AN APPRAISAL OF THE INTERNATIONAL GOVERNANCE OF TRANSBOUNDARY MOVEMENTS OF GENETICALLY MODIFIED ORGANISMS TWENTY YEARS AFTER THE RIO DE JANEIRO EARTH SUMMIT

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INTRODUCTION

- Genetically Modified Organisms: any organism, plant or animal which genetic material has been modified not by natural recombination or reproduction.
- Living Modified Organisms: any organism, plant or animal which genetic material has been modified not by natural recombination or reproduction, which is capable of replication.

INTRODUCTION

- Genetically Modified (GM) products have increased on the market as foods and food additives, beverages, fuels and pharmaceutical products since the 1990's but there are concerns about potential side effects on human health and the environment.
- From 1.7 million hectares of GM crops cultivated in 1996, this multi-billion-dollar global industry has increased to 160 million hectares in 2011.

AT THE INTERNATIONAL LEVEL

- 1992 Rio Summit: Agenda 21 (chapter 16)
- The 1992 Convention on Biodiversity (CBD) includes international rules on access to genetic resources and transfer of biotechnology techniques but no detailed regulation on Genetically Modified Organisms (GMOs).
- The 2000 Cartagena Protocol on the safety of transboundary movements of Living Modified Organisms (LMOs), (Cartagena Protocol).
- The 2010 Nagoya-Kuala Lumpur Supplementary Protocol on liability and redress for damages resulting from transboundary movements of LMOs (the Nagoya Supplementary Protocol).

KEY ISSUES TO BE ADDRESSED

- The scope of the GMOs to be regulated
- Identification and traceability issues
- The relationship of the Cartagena Protocol with other prior international agreements
- Liability and redress issues
- Harmonisation of biosafety regulation issues
- Other issues (socio-economic considerations, risk assessment and risk management, financial guarantees, compliance…)

SCOPE OF THE GMOS COVERED

- Only LMOs (but not GMOs) are covered by the Cartagena Protocol and the Nagoya Supplementary Protocol.
- LMOs to be released into the environment (GM seeds).
- LMOs destined for contained use (GM viruses or bacteria).
- LMOs intended for direct use as food, feed or to be processed (live GM salmon, GM grains intended for feed) but there is no compliance mechanism as to the final use of this category. GM food aid?

GMOS WHICH ARE NOT COVERED

- LMOs to be used as raw material for the production of pharmaceuticals.
- GM agricultural products with added health value (nutraceuticals such as rice with enriched vitamins) or GM products modified as edible vaccines.
- GM additives and flavourings (GM strawberry).
- Products derived from LMOs to be used directly as food and feed (oil, flour, tomato sauce, chicken eggs from chicken fed with GM feed) which cannot replicate themselves or transfer genetic material.

SCOPE OF THE ADVANCE INFORMED AGREEMENT PROCEDURE

- **Not subjected to the AIA procedure:**
- Pharmaceuticals to be used by human beings which are subjected to other agreements or relevant international organisations are not subjected to the AIA procedure however these instruments may deal with human health concerns but do not address directly the environmental and biodiversity impacts of LMOs.

SCOPE OF THE ADVANCED INFORMATION AGREEMENT PROCEDURE

- **Not subjected to the AIA procedure:**
- LMOs in contained use.
- LMOs in transit (only placed under customs procedures applicable in different States).
- LMOs to be used as food and feed or food to be processed.
- Simplified procedures for LMOs considered as less dangerous (Articles 11 and 13 of the Cartagena Protocol).

MAIN ISSUES ABOUT LABELLING AND TRACEABILITY:

- Whether the labelling of GM products must be mandatory or voluntary? **No international labelling obligation.**
- Which products should be labelled and the contents of the labels?
- Whether traces of GM content in the final product must be labelled and at which thresholds? **No international threshold on the labelling of GM products.**

IDENTIFICATION AND TRACEABILITY ISSUES

- Labelling obligation in the protocol only for LMOs intended for direct use as food and feed or to be processed (Annexure II of the Cartagena Protocol).
- No official inspection mechanism for this labelling obligation.
- Grain shippers have been using the “may contain LMOs” designation on commercial invoices.

IDENTIFICATION AND TRACEABILITY ISSUES

- **No international labelling obligation amounts to:**
- Different standards in different countries.
- Consequences on the organic products' industry.
- No segregation and risks of mixing GM and non-GM products during transboundary movements.
- Lack of traceability of GM products in case of health hazards or unintentional release into the environment.

RELATIONSHIP OF THE BIOSAFETY PROTOCOL WITH OTHER PRIOR INTERNATIONAL AGREEMENTS

- The WTO Agreement on the application of Sanitary and Phytosanitary Measures (the SPS Agreement).
- The WTO Agreement on Technical Barriers to Trade (TBT Agreement).
- The General Agreement on Tariff and Trade (GATT) 1994
- The WTO Reference bodies (Codex Alimentarius, World Health Organisation (WHO), World organisation for Animal Health (OIE)).
- The International Plant Protection Convention (IPPC)

RELATIONSHIP OF THE BIOSAFETY PROTOCOL WITH OTHER PRIOR INTERNATIONAL AGREEMENTS

- Existence of a saving Clause in the Cartagena Protocol stating that it is not subordinate or superior to other prior international instruments.
- The Cartagena Protocol applies only to LMOs whereas the trade agreements apply to all categories of GMOs.
- But the Cartagena Protocol fully applies to a transboundary movement of LMOs for non-commercial purposes.
- The Cartagena Protocol rests on the Precautionary principle whereas the trade agreements apply the principle of substantial equivalence.
- Which standards will apply in case of international trade of GMOs and which dispute settlement mechanism will apply?

LIABILITY AND REDRESS ISSUES

- The Nagoya-Kuala Lumpur Supplementary Protocol 2010 sets up mainly administrative and civil liability rules and procedures to be implemented by States Parties.
- The national competent authority of the country affected by the damage needs to investigate the matter, evaluate the damage and determine which response measures need to be taken by the operator.

LIABILITY AND REDRESS ISSUES

- Standard of civil liability (fault-based or strict liability) for damages resulting from transboundary movements of LMOs.
- Causal link (the burden of proof will be different depending on whether a fault-based or strict liability is applicable).
- Damages (adverse effects on the sustainable use of biological diversity taking into account human health)
- Exemption to liability (acts of war and civil unrest)
- Which dispute settlement procedures will apply?

HARMONISATION OF BIOSAFETY REGULATION ISSUES

- Increase of national biosafety frameworks (NBFs) since the adoption of the Cartagena Protocol (in 2012, 118 States have NBFs).
- Influence of weaker or stronger regional biosafety mechanisms.
- Influence of the biotech industry for weaker mechanisms.
- Bilateral or multilateral agreements.

OTHER ISSUES

- Socio-economic considerations (SA communication on GM crops' impact on small-scale farmers, Indian farmers and the negative effects of using corporate GM seeds instead of farm-saved seeds?)
- Risk assessment and risk management (which methods, sound science?)
- Compliance (reporting, Biosafety Clearing House (BCH..)
- Financial guarantees in relation to transboundary movements of LMOs.

CONCLUSION

- The Cartagena Protocol provides for a baseline of legal control on the import and export of GMOs that needs to be translated into national regimes.
- Additional categories of GMOs need to be regulated since the Cartagena Protocol was drafted targetting mainly GM agricultural products.
- Need for a better control of illegal movement of GMOs considered as hazardous (pathogenic GM microorganisms) for public health or security (bioterrorism).

CONCLUSION

- **Need for harmonisation of standards** : different standards applicable for different countries resulting in a less efficient biosafety system.
- Harmonisation of identification and traceability standards, risk assessment and risk management standards and communication of information on biotechnological risks.
- Harmonisation with inter-State cooperation (at best by competent international bodies) and not by influential private actors with vested interests.

CONCLUSION

- **Need for an international liability and redress regime.**
- Procedures to bring redress depend too much on the area in which the damage occurred and domestic laws on liability .
- Damages caused to the neighbouring areas and their biological diversity may be irreversible and there is no redress for damages in areas beyond national jurisdiction.
- **20 years after Rio, existing biosafety instruments represent milestones paving the way ahead. These existing biosafety instruments need to be deepened and implemented at the national level for more efficiency rather than elaborating more instruments.**

- Thank you for your attention.