunctata in Laboratory Ecotoxicity Testing. *Arch Environ Contam Toxicol* 56:221–228.

3 Ramirez-Romero R.; Desneux N.; Decourtye A.; Chaffiol A.; Pham-Delègue M.H. (2008). Does Cry1Ab protein affect learning performances of the honey bee Apis mellifera L. (Hymenoptera, Apidae)? *Ecotoxicol Environ Saf*. 70:327-33.

4 Stotzky G. (2004). Persistence and biological activity in soil of the insecticidal proteins from *Bacillus thuringiensis*, especially from transgenic plants. *Plant Soil* 266: 77–89.

5 Castaldini, M., Turrini, A., Sbrana, C., Benedetti, A., Marchionni, M., Mocali, S., Fabiani, A., Landi, S., Santomassimo, F., Pietrangeli, B., Nuti, M. P., Miclaus, N., & Giovannetti, M. (2005). Impact of Bt corn on rhizospheric and soil eubacterial communities and on beneficial symbiosis in experimental microcosms. *Appl. Environ. Microbiol*. 71: 6719–29.

6 Dona, A,; Arvanitoyannis, I. 2009. Health Risks of Genetically Modified Foods. *Critical Reviews in Food Science and Nutrition,* 49:164–175

7 Domingo, J. 2007.Toxicity Studies of Genetically Modified Plants: A Review of the Published Literature. *Critical Reviews in Food Science and Nutrition,* 47:721–733.

2008[8]). These and other potential adverse effects vary in relation to the receiving environment, the socioeconomic context of introduction, and the complex interrelation of multiple socioeconomic and ecological processes. Hence, the potential impacts of LMOs cannot be assumed to be uniform nor predictable. Accordingly, absence of adverse effects of LMOs cannot be determined *a priori*, and all LMOs need to be subject of a case-by-case risk assessment in relation to the environment and socioeconomic context of introduction.

2.3 Adequate risk assessment questions needed instead of criteria for identifying LMOs that are not like have adverse effects

This points addresses: (ii) the criteria that were considered for the identification of such living modified organisms.

Based on the previous point related to the inadequacy of pre-determining that certain LMOs are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, the notion of setting criteria for their identification is erroneous.

The pre-assumption that certain LMOs are not likely to have adverse effects, and setting criteria to identify them will easily lead to Type II errors (false positives) in biosafety research; hence, inadequate regulation. In other words, it will result in the underestimation and lack of detection of potential adverse effects[9]. The final result of this will be delaying or neglecting measures to prevent or remedy those adverse impacts[10].

The Plurinational State of Bolivia is of the view that setting criteria for identifying 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 a mistaken approach for the effective implementation of the CPB. Instead, rigorous risk assessment based on robust and transparent biosafety research is needed. Robust biosafety research and risk assessment (namely adequate research questions, sample size and statistical analysis) will avoid dangerous and misleading conclusions on "LMOs are not likely to have adverse effects" (See article in foot note 11). Robust and transparent biosafety research and risk assessment is not only more feasible but also correct from a scientific, regulatory and ethical point of view. It is also essential in achieving the objectives of the Cartagena Protocol on Biosafety.

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8 Malatesta, M.; Boraldi, F.; Annovi, G.; Baldelli, B.; Battistelli, S.; Biggiogera, M.; Quaglino D.(2008). A long-term study on female mice fed on a genetically modified soybean: effects on liver ageing. *Histochem Cell Biol.* 130:967–977.

9 McGarvey, D. (2007). Merging Precaution with Sound Science under the Endangered Species Act. *BioScience* 57(1):65-70

10 Underwood, A.J.; Chapman, M.G. (2003). Power, precaution, Type II error and sampling design in assessment of environmental impacts. *Journal of Experimental Marine Biology and Ecology* 296: 49– 70.

11 Séralini, E-G.; de Vendômois, J.; Cellier, D.; Sultan, C.; Buiatti, M.; Gallagher, L.; Antoniou, M.; Dronamraju, K. (2009). How Subchronic and Chronic Health Effects can be Neglected for GMOs, Pesticides or Chemicals. *International Journal of Biological Sciences* 5(5):438-443