



**Asia-Pacific  
Economic Cooperation**

---

2012/SOM2/HLPDAB/019

## **An Insight into the Cartagena Protocol on Biosafety**

Purpose: Information  
Submitted by: Russia




**11<sup>th</sup> High Level Policy Dialogue on  
Agricultural Biotechnology  
Kazan, Russia  
26-27 May 2012**



# An insight into the Cartagena Protocol on Biosafety

A.Golikov - An insight into the Cartagena Protocol on Biosafety 26-27 May 2012, Kazan', Russia

A.Golikov - An insight into the Cartagena Protocol on Biosafety 26-27 May 2012, Kazan', Russia



## outline

- Cartagena Protocol on Biosafety to the Convention on Biological Diversity – history and background
- Cartagena Protocol on Biodiversity and WTO

## international regulations...



- Increased emphasis on biosafety and supply security will continue as a significant trend
- There will be rapid changes in technology to produce and process food, pharmaceuticals, etc.
- Information overload will be a continuing challenge
- There is growing awareness of the world as an interdependent food and agricultural community, therefore food and agriculture will continue to be a large icon for special interest groups who challenge the validity and safety about food and agriculture to further their own agendas

## Cartagena Protocol on Biosafety



- Rio Declaration (World Summit) – 1992
  
- Convention on Biological Diversity – 1992

## international regulations



### LEGALLY NON-BINDING AGREEMENTS:

OECD "Blue book"

UNIDO Voluntary Code of Conduct for Release of Organisms into the Environment

UNEP International Technical Guidelines for Safety in Biotechnology

FAO Codes (pesticides, fisheries, etc.)

CODEX *Alimentarius*

## international regulations



### LEGALLY BINDING AGREEMENTS:

#### WTO

- General Agreement on Tariffs and Trade (GATT)
- Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)
- Agreement on Technical Barrier to Trade (TBT)
- Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

#### Cartagena Protocol on Biosafety

- Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress(?)
- COMPACT (?)

#### Nagoya Protocol on Access and Benefit Sharing (?)

Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters

## Cartagena Protocol on Biosafety



- Rio Declaration (World Summit) - 1992
- Convention on Biological Diversity - 1992

### Article 8. In-situ Conservation

(g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health;

### Article 19. Handling of Biotechnology and Distribution of its Benefits

(3) The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

## Cartagena Protocol on Biosafety



In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of the 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.

## Who's Who in negotiations?



- ❑ Miami Group (Argentina, Australia, Canada, Chile, the United States and Uruguay)
- ❑ Like-Minded Group (the majority of developing economies) – emerged from G77/China
- ❑ European Union
- ❑ Compromise Group (Japan, Mexico, Norway, Singapore, South Korea, Switzerland and, in Montreal, New Zealand)
- ❑ Central and Eastern European bloc of economies

## What does the Protocol do...



The Protocol applies to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health (Art. 4)

- ❑ Establishes the AIA (Advanced Informed Agreement)
- ❑ Establishes Biosafety Clearing House
- ❑ Established requirements for Risk Assessment and risk Management (on a case by case basis)
- ❑ Establishes the clause on socio-economic considerations
- ❑ Establishes relations with other international agreements
- ❑ Establishes labeling requirements for LMO bulks in the move
- ❑ Establishes simplified procedure
- ❑ Establishes "negative" list

## Advanced Informed Agreement



Notification – 90 days – wait for a written consent or proceed without written consent

If "wait for written consent" – 270 days for a Party of import to decide:

- Approve the import, adding conditions as appropriate, including conditions for future imports of the same LMO
- Prohibit the import
- Request additional information, or
- Extend the deadline for response by a defined period
- A Party of import may, at any time, in light of new scientific information, review and change a decision. A Party of export or a notifier may also request the Party of import to review its decisions

## Advanced Informed Agreement



Does not apply to:

- pharmaceuticals for humans (if covered by relevant international agreements);
- LMOs in transit to a third Party;
- LMOs destined for contained use;
- LMO– FFPs (discussed below), and;
- LMOs that have been declared safe by a meeting of the Parties... ("negative" list)
- subsequent supplies of LMO's

## What does the Protocol not do...



- ❑ The Protocol does not address food safety issues. This is addressed by experts in other international fora
- ❑ The Protocol does not require segregation of bulk shipments of commodities that may contain living modified organisms
- ❑ It does not require consumer product labeling
- ❑ It does not subject shipments of bulk commodities to the Protocol's AIA procedure

## decision and scientific basis



- ❑ The Party of import makes its decisions in accordance with scientifically sound risk assessments
- ❑ The Protocol sets out principles and methodologies on how to conduct a risk assessment (Annex III)
- ❑ In case of insufficient relevant scientific information and knowledge, the Party of import may use precaution in making their decisions on import
- ❑ Parties may also take into account, consistent with their international obligations, socio-economic considerations in reaching decisions on import of LMOs



A.Golikov - An insight into the Cartagena Protocol on Biosafety 26-27 May 2012, Kazan', Russia

socio-economics... 


**Corrida, Spain**



**Courban Bairam, Tartarstan**

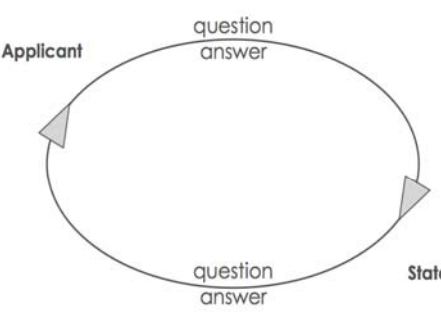


A.Golikov - An insight into the Cartagena Protocol on Biosafety 26-27 May 2012, Kazan', Russia

Protocol = regulations 

Reasonable decision via:

- definite answer to definite question within defined time
- plans and strategy in case...
- shared liability...
- appellation and revisit mechanism – both regulations and decisions
- settlement of disputes



## Cartagena Protocol on Biosafety



definite answer to definite question within defined time?

A failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement (Art. 9.4)

A failure by the Party of import to communicate its decision within two hundred and seventy days of the date of receipt of the notification shall not imply its consent to an intentional transboundary movement (Art. 10.5)

## Cartagena Biosafety Protocol



plans and strategy in case...?

shared liability...?

appeal and revisit mechanism – both regulations and decisions?

settlement of disputes?

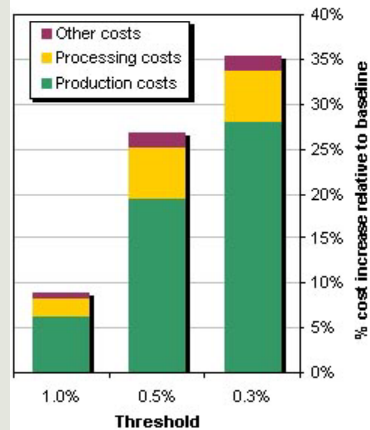
simplified procedure, "negative" list, socio-economic considerations, clear labeling...

## adventitious presence



Established best management practices and quality control systems are intended to minimize the accidental presence of genetic material or whole seeds from other varieties, crops, or weeds in every commercial seed shipment. Despite strict standards, however, virtually every seed shipment contains small amounts of adventitious material, as seed production occurs in open environments where other seeds and crops are also produced and processed. Such realities are recognized in various national and international standards of seed purity (e.g. AOSCA, 2004; OECD, 2003...).

Most economies have ZERO AP threshold relative to GM material



"Choices", 2<sup>nd</sup> quarter 2004

## regulations



Regulation is a means by which governments seek to gain benefits and ameliorate the potential negative consequences of a free market economy

The US-EU Consultative Biotechnology Forum, December 2000

## get what you want...



The final text does not settle the question of how the Protocol relates to the WTO and other international agreements. In fact it looks like a conflict postponed, rather than a conflict avoided...

- Miami group: "this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreement."
- EU: "the above recital is not intended to subordinate this Protocol to other international agreements."
- Like-minded: both statements appear in the Preamble, not in the text...

## CPB vs WTO: main question



**Does the Protocol in any respect change the Parties' ability to exercise the precautionary principle?**

It does, by better defining that principle in at least the following ways:

## CPB vs WTO: main question



- The SPS does not spell out exactly what a risk assessment entails, but the Protocol does so in detail in Annex II
- The SPS does not mention risk management, but only risk assessment. The Protocol (in Articles 15 and 16) makes it clear that both exercises are necessary, defining the latter as the gathering of the data, and the former as the building of a regulatory regime based on that data. It further sets out some guidance in creating that regime; for example, asking Parties to try to ensure that any LMO should undergo an appropriate period of observation commensurate with its life-cycle or generation time before it is put to its intended use
- SPS Agreement is the applicable WTO law for trade in LMOs. This is likely the case, but it is not a settled issue
- The Protocol explicitly allows Parties to take into account socio-economic considerations in making their decisions, whereas the SPS says nothing on the subject
- The Protocol is specific about the process for review of decisions in the light of new evidence (Article 12), whereas the SPS is ambiguous about how to treat measures adopted provisionally in the face of uncertainty.
- The provisions in Article 15 go some distance toward laying the onus on the exporter to establish the harmless nature of the LMO in question. Paragraphs 2 and 3 state that the party of import may require the exporter to carry out the risk assessment, and it may require the notifying party to foot the bill.<sup>9</sup> Again, on this question, the SPS is silent.

## CPB vs WTO: main question



- an environmental agreement is in effect giving specificity to a trade agreement
- a sign that the two treaties could complement

thank you!

