



Presentation Outline

Part I: Background to the Protocol

Part II: Overview of the Protocol

Part III: Concluding Remarks





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PART I: und to the Protoc

- Negotiated under the Convention on Biological Diversity (CBD)
- Adopted 29 January 2000 after 4 years of intense negotiations
- Entered into force: 9 September 2003
- 160 ratifications/ accessions
- 5 meetings of the governing body (COP-MOP) held; 42 substantive decisions
- Last COP-MOP: 11 15 Oct 2010; Nagoya





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General Context

- CPB is the only international instrument that deals exclusively with LMOs
- Other international instruments and standard-setting processes addressing aspects of biosafety:
 - International Plant Protection Convention (IPPC) GM plant pests
 - · Codex Alimentarius GM food safety
 - World Organization for Animal Health (OIE) standards and guidelines, e.g. for GM vaccines
 - WTO Agreement on the Application of Sanitary and Phytosanitary (SPS) measures



PART II: OVERVIEW OF THE PROTOCOL Objective of the Protocol

To contribute to ensuring the <u>safe</u>
<u>transfer, handling and use of LMOs</u>
resulting from modern biotechnology
<u>that may have adverse effects on the</u>
<u>biological diversity</u>, taking also into
account risks to human health



*In accordance with the precautionary approach





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Potential Adverse Effects of LMOs

Environmental <u>concerns</u> (examples)

- · Impacts on non-target organisms
- Transfer of genes from cultivated species to wild relatives
- · Potential creation of super weeds
- · Ripple effects within ecosystems difficult to predict

Health concerns

- Potential allergenicity
- Antibiotic-resistance



Scope of the Protocol

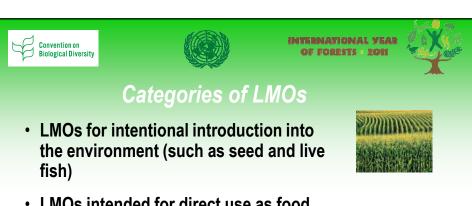
Applies to:

 Transboundary movement, transit, handling and use of LMOs that may have adverse effects on biodiversity, taking also into account risks to human health

Exclusion:

 Pharmaceuticals for humans are addressed by other international agreements or organisations



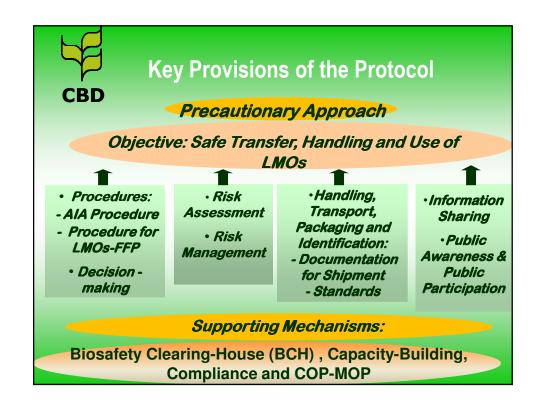


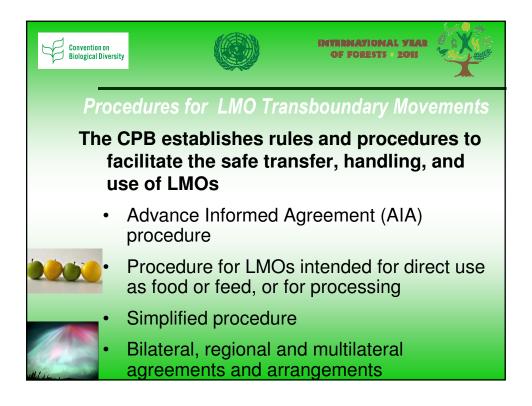
- LMOs intended for direct use as food, feed or processing, LMOs-FFP (such as agricultural commodities – corn, canola and cotton)
- LMOs for contained use (such as bacteria for laboratory scientific experiment)

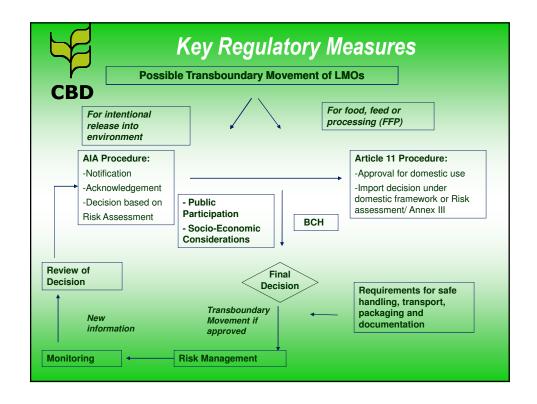
















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Advance Informed Agreement (AIA) Procedure

Application:

The <u>first</u> intentional transboundary movement of LMOs for <u>intentional introduction into the environment</u> of the Party of import

Procedural steps:

- Notification by the exporting Party
- Acknowledgement of notification by Party of import (90 days)
- Decision-making (with 270 days) the precautionary approach, risk assessments and socio-economic considerations
- Review of decision (new information/change in circumstances)

Exemptions:

LMOs in transit; LMOs for contained use; LMOs-FFP





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Procedure for LMOs-FFP

- Registering in the BCH a decision to approve domestic use (and marketing) of an LMO-FFP
- A Party can subject import of an LMO-FFP to its laws, regulations & guidelines (consistent with the Protocol objective). Copies of these must be availed to the BCH
- A Party without a regulatory framework can declare, through the BCH, its intent to subject the first import of an LMO-FFP to a risk assessment & prior approval





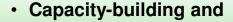
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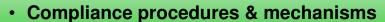
Other Key Provisions of the Protoco

- Risk assessment scientific, case by case
- Safe handling, transport, packaging and proper identification of LMO shipments









· Liability and redress





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Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress

- Adopted by COP-MOP 5 on 15 October 2010 in Nagoya (decision BS-V/11)
- Opened for signature: 7 March 2011; 4 signatures to date (Colombia, Denmark, Netherlands & Sweden
- Objective of the Supplementary Protocol:

"to contribute to the conservation and sustainable use of biological diversity, taking also into account risks to human health, by providing international rules and procedures in the field of liability and redress relating to living modified organisms."





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PART III

Concluding remarks

- Several LMOs have been placed on the market
- It is important to ensure LMOs have no negative effects on biological diversity and human health
- The Protocol establishes procedures and mechanisms for doing so
- The CPB recognises the potential of biotechnology if developed and used with adequate safety measures





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Concluding remarks

- The CPB aims to ensure the safety of LMOs, not to prohibit their trade
- Not all LMOs inherently pose risks to the environment – case by case assessment is needed
- It is important to obtain relevant information and keep abreast with new developments – use the BCH



