Biosafety: Cartagena Protocol

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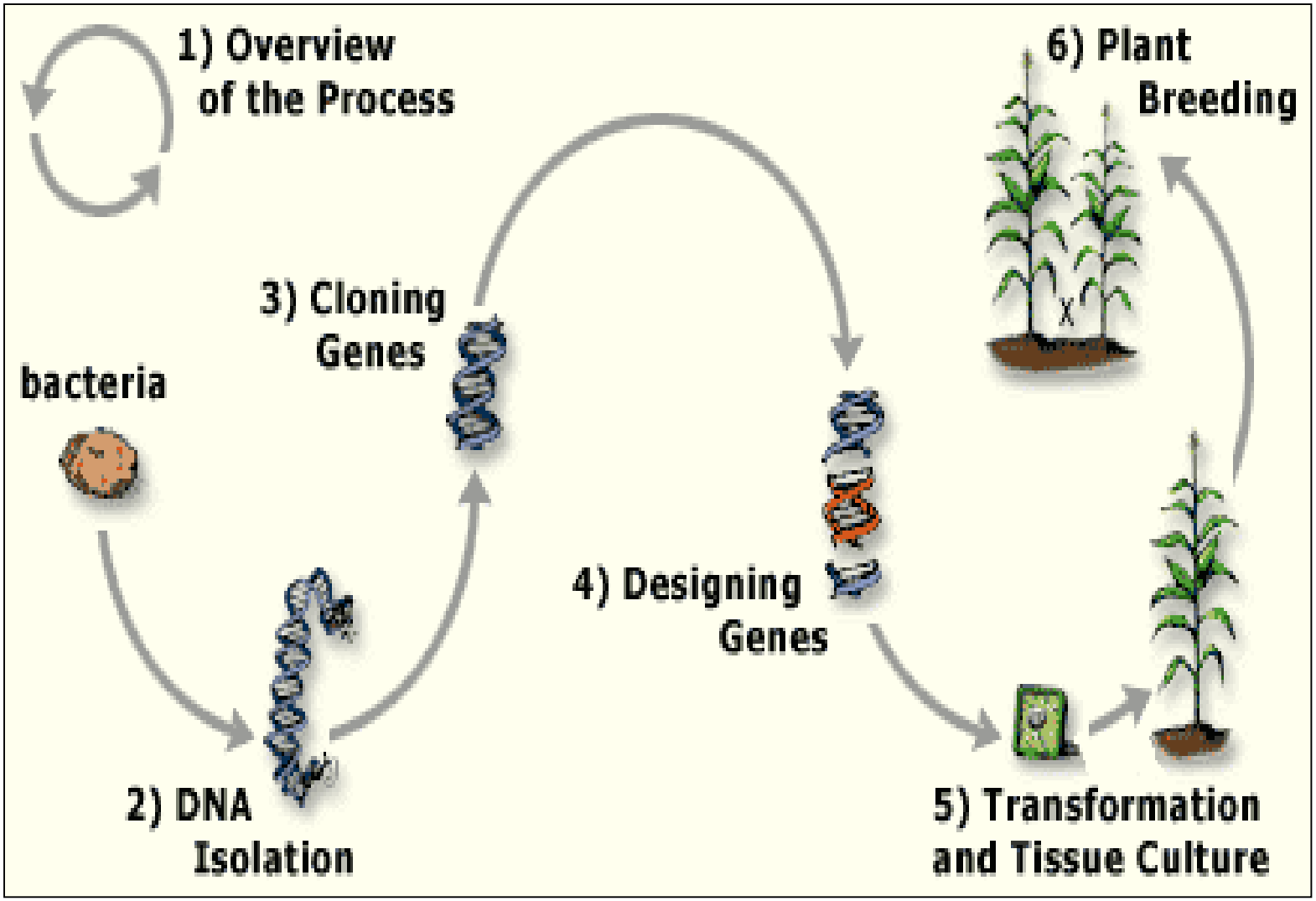
Outline

- Introduction
- Modern biotechnology and GMOs
- Establishing the Cartagena Protocol
- Key provisions of the Protocol
- Linkage with other instruments

What is Biotechnology?

- **Biotechnology uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for a specific use**
- **Genetic engineering is a technique that allows genes and DNA to be transferred from one source to another. It leads to the production of living modified organisms (LMOs)….or GMOs**
- **Modern biotechnology gives scientists molecular tools for obtaining a better understanding of the structure and function of genes in living organisms**

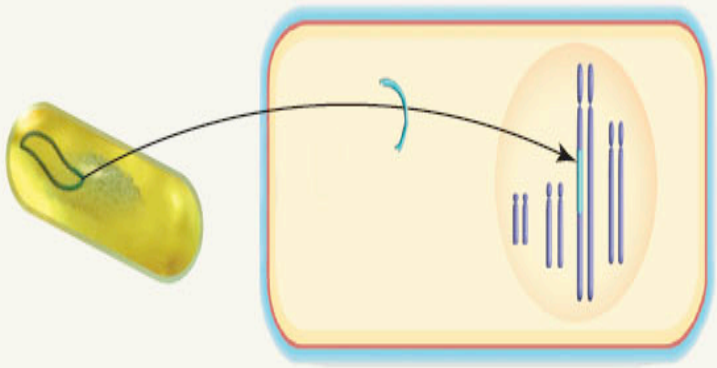
Producing a GM Crop



The Ti Plasmid – a GMO Mechanism

- **Ti plasmid**
  - Plasmid of bacteria *Agrobacterium tumefaciens*
  - Contains tumor-inducing (Ti) genes
  - Used as a vector to transfer foreign or modified genes into plants, including some food crops

Ti Plasmid Transfer Steps

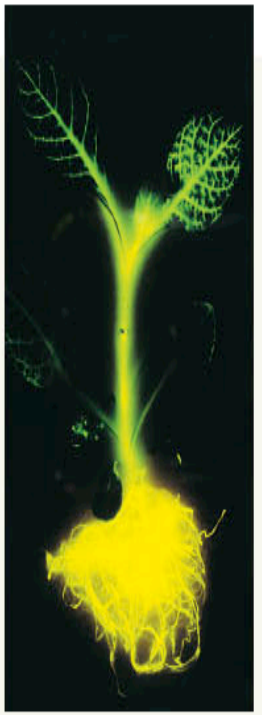


A An *A. tumefaciens* bacterium contains a Ti plasmid that has been engineered to carry a foreign gene.

B The bacterium infects a plant cell and transfers the Ti plasmid into it. The plasmid DNA becomes integrated into one of the plant cell's chromosomes.

C The plant cell divides. Its descendant cells form an embryo, which may develop into a mature plant that can express the foreign gene.

D Transgenic plants



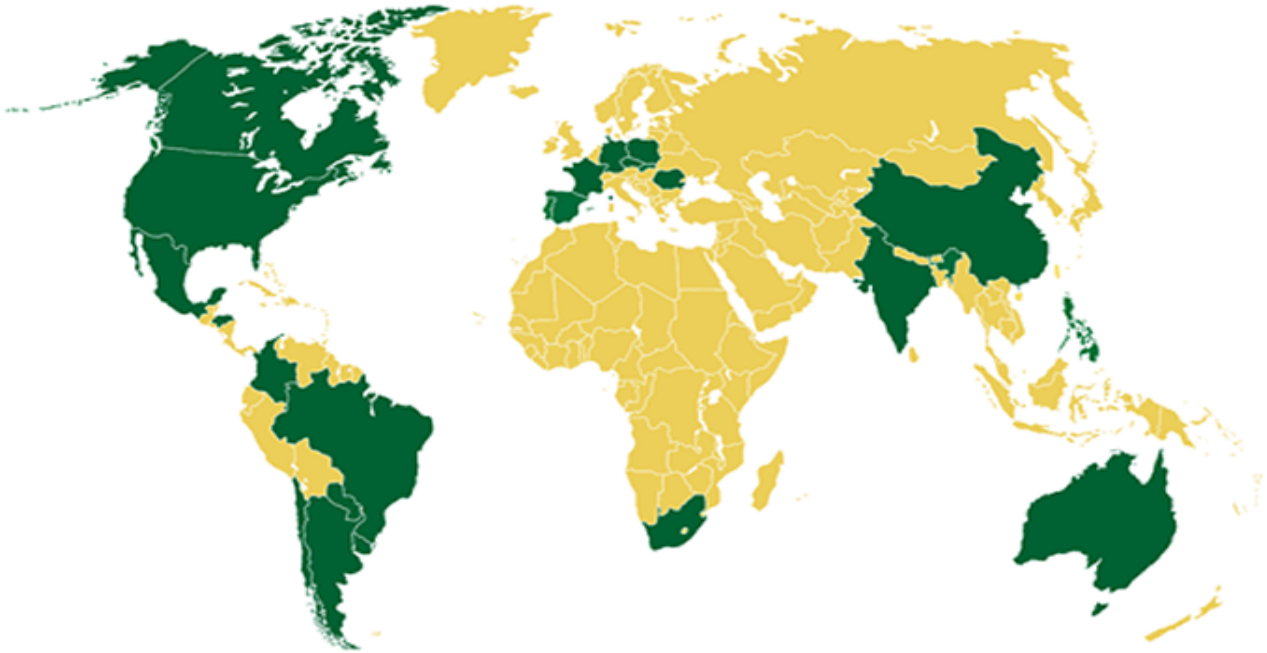
E A young tobacco plant visibly expressing a foreign gene.

Some Available GM Products

Crop	Traits
Maize	Insect resistance, herbicide tolerance
Soybean	Insect resistance, herbicide tolerance
Cotton	Insect resistance, herbicide tolerance
Canola	Modified oil composition, herbicide tolerance
Potato	Virus resistance, insect resistance, higher starch content
Tomato	Insect resistance, longer shelf life
Papaya	Virus resistance
Banana	Virus resistance

Global Area (Million Hectares) of Biotech Crops, 2007: by Country

Global Status of GM Crops in 2007

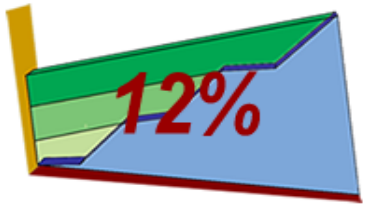


Biotech Mega-Countries

50,000 hectares, or more

USA	57.7 million
Argentina	19.1 million
Brazil	15.0 million
Canada	7.0 million
India	6.2 million
China	3.8 million
Paraguay	2.6 million
South Africa	1.8 million
Uruguay	0.5 million
Philippines	0.3 million
Australia	0.1 million
Spain	0.1 million
Mexico	0.1 million

Increase over 2006



23 countries which have adopted biotech crops

In 2007, global area of biotech crops was 114.3 million hectares, representing an increase of 12% over 2006, equivalent to 12.3 million hectares.

Less than 50,000 hectares

Colombia	Portugal
Chile	Germany
France	Slovakia
Honduras	Romania
Czech Republic	Poland

** Developing countries*

Source: Clive James, 2007

Modern Biotechnology: Promises

- New precision tools and diagnostics
- To speed up breeding gains and efficiency
- To develop pest- and disease-resistant crops
- To combat salinity, drought problems of agriculture
- To enhance the nutritional quality of food
- To increase crop varieties and choice
- To reduce inputs and production costs
- To increase profits

GMOs: Potential Risks and Concerns

- **Health:** Safety of food for humans and livestock
  New allergens, toxins
  Increased resistance to antibiotics

- **Environment:** Impact on biodiversity
  Changes in agricultural inputs
  Gene-flow, gene introgression
  Impact on centers of origin
  Impact on ecosystem

- **Socio-economic:** Lack of access to proprietary technologies
  Food and consumer choice
  Impact on seed sector and on resource-poor farmers

Benefits of GMOs

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

Concerns about 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

Nutritional Diversity

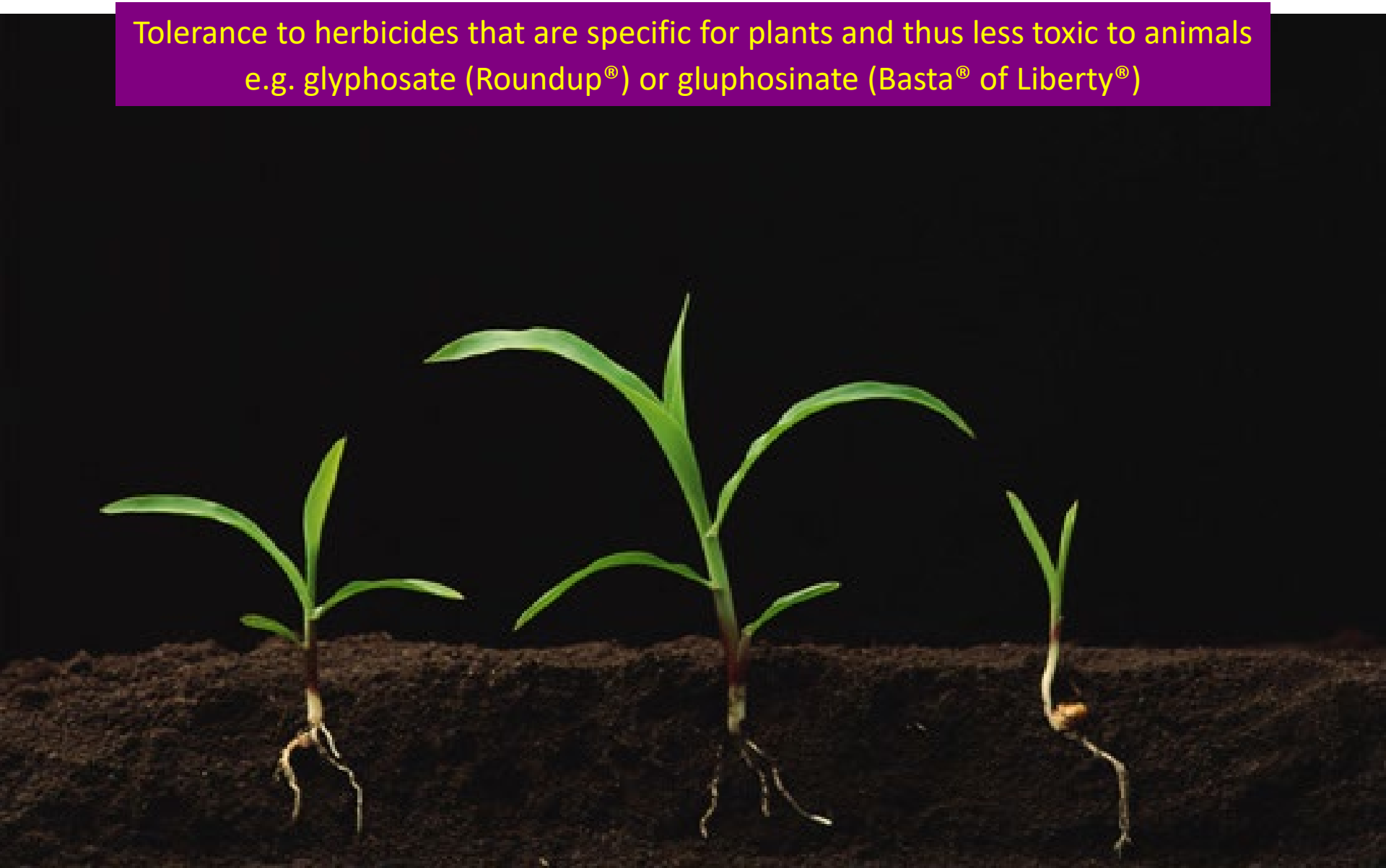
Three billion people live on less than 2 $ per day, 1.5 billion on less than 1 $ per day and cannot afford a diversified diet or industrially produced supplements

Beans	+	+	-	+
Spinach	+	+	+	+
Meat	+	+	Vit A +	-

- Millions are chronically micronutrient malnourished

Case Study: Herbicide tolerant soya or corn or rice

Tolerance to herbicides that are specific for plants and thus less toxic to animals
e.g. glyphosate (Roundup®) or gluphosinate (Basta® of Liberty®)



HT

Roundup ® ready soya (Monsanto)
Glyphosate-tolerant soya

- The herbicide glyphosate blocks EPSP synthase, an enzyme for biosynthesis of aromatic amino acids
- EPSP synthase of Agrobacterium CP4 is relatively insensitive for glyphosate
- Monsanto's transgenic soybean contains :
- P35S - *TP EPSPS Petunia* - EPSPS (CP4) - 3'nos
  Promoter - *localisation* - GENE – terminator
  signal for protein
- This soybean stays as (in)sensitive to other herbicides as non-transgenic soybean, the only change is its tolerance to glyphosate by the intorduction of one gene

Why use it?

- The farmer
  - **Less costs**
  - **simpler**
- The environment
  - **Much less toxic for animals**
  - **10-40% less herbicide needed**
  - **biodegradable**

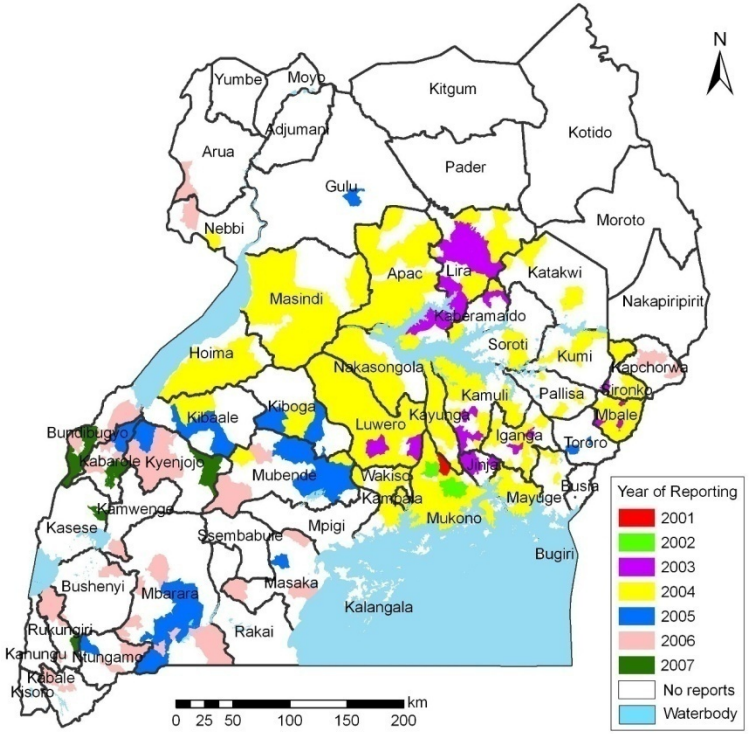
Concerns

- Dependence on chemical herbicides stays in this way of farming
- “superweeds”

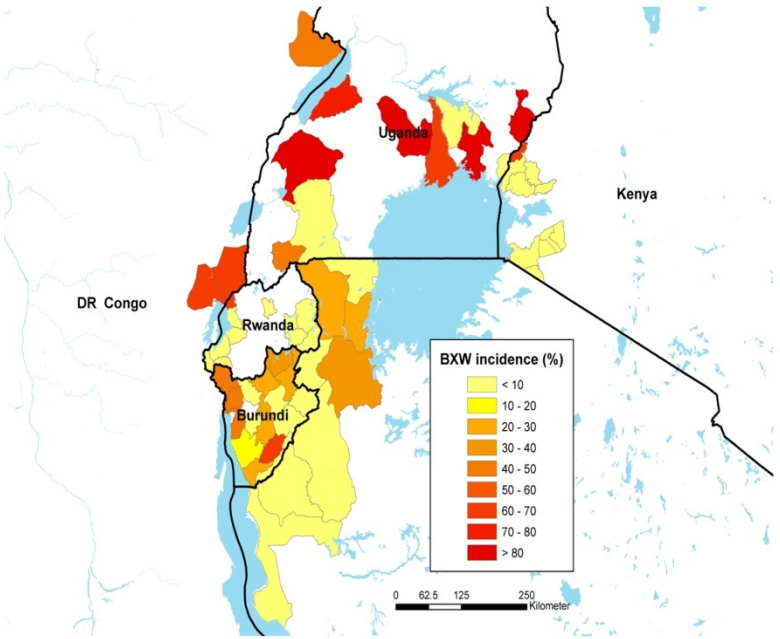
Uncareful use can lead to resistance in weeds (this can also happen in the traditional use of these herbicides or with other herbicides)

Case study- Banana Xanthomonas wilt

• BXW caused by *Xanthomonas campestris* pv. *musacearum* endangers the livelihood of millions of farmers in East Africa.
• First reported in Uganda in 2001.
• The disease has also been reported in DR Congo, Rwanda, Tanzania, Kenya and Burundi.



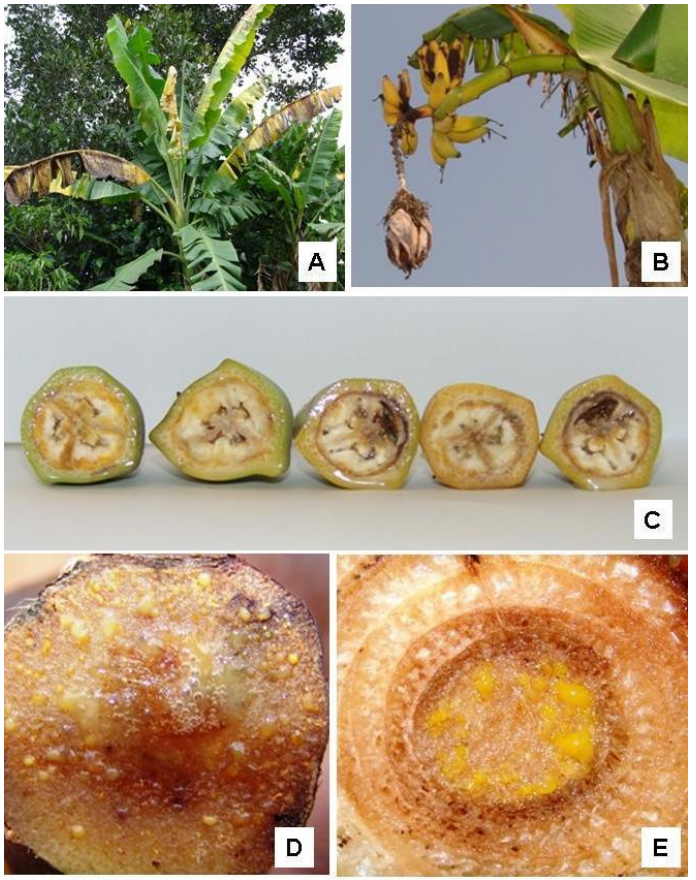
Source: Tushemereirwe *et al*. 2006



Source: Bouwmeester *et al*. 2008

Xanthomonas Wilt

- The disease affects almost all commonly grown banana cultivars.
- The impacts of BXW are both extreme and rapid.



Biruma *et al.* 2007

Tripathi *et al.* 2009

Enhanced resistance against virulent pathogens in transgenic crops

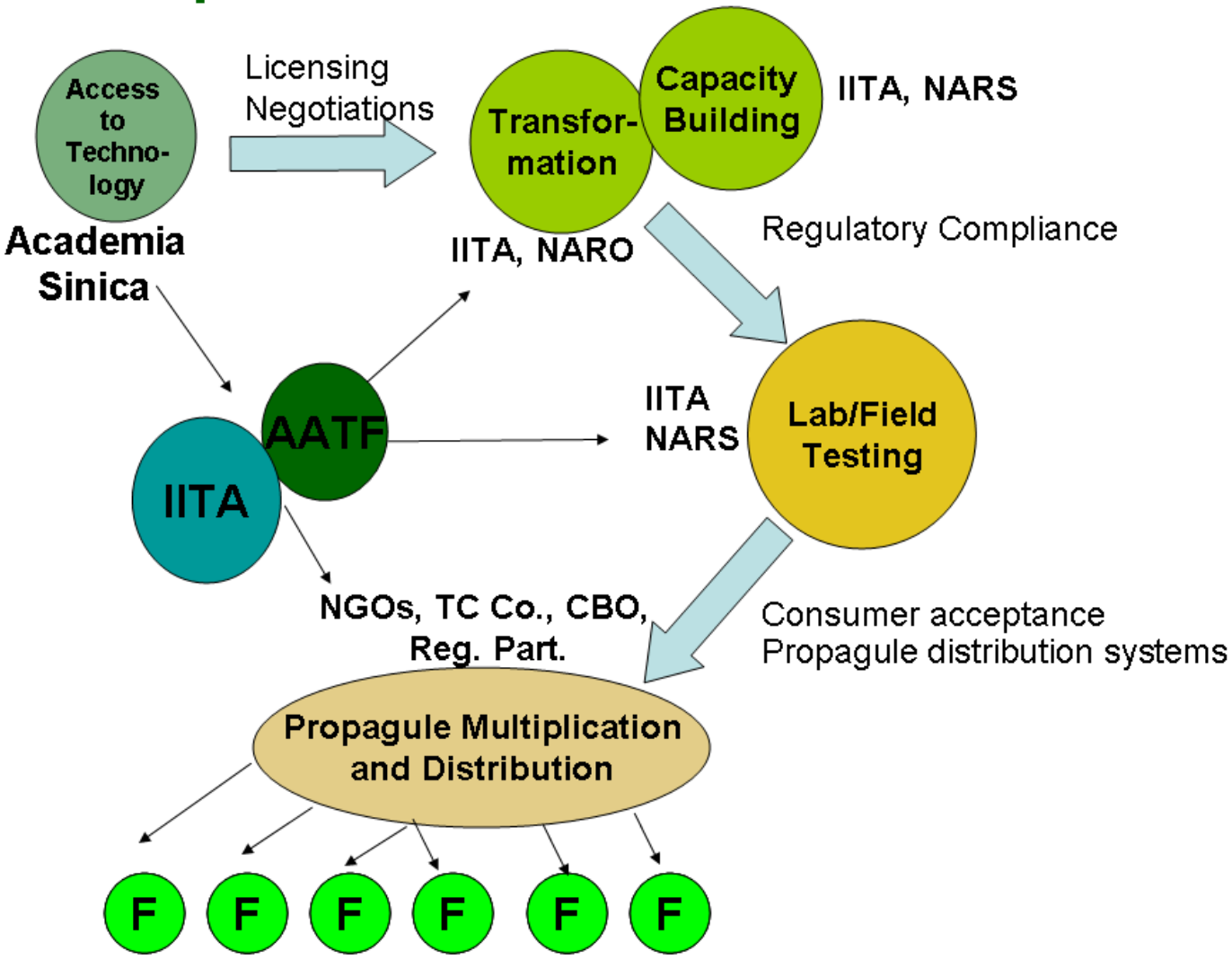
Crops	Transgene	Disease resistance	Pathogen
Tobacco	*hrap* *pflp*	Wild fire Soft rot Gray mold	*Pseudomonas* *Erwinia* *Botrytis*
Arabidopsis	*hrap* *pflp*	Soft rot	*Erwinia*
Broccoli	*pflp*	Soft rot	*Erwinia*
Orchids, Calla	*pflp*	Soft rot	*Erwinia*
Rice	*pflp*	Leaf Blight	*Xanthomonas*
Tomato Potato	*pflp* *hrap*	Soft rot Bacterial wilt	*Erwinia* *Ralstonia*

Source: TY Feng

Access to technology

- Identify possible candidate genes in 2004 from literature search.
- Established research collaboration with Progessor Feng of Academia Sinica and received the construct in 2005 informally. The institute was in the process of patenting in Taiwan.
- Received research use license agreement but inadequate so approached AATF to help gain humanitarian use licence.
- AATF signed licence with Academia Sinica and provided sub-licensing to IITA in 2006.
- Transformation is in progress by IITA in collaboration with NARO and IITA/NARO/AATF signed tripartite agreement for product development.

Development of a BXW-Resistant Banana



Background to the Convention on Biological Diversity and the Cartagena Protocol on Biosafety

- 1962 Rachel Carson's SILENT SPRING
- 1972 UN Conference on the Human Environment organized in Stockholm, Sweden (The Stockholm Conference)
- 1981 IUCN began drafting the "Convention on Biological Diversity"
- 1987 UN World Commission on Environment and Development (The concept of Sustainable Development initiated)
- December 1989 UN General Assembly (UNGA) called for a meeting of all the nations on earth to deal with the problems and resolutions on matters related to the environment and development ("An Earth Summit")

Establishing the Cartagena Protocol

- UNCED Earth Summit, June 1992
  - Agenda 21, Chapter 16
    - Action plan on biotechnology
  - Rio Declaration on Environment and Development
    - Principle 15: Precautionary approach: ***Where there are threats of serious or irreversible damage, lack of full scientific certainty is not a reason for postponing cost-effective measures to prevent environmental degradation.***
- Convention on Biological Diversity (CBD)
  - Objectives: Conservation, sustainable use, fair & equitable sharing of benefits
  - Technology critical for realization of objectives of Convention (Art. 16.1)
  - 'Establish or maintain means to regulate, manage or control the risks…' Article 8(g)

Convention on Biological Diversity
(CBD)

(Conservation of Biological Diversity, Sustainable Use of Its Components and Fair and Equitable Sharing of the Benefit Arising out of the utilization of Genetic Resources)

Article 19 - Handling of Biotechnology and Distribution of Its Benefits

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

Establishing the Cartagena Protocol (contd.)

- Protocol negotiations (Decision II/5 - six BSWG sessions)
  - Binding international instrument separate from but related to another treaty through substantive, procedural & institutional links
  - Must be individually negotiated, signed & ratified
  - Parties to Protocol must also be parties to the parent treaty
- Adopted 29 January 2000
- Entered into force on 11 September 2003
- Governing body is COP-MOP
- 1st COP-MOP held in Kuala Lumpur in February 2004

Cartagena Protocol on Biosafety

International Legally Binding Agreement Under the CBD

(Ensuring an Adequate Level of Protection in the Field of the Safe Transfer, Handling and Use of Living Modified Organisms (LMOs) Resulting from Modern Biotechnology (Genetic Engineering) 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)

Conferences of the Parties
(COPs)

Conference of the Parties to the Convention on Biological Diversity (COP) Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety
(COP/MOP)

Open Ended AD Hoc Working Group on Biosafety
(BSWG)

and

Intergovernmental Committee for the Cartagena Protocol on Biosafety
(ICCP)

Cartagena Protocol on Biosafety Negotiating Groups:

- European Union (EU)
- Central and Eastern European Group (CEE)
- Miami Group (Argentina, Australia, Canada, Chile, United States, Uruguay)
- Like-minded Group (most developing countries)
- Compromise Group (Japan, Mexico, Norway, Republic of Korea and

  Switzerland, later New Zealand and Singapore joined)

Key Elements of the Protocol

- Objective and scope
- Advance informed agreement (AIA)
- LMO-(Living Modified Organism)
- Risk assessment and management
- Identification of LMOs (labeling)
- Information sharing; Biosafety Clearing House
- Capacity building
- Socio-economic considerations
- Liability and redress
- Compliance

Main Pillars of the Protocol

Adapted from P.Kameri-Mbote, 2004

Article 1. Objective

In accordance with the precautionary approach contained in Principle 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 Protocol

- Article 4 – "…the transboundary movement, transit, handling and use of all living modified organisms (LMOs) …"
- Article 5 – "…this Protocol shall not apply to … (LMOs) which are pharmaceuticals for humans …"
- Article 6
  - Paragraph 1 – "… the advance informed agreement procedure shall not apply to (LMOs) in transit."
    - Example – transgenic yeast for food processing being sent from Spain to Guatemala but passing through Mexico.
  - Paragraph 2 – "… shall not apply to (LMOs) destined for contained use undertaken in accordance with the standards of the Party of import."
    - Example – transgenic cassava sent from Colombia to Costa Rica for field trials

Article 3 Definitions

(g) "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

(i) "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;

Advanced Informed Agreement

- Differentiated procedures for LMOs for intentional introduction into the environment and LMOs for direct use as food, feed or for processing (LMO-FFPs)
- AIA=Prior Informed Consent (PIC)
  - For first movement of LMOs for intentional introduction into environment
  - Exporter must provide detailed information in advance of first shipment
  - Importer may then authorize/refuse shipment, depending on RA
- AIA Procedure (Articles 7-10, 12):
  - Notification
  - Acknowledgement by importer (90 days)
  - Decision procedure and review of decisions

Living Modified Organisms Transboundary Movement

- Art. 7 – "… first intentional transboundary movement of (LMOs) for intentional introduction into the environment …"
- Advance Informed Agreement Procedure
  - Art. 8 – Notification through detailed written information to importing nation
  - Art. 9 – Acknowledgement by importing nation
    - 90 days to acknowledge receipt of notification
    - Proceed to Art. 10 decision procedure; or
    - Use domestic regulatory framework consistent with Protocol

Article 7. Application of the Advance Informed Agreement Procedure

1. ...the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.
2. "Intentional introduction into the environment" ...does not refer to LMOs intended for direct use as food or feed, or for processing.

....

4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of LMOs 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.

Decision Procedure

- Importer asks exporter to do a risk assessment
  - The onus is on the Party of export to establish the harmless nature of the LMO in question
- Importer submits risk assessment
- Importer communicates decision (+ reasons) to exporter & BCH in **270 days**
  - To exporter & the BCH:

    i) approval with or without conditions

    ii) prohibition/refusal

    iii) request for additional information or

    iv) extension of decision-making period beyond the 270 days
- Importer may review/change its decision in light of new information
- Exporter may also request a review

Risk Assessment & Risk Management

- Risk Assessment
  - Identification of potential environmental adverse effects or hazards, and determining, when a hazard is identified, the probability of it occurring
  - In accordance with principles, methodologies & details in Annex III
  - Identify/evaluate potential adverse effects—scientifically, case by case
  - Minimum information, Annex 1: Ensured by importer, cost by exporter
  - Lack of knowledge, not lack of risk
- Risk Management
  - Methods applied to minimize potential hazards or adverse effects identified by the assessment
  - Measures to manage and control risks
  - Prevent unintentional LMO movement
  - Ensure LMOs are observed for an appropriate period before use

Handling, Transport, Packaging & Identification

- Shipments of different categories of LMOs will be accompanied by documentation with varying details:
  - *LMO-FFPs:* will identify them as 'may contain' LMOs, not intended for introduction into the environment and contact details of consignee (details to be defined by COP-MOP)
  - *Contained use:* clearly identifies them as LMOs, specifies conditions for safe handling, storage/use and contact details of consignee
  - *For introduction into environment:* clearly identifies them as LMOs, specifies the identity and relevant traits and/or characteristics, along with any requirements for their safe handling, storage, transport and use, contact information and declaration that the movement conforms to the requirements of the Protocol

Information Sharing

Article 20 establishes a Biosafety Clearing House (BCH)

- To facilitate information exchange on LMOs: scientific, technical, environmental and legal information and experience
- To assist Parties in implementing the Protocol
- BCH will contain:
  - National laws, regulations, guidelines
  - Bilateral, regional, multilateral agreements
  - Risk-assessment summaries
  - Final decisions on importation or release
  - Reports

Unintentional Transboundary Movement of LMOs

- Article 17: calls for responses and necessary actions when there is unintentional transboundary movement of LMOs that are likely to have significant adverse effects on biological diversity including emergency measures in the event of such an event.

- Article 27 : Asks to adopt an appropriate process for liability and redress for damages from international movement of LMOs.

Capacity Building

- Recognition of need & dearth of capacity, especially in developing countries
- Technological/institutional capabilities
- Regulatory capacity
- Training in safe management of biotechnology, risk assessment and risk management
- Roster of experts
- Capacity-building action plan

Article 26: Socio-economic considerations

Decision BS-II/12

1. *Invites* Parties and other Governments to continue to cooperate within relevant processes under other organizations and arrangements on socio-economic considerations: cooperation on research and information exchange (UNEP/CBD/BS/COP-MOP/2/12), which deal with socio-economic impacts of living modified organisms;
2. *Urges* Parties, other Governments and relevant organizations to provide more emphasis to research on socio-economic impacts of living modified organisms (LMOs) and to allocate resources for that purpose;
3. *Invites* Parties, other Governments and organizations with research activities related to socio-economic impacts of LMOs arising from the impacts of these organisms on the conservation and sustainable use of biological diversity, to share information with other on their research methods and results, both positive and negative;

Article 26: Socio-economic considerations

Decision BS-II/12

4. *Further invites* Parties and other Governments to share, through the Biosafety Clearing-House, their information and experiences in taking into account socio-economic impacts including experiences in implementing the Akwé:Kon Voluntary Guidelines;

5. *Requests* Parties, other Governments and relevant international organizations to provide to the Executive Secretary their views and case-studies, where available, concerning socio-economic impacts of living modified organisms;

Article 26: Socio-economic considerations

- Article 26 establishes the right of Parties to take into account socio-economic considerations arising from the impact of living modified organisms in reaching a decision on whether to import these organisms, especially with regard to the value of biological diversity to indigenous and local communities. However, when Parties are taking into account such considerations, they are at the same time required to ensure that the decision is consistent with their other international obligations.

- Article 26: Socio-economic considerations
- Paragraph 2 of Article 26 calls upon Parties to cooperate on research and information exchange on socio-economic impacts of LMOs, especially on indigenous and local communities. In accordance with the medium term programme of work adopted by the first meeting of the COP-MOP (decision BS-I/12). COP-MOP 2 requested Parties and other Governments to provide their views and case studies concerning socio-economic impacts of LMOs. It also invited Parties and other Governments to share information and experiences on socio-economic impacts of LMOs through the BCH.

Article 23: Public awareness and participation

- Article 23 requires to promote and facilitate public awareness and education, including access to information, regarding the safe transfer, handling and use of living modified organisms (LMOs). It also requires Parties to consult the public in the decision-making process, to make public the final decision taken and to inform public about the means of access to the Biosafety Clearing-House.
- Public awareness, education and participation are fundamental elements for the effective implementation of the Protocol. It is important for the public to know and understand the issues and processes related to LMOs and to have access to relevant information in order to make informed choices and actions, and to be able to participate effectively in the decision-making processes.


BIODIVERSIDADE '
BASE DA NOSSA SOBERANIA
ALIMENTAR
BIODIVERSITY
BASE OF OUR FOOD SAFETY
GMO
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NÃO CONTAMINE
NOSSA BIODIVERSIDADE
DONT CONTAMINA
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NÃO PRECISAMOS
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WE DON'T NEED
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Article 27: Liability and Redress

- The issue of liability and redress for damage resulting from the transboundary movements of LMOs was one of the themes on the agenda during the negotiation of the Biosafety Protocol. The negotiators were, however, unable to reach any consensus regarding the details of a liability regime under the Protocol.
- Accordingly, COP-MOP-1 established an Open-ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress to fulfil the mandate under Article 27.

- Article 27: Liability and Redress
- The first meeting of the Ad Hoc Group on Liability and Redress took place from 25 to 27 May 2005 in Montreal, Canada
- The second meeting of the Working Group on Liability and Redress was held from 20-24 February 2006 in Montreal, Canada. At this meeting, the Working Group developed an indicative list of criteria for the assessment of the effectiveness of any rules and procedures referred to in Article 27
- The Working Group developed different options for operational text on scope, damage and causation. The outcome of these deliberations is contained in annex to document UNEP/CBD/BS/COP-MOP/3/10

- Article 27: Liability and Redress
- The third meeting considered a blueprint for a COP-MOP decision on international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms.
- The Working Group discussed a synthesis of proposed operational texts on approaches, options and issues identified pertaining to liability and redress in the context of Art. 27 of the Biosafety Protocol.

General Obligations

- Before entry into force, Parties were required to
  - Designate national focal points
  - Avail BCH contact point for receiving notifications under Art.17: unintentional LMOs
- After entry into force
  - Put in place legal, administrative and other measures to implement Protocol obligations
  - Ensure the development, handling, transport, use, transfer and release of any LMOs prevents risks to biodiversity
  - Make available through the BCH copies of any laws, regulations and guidelines applicable to the import of LMO-FFPs

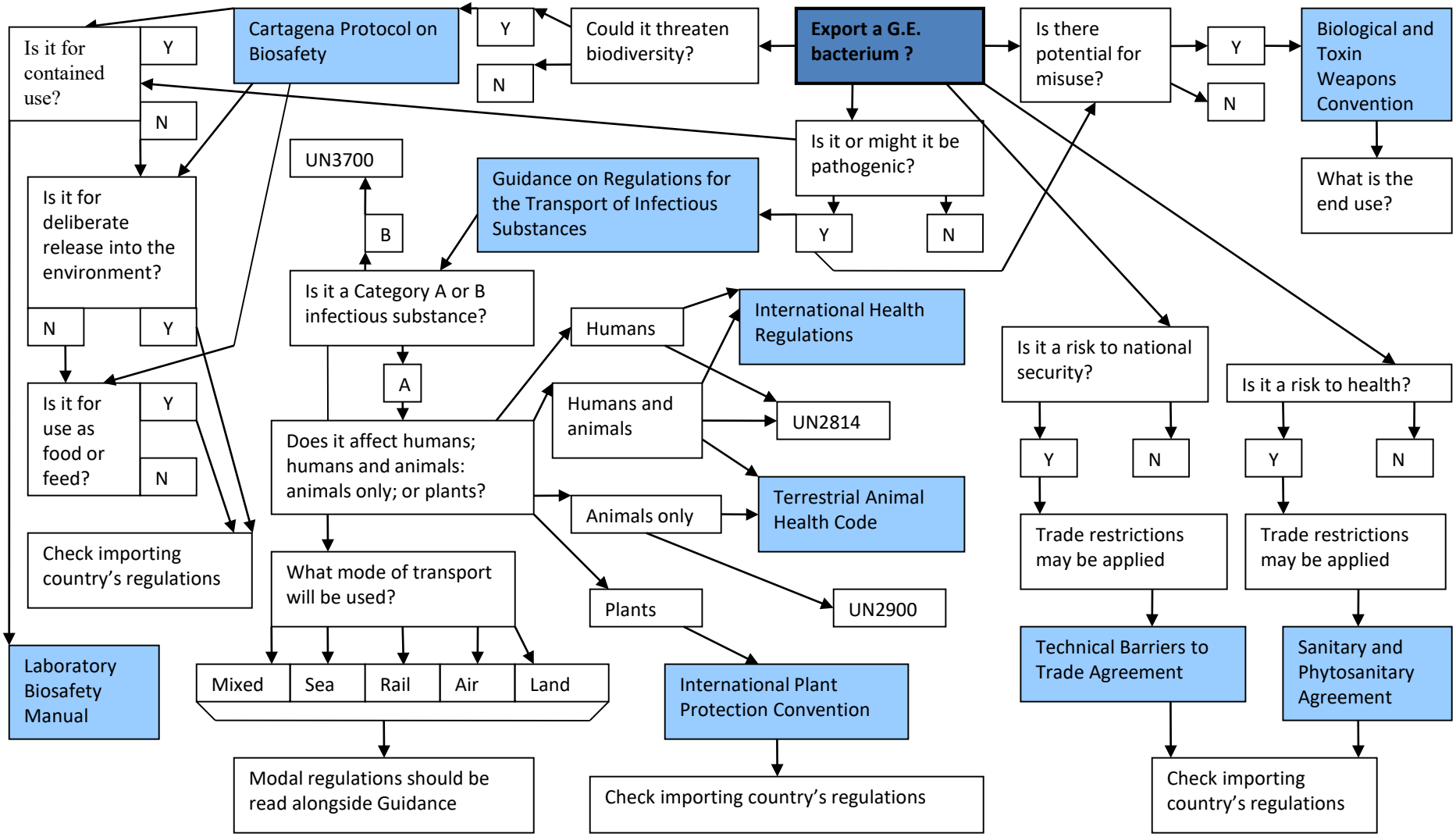
Management of GMOs in Genebanks

- The Protocol has no specific provisions for management of GMOs in a genebank.
- It is likely, that national genebanks will adopt and follow the national policy and procedures on GMOs (LMOs), in case of any transboundary movement or storage of such material in genebanks.
- Access to information, adequate risk analysis procedures and good management practices will be essential for PGR managers.

LMOs and Other Regulatory Instruments

- IPPC
- WTO Regimes: SPS and TBT
- Link with Cartagena Protocol

2. Complexity of decision whether to export a genetically engineered bacterium



International Plant Protection Convention (IPPC)

- Regulates plant pests, Secures action to prevent the spread and introduction of pests of plants and plant products; and promote appropriate measures for their control
- Formalizes procedures for standard setting such as pest risk analysis to support phytosanitary measures, the designation of pest free areas and the phytosanitary security of export consignments after certification
- Develops International Standards on Phytosanitary Measures (ISPM) which shape the measures under the Sanitary and Phytosanitary Standards Agreement of the WTO
- Scope includes living modified organisms/products of modern biotechnology that may directly or indirectly damage plants, which requires cooperation with the CBD and Cartagena Protocol

More info:https://www.ippc.int/IPP/En/default.jsp

ISPM No. 11:

Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms

- Provides details for the risk assessment and selection of risk management options
- Takes into account risks to the environment and biological diversity (including from weeds and invasive plants)
- Includes guidance on evaluating potential phytosanitary risks to plants and plant products posed by living modified organisms (LMOs)

WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)

- Allows countries to set their own standards, to the extent necessary to protect human, animal or plant life or health.
- All SPS measures and regulations must be based on science-based risk assessment.
- Encourages Members to use international standards, guidelines and recommendations like ISPMs.
- Complements the Agreement on Technical Barriers to Trade

More info: http://www.wto.org/english/tratop_e/sps_e/sps_e.htm

WTO Agreement on Technical Barriers to Trade (TBT Agreement)

- Recognizes countries' rights to adopt the standards they consider appropriate —for human, animal or plant life or health, for the protection of the environment or to meet other consumer interests.
- Ensures that regulations, standards, testing and certification procedures do not create unnecessary trade obstacles.
- Does NOT prevent Members from taking measures necessary to ensure their standards are met.
- Requires that all Members establish national enquiry points to help ensure that necessary information is made available conveniently.
- http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm

Linkage with Cartagena Protocol

- Cartagena Protocol is not subordinate to other international agreements but recognises that trade and environment agreements should be mutually supportive.
- IPPC sets standards for WTO-SPS TBT agreements. It also coordinates with the Cartagena Protocol on matters related to LMOs as pests.
- While there are no direct links, issues arising from transboundary movement of LMOs, and international trade, like liability and redress will need to be addressed in the future.

Control of plant gene expression, US Patent, 5,723,765

registered in 1998 by the United States Department of Agriculture ('USDA') and the Delta & Pine Land Company.

- A method for making a genetically modified plant comprising regenerating a whole plant from a plant cell that has been transfected with DNA sequences comprising a first gene whose expression results in an altered plant phenotype linked to a transiently active promoter, the gene and promoter being separated by a blocking sequence flanked on either side by specific excision sequences, a second gene that encodes a recombinase specific for the specific excision sequences linked to a repressible promoter, and a third gene that encodes the repressor specific for the repressible promoter.

Genetic Use Restriction Technology (GURT)

(i) v-GURTs, where the use of a crop variety is controlled through genetically induced seed sterility;

(ii) t-GURTs, where the use of a trait such as disease resistance or early ripening is controlled.

GURTs use ‘a chemical sensitive genetic switch’ (responsive, for example, to alcohol or the antibiotic tetracycline) linked to a gene for an enzyme which activates a toxin gene. In the t-GURT system when the toxin gene is switched on, it becomes active in the late stage of seed formation to prevent it germinating.

Advantages of GURTS

for seed companies to prevent seed-saving (it overcomes the cost, expenditure of time and unpredictability of patent litigation)

Kojo Yelpaala, 'Owning the Secret of Life: Biotechnology and Property Rights Revisited' (2000) 32 McGeorge L. Rev. 111, at 172.

Reducing the possibility of genetic pollution from GMOs

Committee on Genetically Modified Pest-Protected Plants, National Research Council, *Genetically Modified Pest-Protected Plants: Science and Regulation (Washington, DC: National Academy Press, 2000) at 90.*

Disadvantages of GURTs

- Environmental effects – “genetic pollution”
- Economic effects – seed saving no longer a possibility
- Morality issues - Article 27.2 of TRIPS Agreement provides for the exclusion ‘from patentability inventions, the prevention within their territory of the commercial exploitation which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment …’.

Conference of Parties, VIII, Convention on Biological Diversity, 2006

in the current absence of reliable data on genetic use restriction technologies, without which there is an inadequate basis on which to assess their potential risks, and in accordance with the precautionary approach, products incorporating such technologies should not be approved by Parties for field testing until appropriate scientific data can justify such testing, and for commercial use until appropriate, authorized and strictly controlled scientific assessments with regard to, inter alia, their ecological and socio-economic impacts and any adverse effects for biological diversity, food security and human health have been carried out in a transparent manner and the conditions for their safe and beneficial use validated.

- D. J. F. Eaton & F. W. van Tongeren, 'Genetic Use Restriction Technologies (GURTs): Potential Economic Impacts at National and International Levels,' Report submitted by the Hague Agricultural Economics Research Institute in 2001, 6.02.01 <http://www.lei.dlo.nl/publicaties/PDF/2002/6_xxx/6_02_01.pdf>.
- M. Blakeney, 'Terminator' Technology: A Technological Fix for an IP Problem?' (2004/05) 7 *Bio-Science Law Review* 229.
- M. Blakeney, *Intellectual Property Rights and Food Security,*, CAB International, 2009.