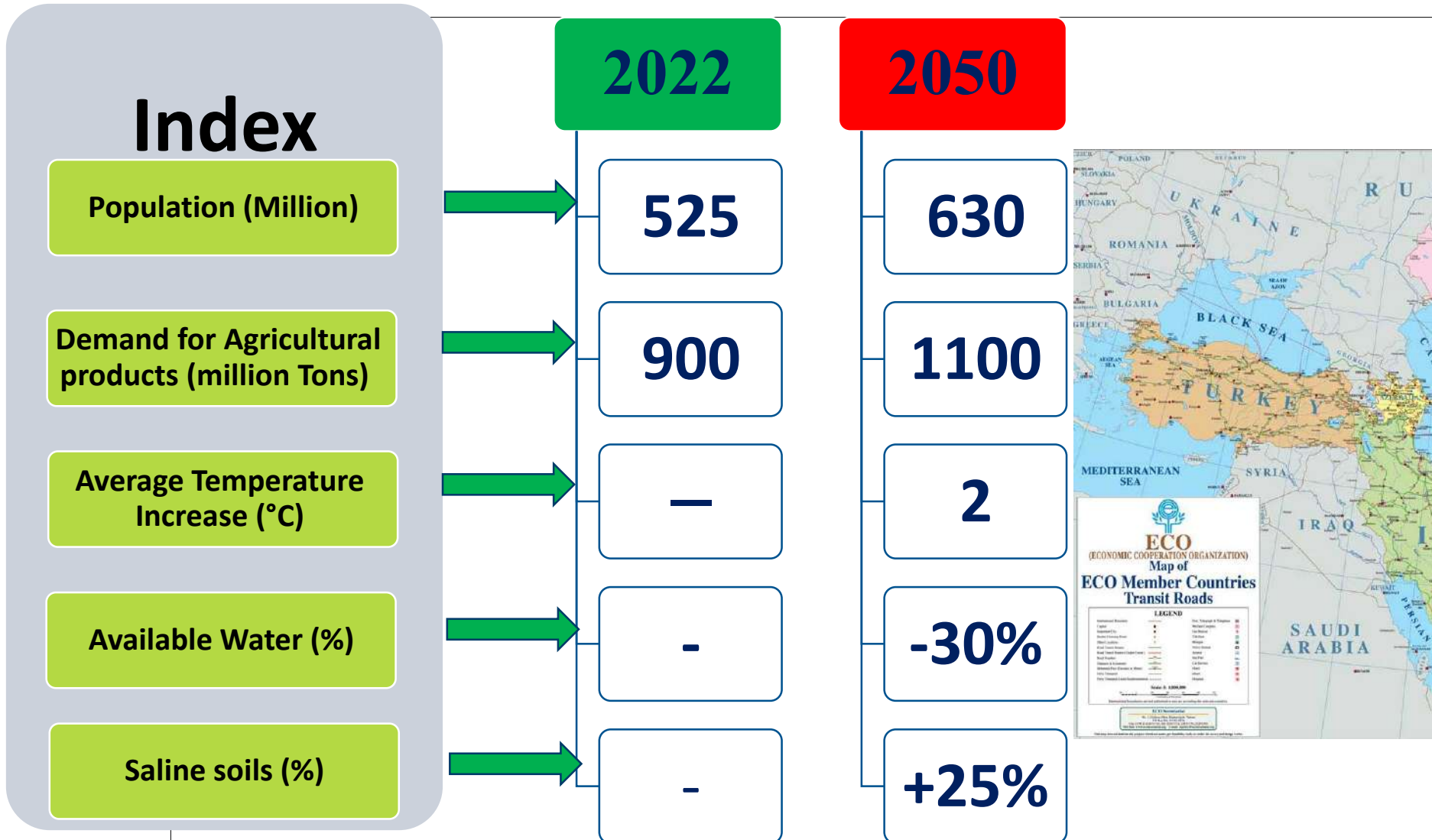


GMO Bio-Safety Regulations: Similarities and "Differences"

Gholamreza Salehi Jouzani

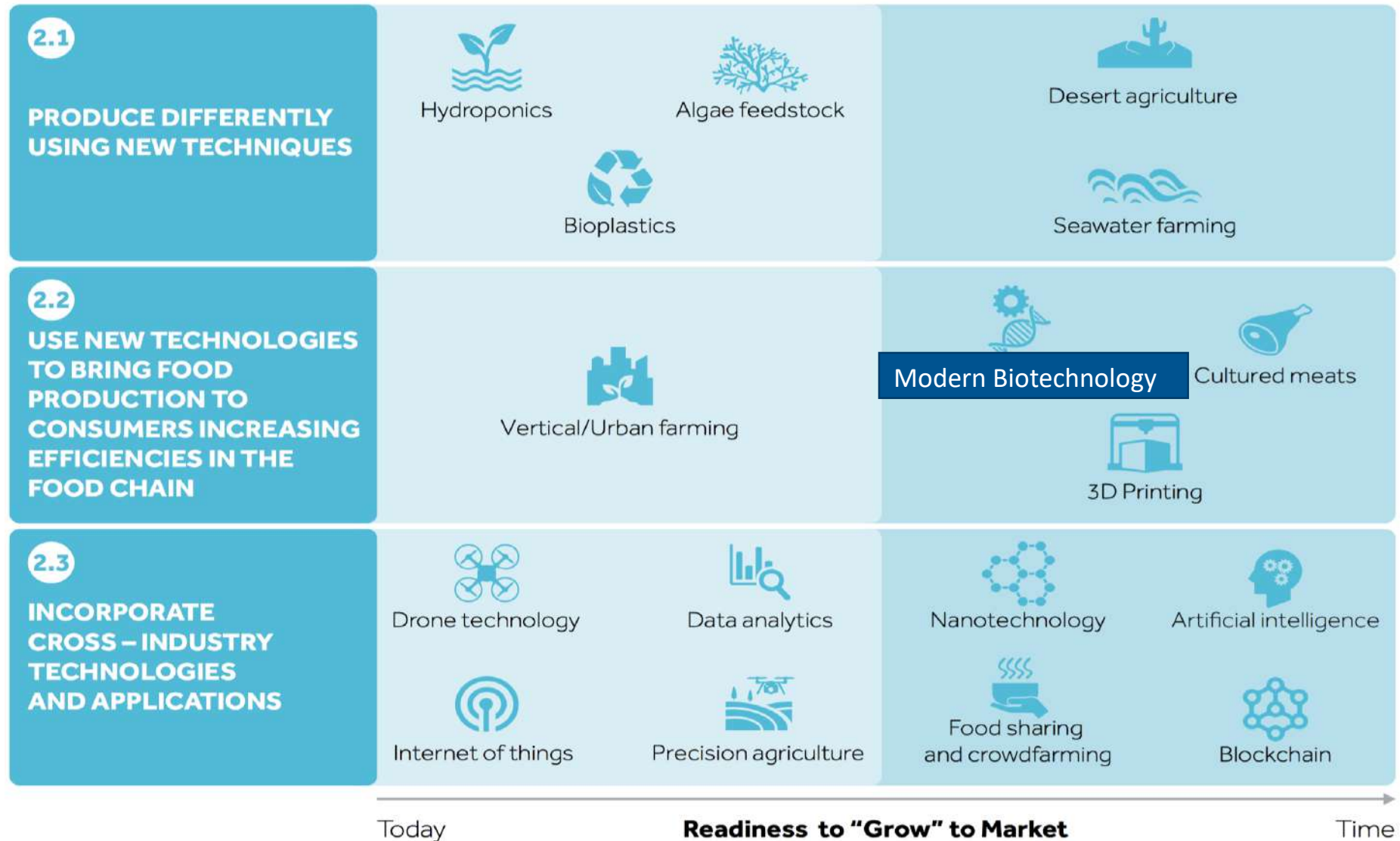
Microbial Biotechnology Research Department
Agricultural Biotechnology Research Institute of Iran
gsalehi@abrii.ac.ir

Current Situation and Future of Agriculture and Climate Change in the ECO Countries

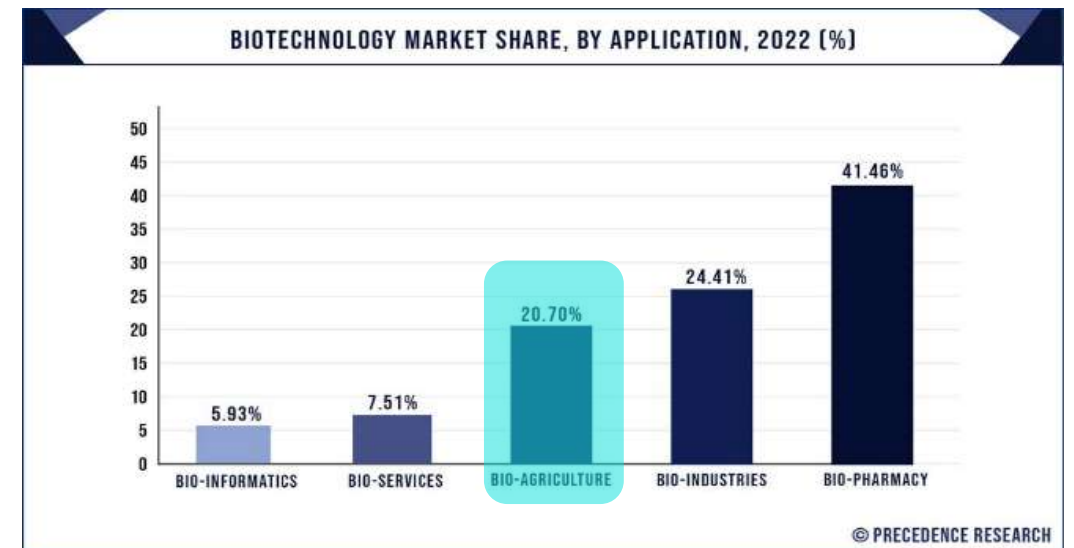
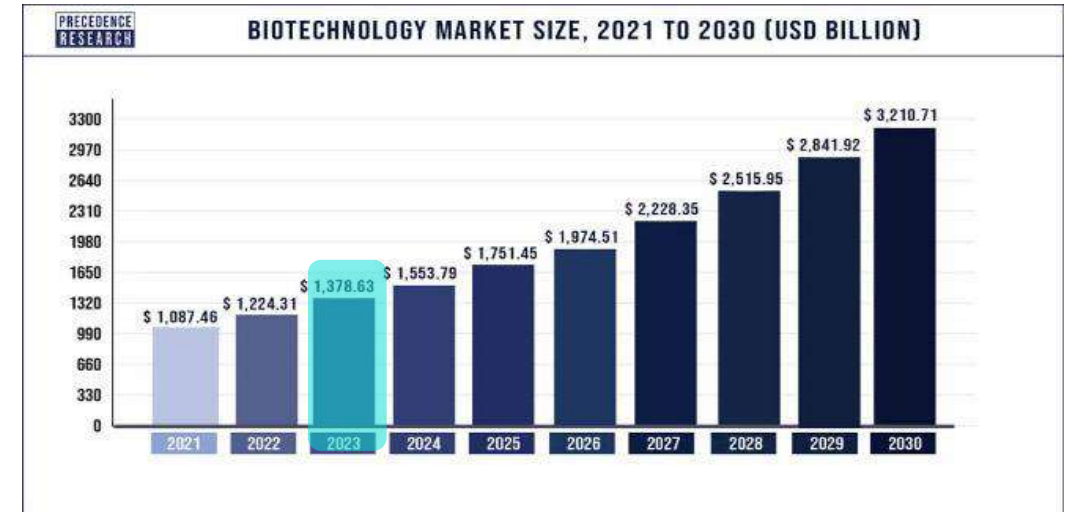
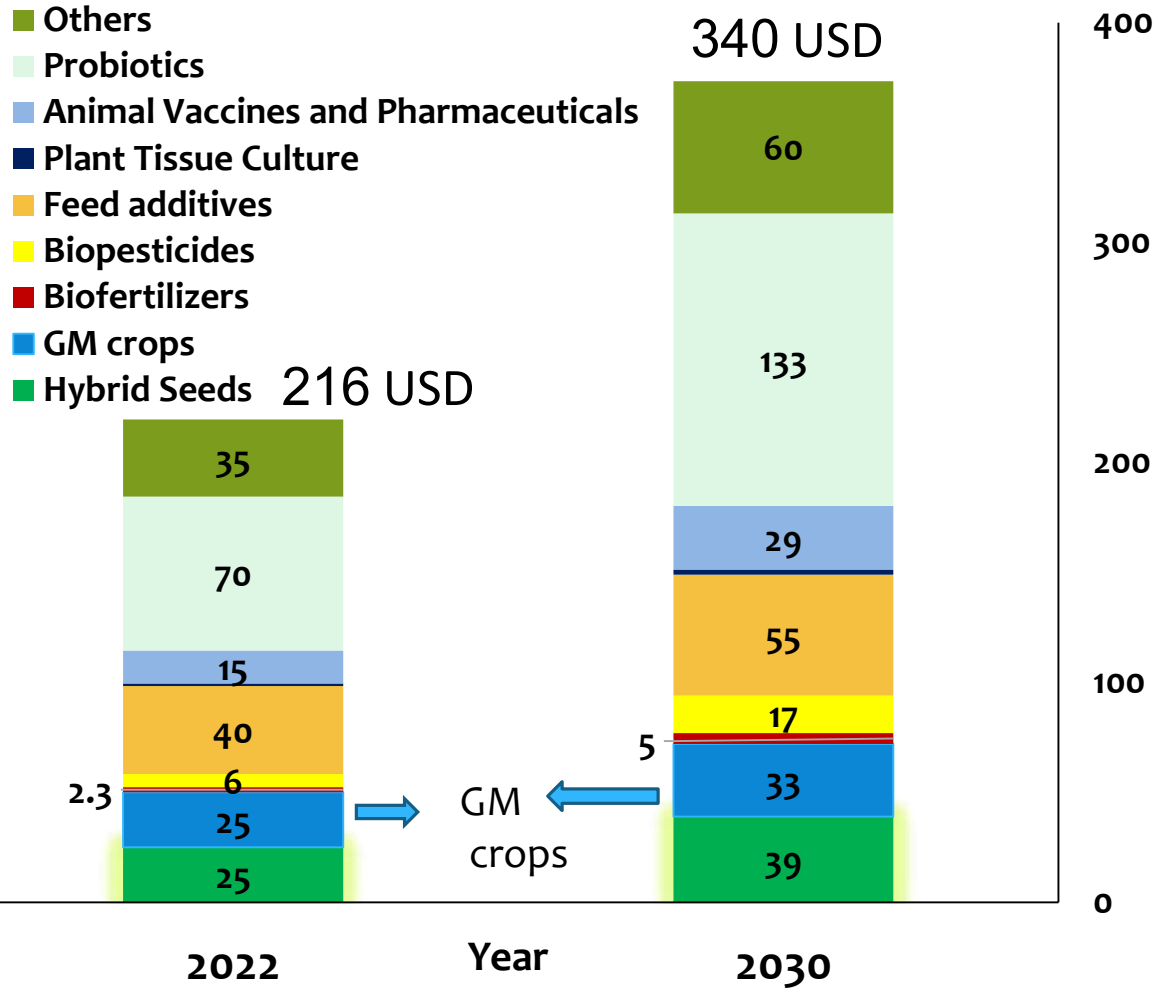


Future Technologies in Agriculture-2050

MAP OF TECHNOLOGIES AND MATURITY



Role of Agricultural Biotechnology in Food Security



The Global status of commercialization of GM crops

GM Crop Area by Leading Country

Rank	Country	GM Area (Ha m.)
1	USA	74.7
2	Brazil	63.2
3	Argentina	23.5
4	India	12.4
5	Canada	11.3
6	Paraguay	3.7
7	South Africa	3.2
8	China	2.9
9	Pakistan	1.7
10	Australia	1.5
Na	Others	4.2
Total		202.2

Global GM Crop Area by Crop

Crop	GM Area (Ha m.)
Alfalfa	1.1
Brinjal	0.03
→ Canola	9.9
→ Cotton	25.4
→ Maize	66.2
Rice	0.02
→ Soybean	98.9
Sugar beet	0.5
Sugarcane	0.1
Wheat	0.1
Total	202.2



Proposed Risks of GMOs

■ Health

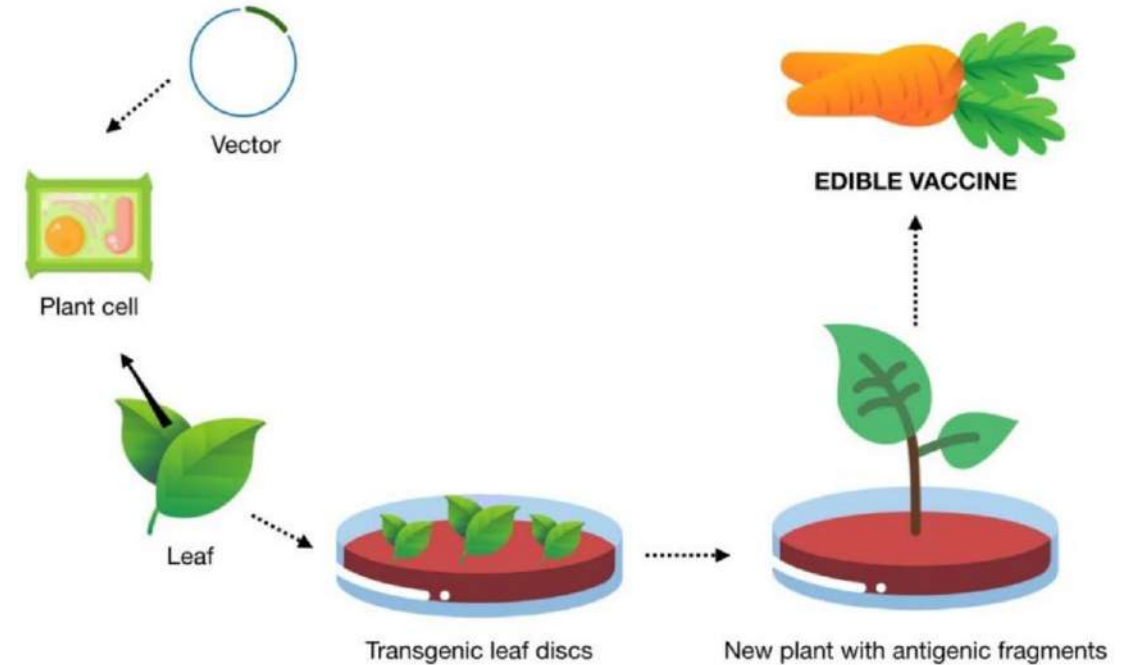
■ Economic

■ Ethical Concerns

■ Environmental

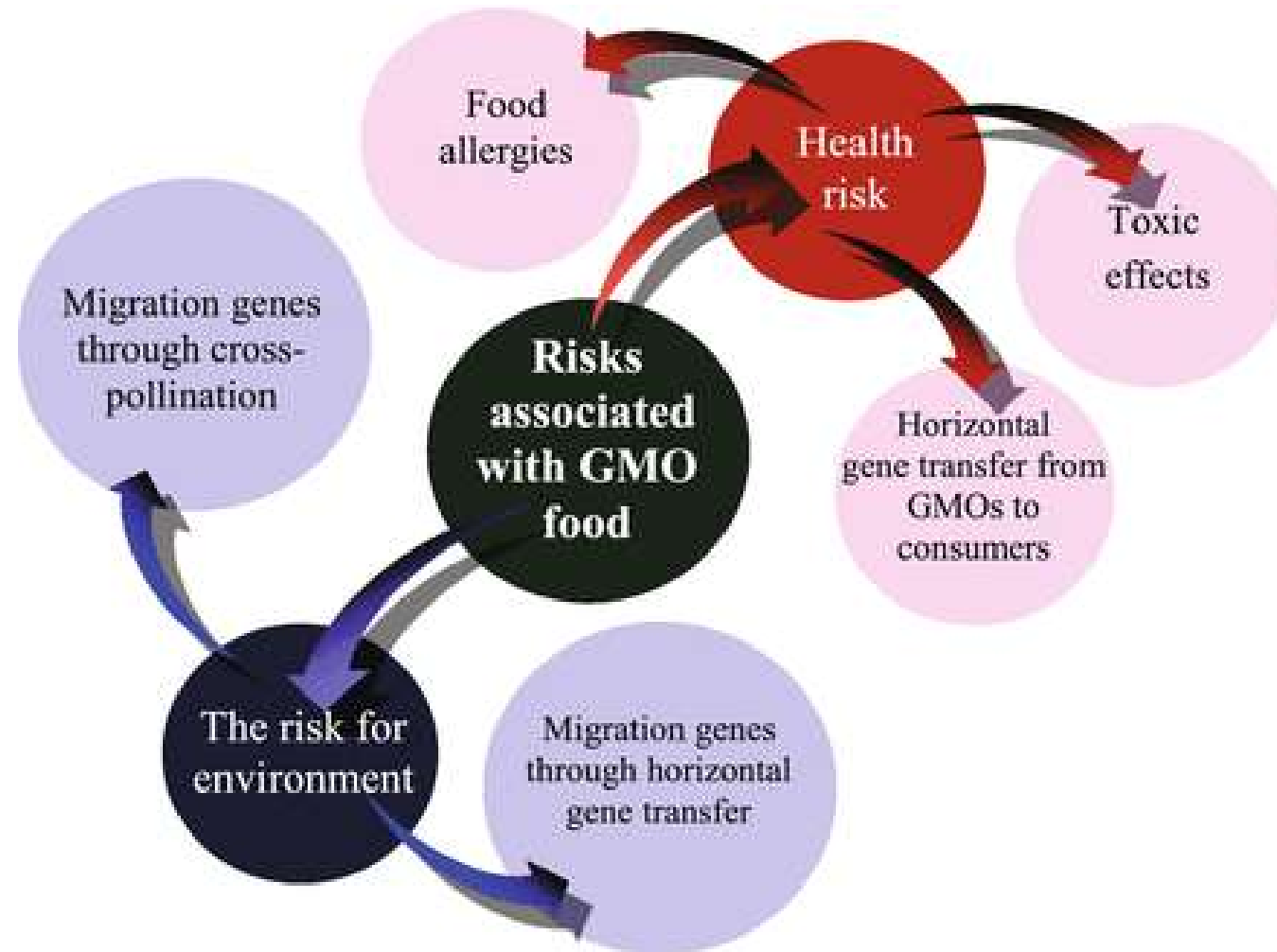
- **1. Food toxicity**
- **2. Allergenicity**

- **1. Effect on non-target organisms**
- **2. Evolution of pests resistant to GMP.**
- **3. Gene Flow**



What is Biosafety?

The measures and strategies invested to enhance safe production, trade and use of GMOs and reduce or minimize their potential risks on the environment, biodiversity and human and animal health



Different Biosafety Regulations and Standards

◎ **The Cartagena Protocol on Biosafety**

- * **Objective:** Ensure safe transboundary movement of GMOs
- * Mandatory regulation regarding the safe transportation of living modified organisms (LMOs) at the international level (does not include non-living derivatives of transgenics)



◎ **Codex Alimentarius**

- * **Objective:** is preparation of non legally binding Food Safety assessments Guidelines for GMOs (LMOs and their non-living derivatives)
- * These guidelines are not legally binding
- * Codex Alimentarius or "Food Code" is a collection of standards and guidelines adopted by the Codex Alimentarius Commission.



Codex guidelines on safety assessment of GM foods

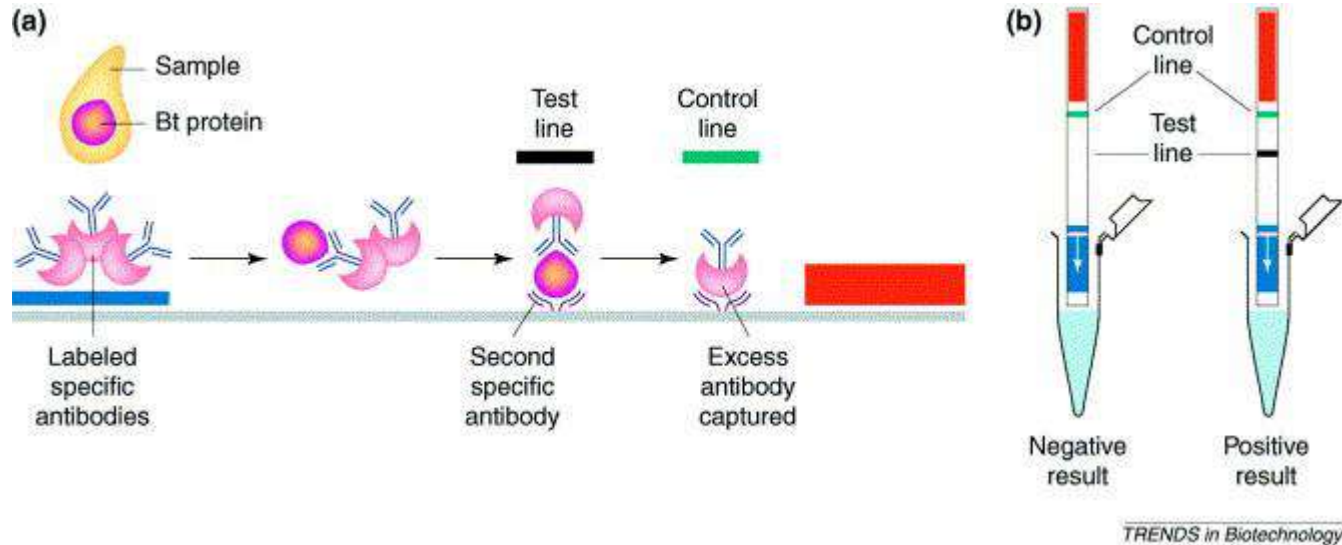
Reference 	Title	Committee	Last modified	EN RU	FR	ES	AR	ZH
CXG 44-2003	Principles for the Risk Analysis of Foods Derived from Modern Biotechnology	TFFBT	2011	✓	✓	✓	✓	✓
CXG 45-2003	Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants	TFFBT	2008	✓	✓	✓	✓	✓
CXG 46-2003	Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms	TFFBT	2003	✓	✓	✓	✓	✓
CXG 68-2008	Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals	TFFBT	2008	✓	✓	✓	✓	✓
CXG 74-2010	Guidelines on Performance Criteria and Validation of Methods for Detection, Identification and Quantification of Specific DNA Sequences and Specific Proteins in Foods	CCMAS	2010	✓	✓	✓	⊘	✓
CXG 76-2011	Compilation of Codex texts relevant to the labelling of foods derived from modern biotechnology	CCFL	2011	✓	✓	✓	✓	✓

<https://www.fao.org/fao-who-codexalimentarius/thematic-areas/biotechnology/en/>

Different Biosafety Regulations and Standards

International Standard Organization (ISO)

- ❖ ISO has defined different standards to ensure that GM products are safe, reliable and of good quality.
- ❖ Technical Committee 34 (TC34) deals with food and fodder.
- ❖ This committee has 25 sub-committees, one of which deals with the preparation of necessary standards regarding food safety assessment methods for GMOs (living and non-living).
- ❖ More than 30 different guidelines related to sampling, detection and characterization of GMOs



Different Biosafety Regulations and Standards

World Trade Organization (WTO)

The WTO also acknowledges the rights of the countries to protect their environment and to ensure food safety.

- ❖ Sanitary and Phytosanitary Measures (SPS agreement) which acknowledges the rights of a country to protect its environment and to ensure food safety and information for consumers
- ❖ General Agreement on Tariffs and Trade (GATT agreement): Focuses on price and trade of different kinds of commodities including GMOs
- ❖ Trade -related aspects of intellectual property rights (TRIPS)



Different Biosafety Regulations and Standards

- ◉ **World Health Organization (WHO)**



Objectives; Guidelines for food safety assessment of GMO



International
Plant Protection
Convention

- ◉ **International Plant Protection Convention: IPPC**

Objectives; preparing Guidelines and standards for risk assessment of plant pests associated with LMOs

- ◉ **World Organization for Animal Health (OIE)**

- ◉ preparing guidelines for recombinant vaccines and



- ◉ **Food and Agriculture Organization (FAO)**

Objectives; Guidelines for food safety assessment of GMOs

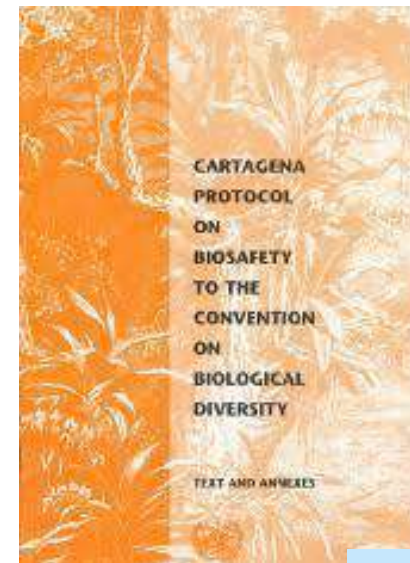
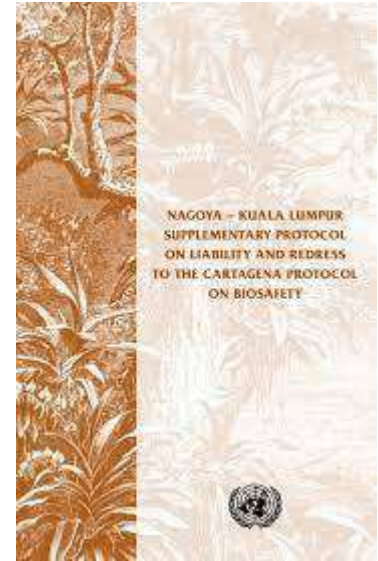


Cartagena Biosafety Protocol-2000

Facts and Figures

It is the first legally-binding international treaty governing shipments & trade of GMOs

- * Protocol adopted on 29 January 2000 in Montreal at an extraordinary meeting of the Conference of the Parties to the Convention on Biological Diversity.
- * Entered into force on 11 September 2003
- * 173 Countries are member of the protocol (ratifications/accessions)



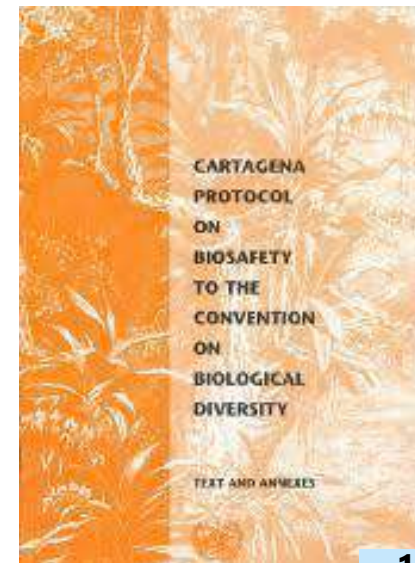
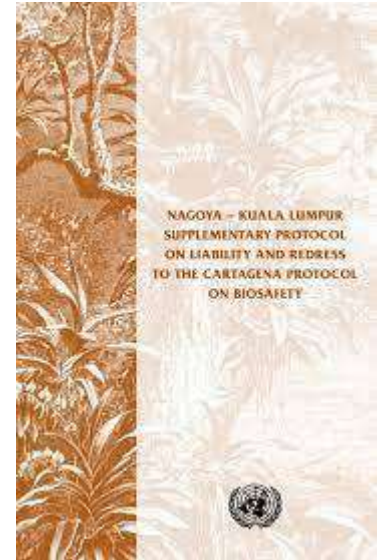
Cartagena Biosafety Protocol-2000

The protocol applies to only ALL Living Modified Organisms (LMOs) in their:

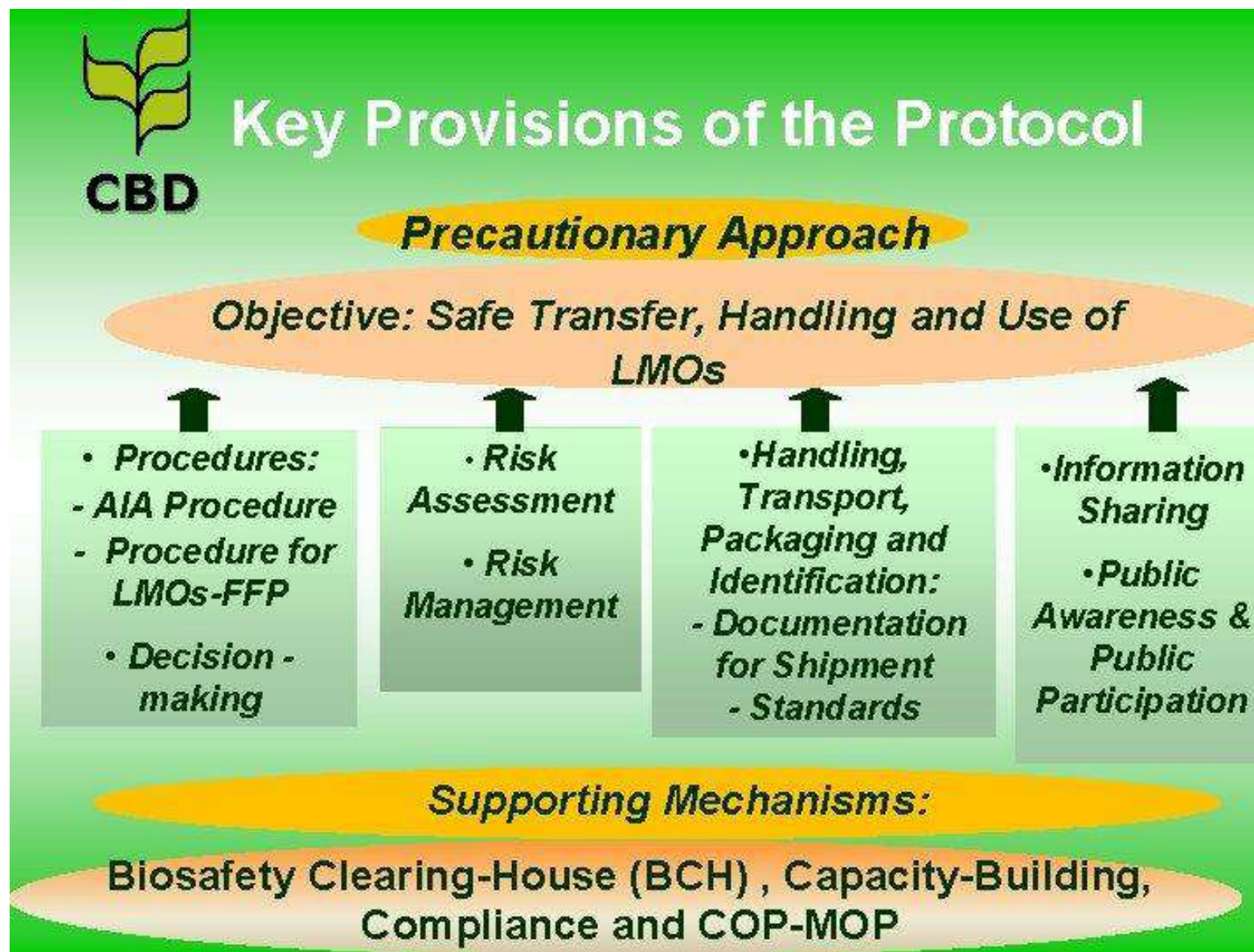
- * Transboundary movement
- * Transit
- * Handling and use

CPB Key Elements

1. Precautionary principles
2. Advanced Informed Agreements (AIA)
3. Food & Feed for processing
4. Risk Assessment & Management
5. Biosafety Clearing House



Structure of Cartagena Protocol on Biosafety



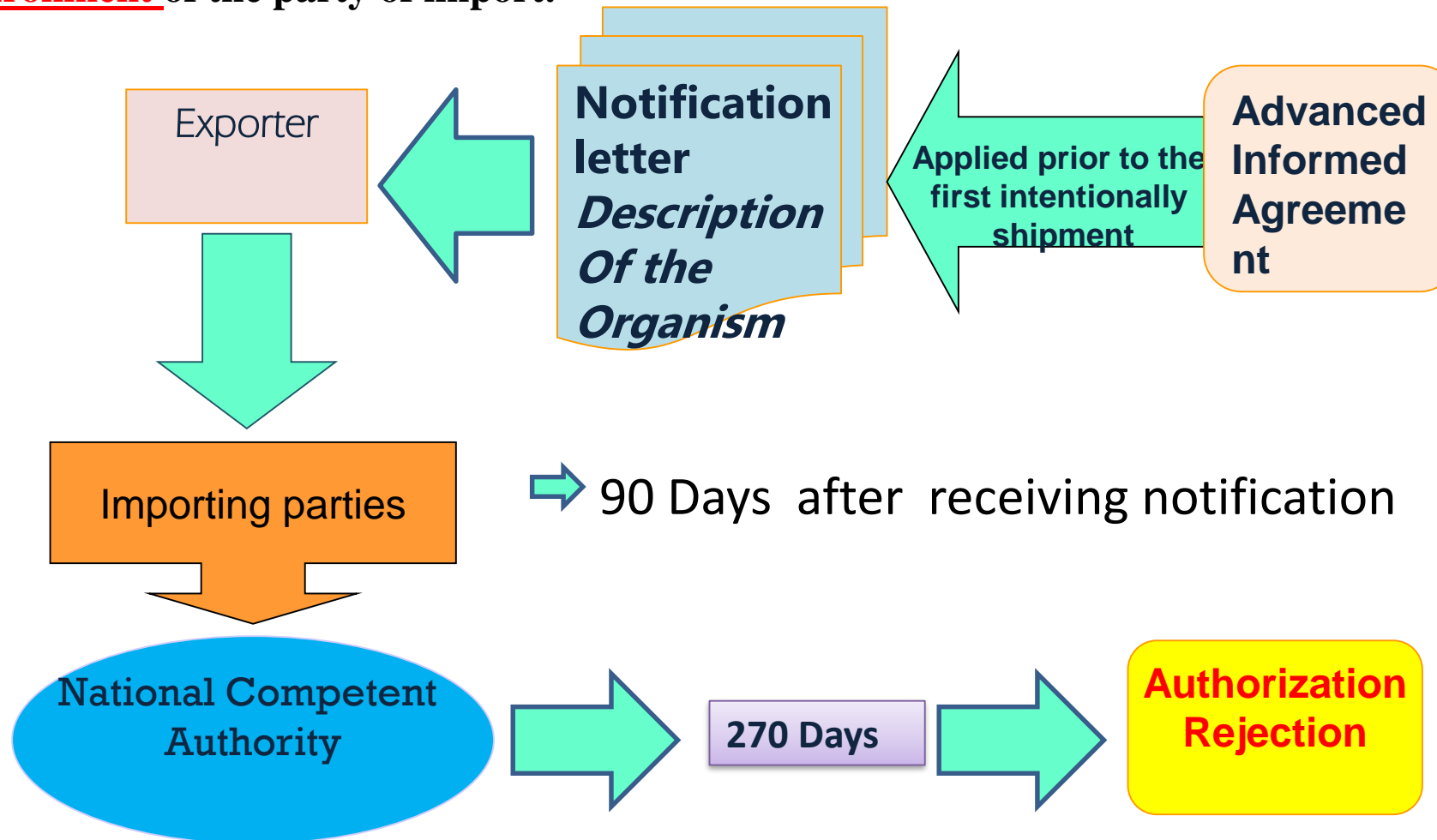
The scope of Cartagena Biosafety Protocol

Included	Excluded
All LMOs that may adverse effects	Pharmaceuticals
Intentional Introduction into the environment (cultivation in the field)	Those LMOs not likely have adverse effects
Contained use	Those LMOs reported by decision of COP-MOP meetings as safe
Food, feed, or processing	Non-living products (Oil extracted from GM seeds)



Advanced Informed Agreement (Articles 7, 8, 9, 10 & 12)

Applies prior to the first intentional transboundary movement of LMOs for intentional introduction into the environment of the party of import.



LMOs not subject to AIA provision

- ◎ **Pharmaceuticals (Art.5)**
- ◎ **Transit & contained use (Art.6)**
- ◎ **LMOs unlikely to have adverse effects (Art.7.4)**
- ◎ **LMOs intended for direct use as food or feed, or for processing (Art.7.2)**

Results of the Advance informed Agreement (AIA) procedure

- Approving the import, with or without conditions
- Rejection of the import
- Requesting additional relevant information
- Extension of the 270 day period by a defined period of time
- Review and change of decisions – at any time

The second Measure: Direct Use as Food, Feed or Processing (FFP) (Article 11)

- Country of import may authorize entry of bulk commodities (FFP)
 - By domestic regulatory framework consistent with Protocol
 - By communicate decision to Biosafety Clearing House
 - Obtaining information listed in Annex II



Risk Assessment & Management (Article 15 & 16)

- Annex III specifies the scope of risk assessment
- **Scientific sound manner; transparency; case by case**
- Absence/Lack or insufficiency of scientific knowledge does not indicate an absence of risk or an acceptable risk
- Each Party shall establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks and to prevent unintentional transboundary movements of LMOs



Handling, Transport, Packaging & Identification (Article: 18)

- 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,
 - requirements for their safe handling, storage, transport and use,
 - contact information and declaration that the movement conforms to the requirements of the Protocol



GMO s Labelling issues

GMO labelling requirements in different countries

Country	Mandatory vs. voluntary labelling	Product vs. process labelling	Threshold level (%)
European Union	Mandatory	Process	0.9
China	Mandatory	Process	0
Brazil	Mandatory	Process	1
Australia/ New Zealand	Mandatory	Product	1
Japan	Mandatory	Product	5
Korea	Mandatory	Product	3
Canada	Voluntary	Product	5
USA	Voluntary	Product	N/A

Milavec M, Dobnik D, Yang L, Zhang D, Gruden K, Žel J. GMO quantification: valuable experience and insights for the future. Analytical and bioanalytical chemistry. 2014 Oct;406:6485-97.



Article 23

PUBLIC AWARENESS AND PARTICIPATION

Member States must:

- ❖ Facilitate public awareness, education and public participation in the safe transfer, production and consumption of GMOs.
- ❖ In doing this, they can cooperate with other members and organizations.
- ❖ Facilitate access to the required information.
- ❖ In making decisions about living transgenic organisms, use public participation and inform them about the decisions made.
- ❖ Inform the public how to access the biological safety clearing room

Biosafety Clearing House

- 1. Established as part of the Clearing House Mechanism (under the CBD)**
- 2. Facilitate the exchange of information on LMOs**
- 3. Assist parties to implement the protocol**
- 4. Serve as means through which information is made available**



Biosafety Clearing-House



Welcome

The Biosafety Clearing-House is an online platform for exchanging information on biosafety obligations under the Convention on Biological Diversity and the Cartagena Protocol on Biosafety.

BCH accounts are available for registration. Register your account now.

Latest News

- 2017-07-06 [Malaysia - DEPARTMENT OF BIOSAFETY MALAYSIA AND THE ASIA BIOSAFETY CLEARING HOUSE...](#)
- 2017-06-29 [Senegal - Atelier national sur la révision de la loi sur la biosécurité...](#)
- 2017-06-29 [Mexico - Submissions from Parties, other Governments or relevant organizations](#)
- 2017-04-29 [Mongolia - National Focal Point](#)
- 2017-04-29 [Yemen - National Focal Point](#)
- 2017-03-06 [Submissions from Parties, other Governments or relevant organizations](#)

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The Biosafety Clearing-House

- [Modalities of Operation](#)
- [Multi-year Programme of Work](#)
- [Strategic Plan](#)
- [Decisions on the BCH](#)
- [Reports & Reviews](#)
- [Development of the BCH](#)

The BCH Collaborative Portal

- [About this Portal](#)
- [The BCH Informal Advisory Committee \(BCH-IAC\)](#)
- [BCH National Focal Points \(BCH on BCH\)](#)
- [UNEP-GEF BCH Projects](#)

Highlights

- [BCH News](#)
- [Latest Additions](#)
- [Notifications](#)
- [Meetings and Documents](#)

Policies

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Central Portal

The Central Portal is a web-based system set up by the Cartagena Protocol on Biosafety to facilitate the exchange of information on biosafety obligations (LMOs) and assist the Parties to better comply with their obligations under the Convention and the Protocol. It provides a variety of scientific, technical, environmental, legal and capacity building information in the various languages of the UN.

Users can register their accounts in the BCH by signing in through the Management Centre.

Latest Additions [More additions...]

- 2017-08-28 [India - National Focal Point](#)
- 2017-08-28 [South Africa - Submissions from Parties, other Governments or relevant organizations](#)
- 2017-08-28 [Mexico - Submissions from Parties, other Governments or relevant organizations](#)
- 2017-08-28 [Scientific Bibliographic Reference](#)
- 2017-08-28 [Scientific Bibliographic Reference](#)

Latest updates

- 2017-08-29 [Submissions from Parties, other Governments or relevant organizations](#)
- 2017-08-29 [Mongolia - National Focal Point](#)
- 2017-08-29 [Yemen - National Focal Point](#)
- 2017-08-29 [Submissions from Parties, other Governments or relevant organizations](#)
- 2017-08-29 [Submissions from Parties, other Governments or relevant organizations](#)

COP13-COPMOP8-COPMOP2
CANCUN, MEXICO 2016

COP-MOP 8
4 Dec - 17 Dec 2016
Webpage | Documents

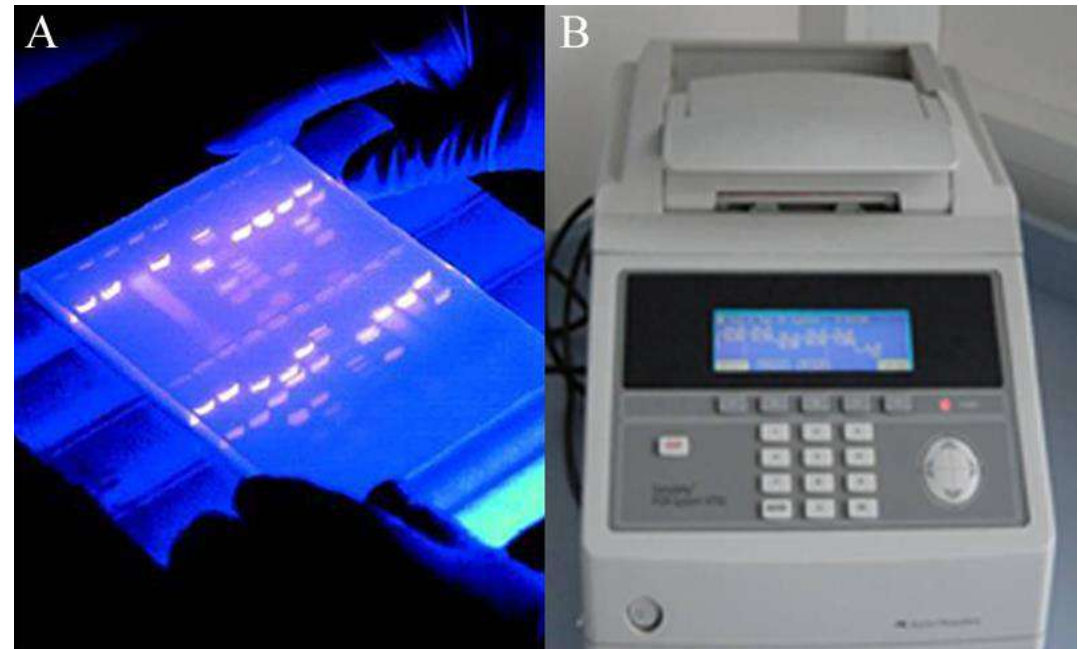
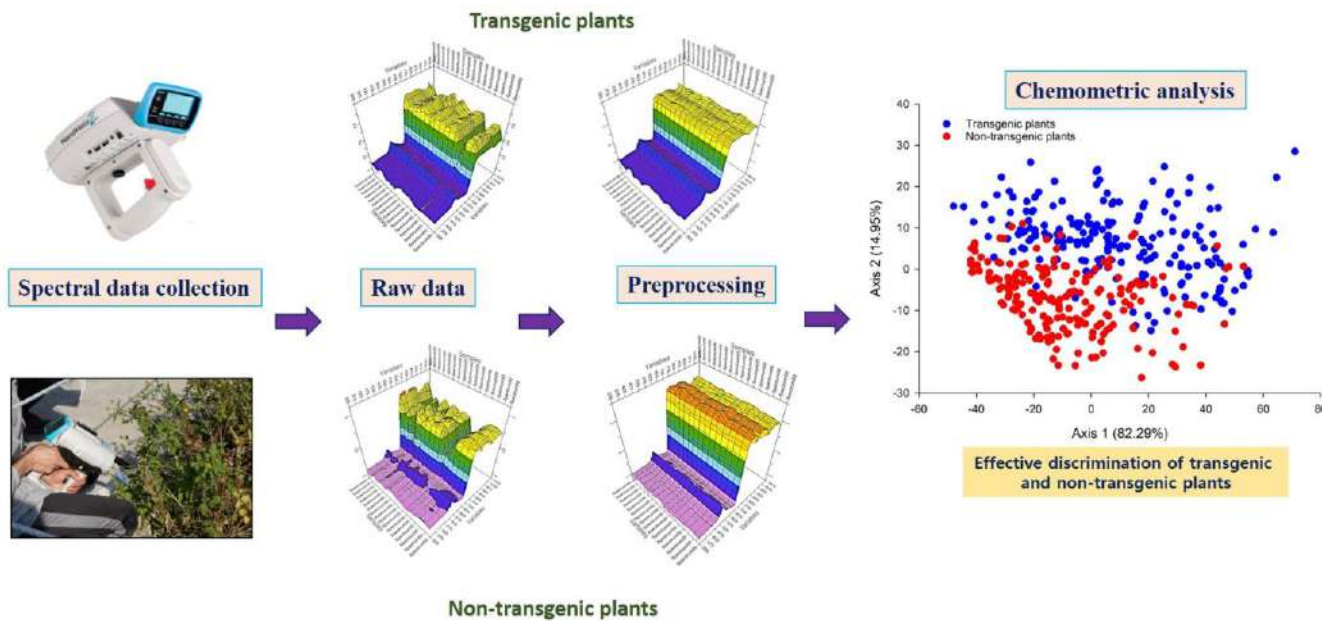
NBSAP FORUM
Support for action on NBSAPs

BIO SAFETY

Third National Report NFPs & NAUs

Capacity Building (Article 22)

- Parties should cooperate in the development and/or strengthening of human resources and institutional capacities
- Build capacities for the implementation of the Protocol



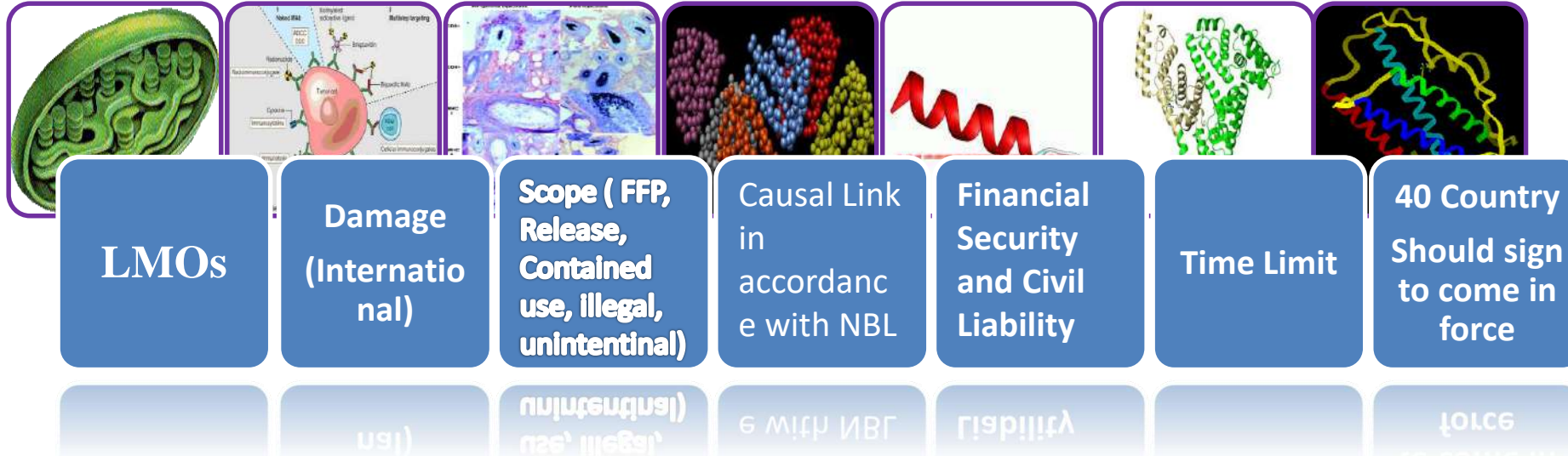
Socio-Economic Considerations (Article 26)

- In reaching a decision on import, Parties may take into account socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities
- However, this must be consistent with other international obligations

Liability and Redress (Article 27)

- The Protocol provides for a process to elaborate appropriate international rules and procedures regarding liability and redress for damage resulting from transboundary movements of LMOs
- The first meeting of the Parties has set this process in motion by establishing an Open-ended Working Group of Legal and Technical experts to develop options for a liability and redress regime under the Protocol
- Negotiations expected to be completed in 2007

Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress



- If imported LMOs cause damage to biodiversity, the company that developed or imported the LMO would be required to evaluate the damage and respond appropriately. If they fail to do so, a government-appointed "competent authority" would be allowed to step in and clean up the mess, then send the responsible company a bill
- 65 Countries signed- and 54 countries ratified it
- The Supplementary Protocol entered into force on 5 March 2018



Compliance (Article 34)

- Cooperative procedures and institutional mechanisms to promote compliance and to address cases of non-compliance have been approved at the first meeting of the Parties
- Among them, a compliance committee composed of 15 experts has been set up

ECO countries are member of Cartagena Protocol on Biosafety

- ❖ All ECO countries are member of Cartagena protocol on biosafety
- ❖ No ECO countries are member of the Supplementary Protocol on Liability and Redress





Thanks for your attention!