NRE/UNDP Policy Dialogue on Liability and Redress of the Cartagena Protocol on Biosafety

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Brief Introduction to the Cartagena Protocol on Biosafety and the Liability and Redress Issue

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MINISTRY OF NATURAL RESOURCES AND ENVIRONMENT, MALAYSIA

Presentation Outline

- Background
  - Biosafety
- Snap shot on
  - Cartagena Protocol on Biosafety
    - The Liability and Redress Issue
- The Malaysian Story…so far
- The end

The Scope of our Today's Discussion

- Biotechnology is a wide area
- The Cartagena Protocol only deals with modern biotechnology.

  "Modern biotechnology" means the application of:

  a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

  b. Fusion of cells beyond the taxonomic family,

  that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

Background- Biotechnology

- The knowledge on techniques of genetic modification dates from the 1950s when Watson and Crick discovered the structure of DNA.
- In 1970s it became possible to isolate individual genes, refashion them and copy them into cells – living organisms into "factories"- huge commercial potential.
- 1994- Flav'r Sav'r Tomatoes became the first genetically altered whole food to enter the US market

Background- Biotechnology

- Most prominent development is the creation of transgenic crops.
- The commercial use of GMOs in agriculture is now on 4 main crop species: soybeans, maize, oilseed rape (canola) and cotton.
- Herbicide tolerant has been the main trait introduce into GM plants followed by insecticide properties

Background- Biotechnology

- As general public became more aware of the impact of GMOs, concerns over the use and safety of genetic modification and its products began to rise.

Benefits of GMOs

- Better agriculture efficiency, could reduce the pressure for land and thus reduce the impact on bio-d
- Reduce the application of pesticides pesticide resistant plants
- Industrial application-use of microbes

Concerns on GMOs

- Dispersal to the environment-invasiveness
- Potential transfer of genetic material-cross pollination
- Impact on non-targeted species
- 'contamination'
- Potential effect on human, animal and plant health
- Socio-economic impacts

The International Scene

- Agenda 21 (1992) recognised the benefits of modern biotechnology but in Principle 15 of Rio Declaration calls for the application of the Precautionary Principle
- The Convention on Biological Diversity (CBD) has **3 provision directly related to LMOs and biosafety**

Cartagena Protocol on Biosafety (CPB)

Negotiation Process

- Initial proposal from **Malaysia** in 1991 during the negotiation of the CBD on Article 19(3) and Sweden proposed a Protocol
- Decision II/5 of the Jakarta Mandate (COP 2) established the BSWG
  - Six meetings of the BSWG (July, '96- Feb.'99)
  - First extraordinary meeting of the COP (ExCOP) in Cartagena, 1999
  - Resumed session of the ExCOP in Montreal, 2000 (intense negotiations, Protocol was adopted at around 4.35 am on 29 January 2000)

CPB- Key elements

- Objective
- Scope
- Advance informed agreement (AIA)
- Identification
- Risk assessment
- Socio-economic considerations
- Liability and redress
- Capacity-building
- Relationship with other international agreements

CPB- Objective

Article 1

"In accordance with the **precautionary approach** contained in Principal 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the **safe transfer, handling and use** of **living modified organisms resulting from modern biotechnology** that may have adverse effects on the conservation and sustainable use of **biological diversity**, taking also into account risks to **human health**, and **specifically focusing on transboundary movements**"

Scope of CPB

- Primarily regulates the transboudary movement of LMOs
- It covers all LMOs [its application to LMOs in transit; contained use; food, feed and processing (FFP)is limited]
- LMOs that are pharmaceuticals for humans addressed by other international organisation is excluded

AIA

- Article 4 – 7 of CPB
- 'backbone' of the Protocol – procedure of obtaining prior informed consent from the importing Party, before a GMO crosses national boundaries
- The onus is on the exporting Party to notify the importing Party
- The importing party decides based on Risk Assessment *(the Precautionary Principle as well socio economic considerations can be taken into account).*
- There is a simplified procedure of LMOs for Food, Feed and Processing - also subject to national laws

Liability and redress

- Article 27
- A system for liability and redress resulting from transboundary movement of LMOs shall be developed within 4 years of MOP1, which means – 2008
- Still been negotiated – very contentious
- Our FOCUS topic for today

Liability and redress

- The introduction of GMOs into the environment raise questions concerning the legal consequences of the potential negative outcomes arising from GMOs' introduction into the environment.

Potential issues- Liability and redress

- Environment:
  - instability of the genetic material;
  - the possibility of further changes in the GMOs,
  - the potential for transgenic varieties to displace wild species (loss of biodiversity)
  - Impact on non-target species

Potential issues- Liability and redress

- Socio-economic:
  - contamination of organic crops by GMOs;
  - displacement of wild species, which may have economic and cultural importance;
  - Loss of income (movement of planting GM from areas they are normally grown)
- Intellectual Propriety Rights Issue
  - Seeds at higher cost
  - The Schmeiser's case in Canada

The Malaysian Story

Biotechnology

- Malaysia a mega biodiverse country has huge potential for 'bio-wealth' creation through biotechnology
- identified as one of the new sources of growth in the National Agriculture Policy 3 (NAP3) for 1998-2010 and the Biotech Policy (April 2005)

Setting the Scene

The National Biosafety Framework is best reflected by…..

"…..while Malaysia is aware that biotechnology holds much promise, we are also concerned that biotechnological products should not pose any threat to the environment, or to human health and safety."

"The international community has recognised the potential hazards and risks of genetic engineering. The principle of precaution underpins the Cartagena Protocol on Biosafety as well as its parent convention, the CBD."

Rt. Hon. Prime Minister of Malaysia

24 January 2005, Paris

Biosafety in Malaysia

- NRE is the focal point for CPB and biosafety issues
- to strike a balance (safety, ethics, socio-economic), as highlighted in the National Policy on Biological Diversity (1998)
- To complement the national biotech agenda
- Not intended to disrupt R&D
- At the moment we are the receiving party- need to safe guard our bio-d, human health
- signed the Cartagena Protocol in May 2000 during the High-Level Segment of the COP5 CBD.
- Ratified in September 2003
- Hosted the First Meeting of Parties (MOP1) from 23 to 27 February 2004 in PWTC, Kuala Lumpur

Regulatory Framework

- ✓ **National Guidelines for the Release of Genetically Modified Organisms into the Environment.**
- launched in 1997
- set regulatory framework for biotechnology
- cover the general scientific and technical aspects of the release of GMOs into the environment
- voluntary in nature
- the National Guidelines have been revised and drafted into a new legislation - **The Biosafety Bill.**
- The Bill was *approved* by Cabinet on 30 November 2005

The spirit of The Biosafety Bill

- *to establish the National Biosafety Board;*
- *to regulate the release, importation, exportation and contained use of living modified organisms, and the release of products of such organisms, with the objectives of protecting human, plant and animal health, the environment and biological diversity, and*

The Biosafety Bill

- The Biosafety Bill will among others:
  - complement the implementation of the National Policy on Biotechnology (2005) and also the National Policy on Biological Diversity (1998).
  - Malaysia's obligation under the Cartagena Protocol on Biosafety.
  - Boost the confidence of investors in biotech
  - Give a clear direction on regulatory framework on GM
- An enabling law where most of the operational issues will be spelt out in Regulations such as the liability and redress issue

The current set-up…continued

- In the absence of a national legal instrument on biosafety, GMAC has been advising the Ministry on issues related to biosafety.
- The focal point(NRE) upon receiving an application sends it to GMAC for assessment
- Based on GMAC assessments, the application will be forwarded to the National Steering Committee for approval (if the assessment is favourable).
- Case by case basis
- Members are from the scientific community and a rep from the civil society

Thank you

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