Cartagena Protocol on Biosafety and the Biosafety Clearing-House

Central and Eastern European Workshop on the Detection and Identification of Living Modified Organisms

7 – 11 March 2016, Ljubljana

NATIONAL INSTITUTE OF BIOLOGY

REPUBLIC OF SLOVENIA
MINISTRY OF THE ENVIRONMENT AND SPATIAL PLANNING

CBD

UNEP

The Cartagena Protocol on Biosafety

History

Objective

Scope

Definitions

Main provisions

Risk assessment

Biosafety-Clearing House

What is biosafety?

What is a Protocol?

What is biosafety?

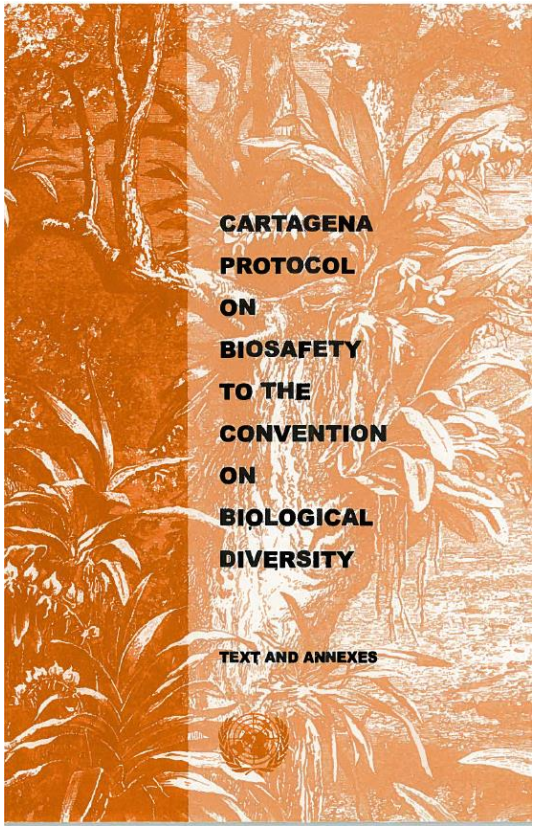
Biosafety is a term used to describe the need to protect the environment and human health from the possible adverse effects of the products of modern biotechnology.

What is a Protocol?

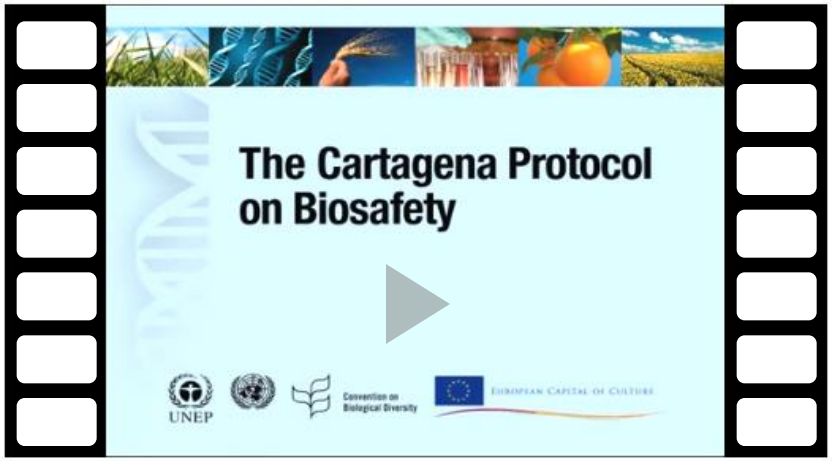
A protocol is a legally binding international instrument that is separate from, but related to, a “parent” treaty.

The Cartagena Protocol on Biosafety is under the Convention on Biological Diversity

Cartagena Protocol on Biosafety



safe handling, transport and use of living modified organisms (LMOs) that may have adverse effects on biodiversity and human health



History of the Cartagena Protocol

1992:	Convention on Biological Diversity (CBD)
1992-2000:	Negotiation process
2000:	Adoption of the Protocol
2003:	Entry into force
2016:	170 Parties

Convention on Biological Diversity (CBD)

Objective

"... the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources..."

Cartagena Protocol on Biosafety

Objective

"...contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of living modified organisms resulting from modern biotechnology..."

Cartagena Protocol on Biosafety

Scope

"The Protocol applies to the transboundary movement, transit, handling and use of living modified organisms that may have an adverse effect on the conservation and sustainable use of biodiversity, taking into account human health."

A few definitions...

Article 3 – Use of Terms (page 4)

(g) Living modified organism (LMO)

(h) Living organism

(i) Modern biotechnology

(k) Transboundary movement

Main provisions

- Capacity Building
- Liability and Redress
- Handling, Transport, Packaging and Identification
- Public awareness and Participation
- Social-economic considerations
- Advanced Informed Agreement
- Risk Assessment
- Risk Management
- Biosafety-Clearing House

Types of LMOs under the scope of the Protocol

- LMOs for intentional introduction into the environment
- LMOs for direct use as food or feed, or for processing

Advanced Informed Agreement (AIA) – Article 7

Notification – Article 8

Acknowledgement of Receipt of Notification – Article 9

Decision Procedure – Article 10

Risk Assessment – Article 15

Competent National Authority – Article 19

Risk Assessment

Article 15 & Annex III

"...risk assessment should be carried out in a scientifically sound and transparent manner..."

"...in order to identify and evaluate the possible adverse effects of LMOs on the conservation and sustainable use of biological diversity..."

Risk Assessment

Key element:

“Carried out in a case-by-case basis”

Risks vary depending on the nature of the LMO, the modified trait, the intended use and the potential receiving environment.

Risk Assessment

Annex III

Methodology (steps of risk assessment):

(a) Identification of novel characteristics;

(b) Evaluation of the likelihood of adverse effects being realized;

(c) Evaluation of the consequences;

(d) Estimation of the overall risk posed by the LMO;

(e) Recommendation as to whether or not the risks are acceptable or manageable.

Risk Assessment

Annex III

Points to consider:

- Recipient/parental organism;
- Donor organism(s);
- Vector, inserts and characteristics of the modification;
- Characteristics of the living modified organism;
- **Methods for identification and detection;**
- Intended use;
- Receiving environment.

Biosafety Clearing-House

Cartagena Protocol on Biosafety – Convention on Biological Diversity

http://bch.cbd.int

CBD

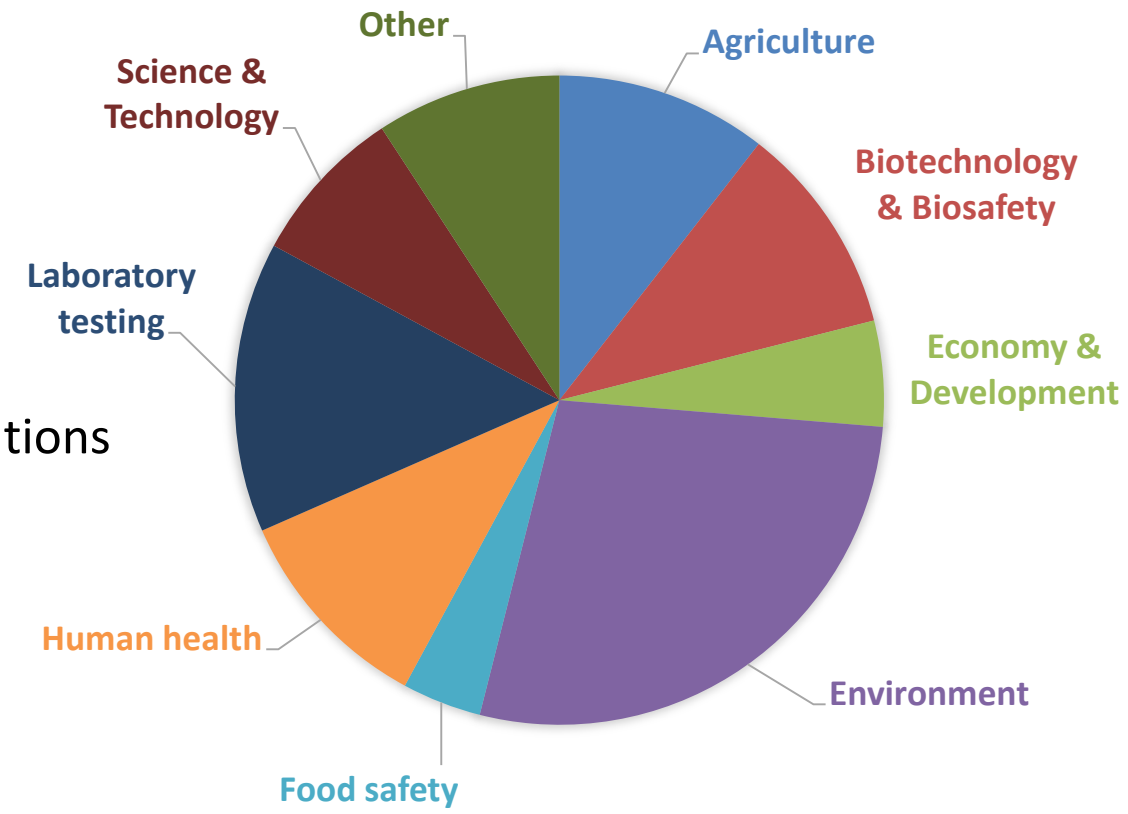
UNEP

Biosafety Clearing-House

- Scope:  Environment –  Human health –  Animal feed –  Processing –  Contained use –  Other
- All types of living modified organisms
- All types of introduction into the environment (e.g. field trials, commercial release)

Biosafety Clearing-House

- 170 Parties
- 300 organizations:
  - ✓ 70 Academic
  - ✓ 76 Governmental institutions
  - ✓ 60 NGOs
  - ✓ 11 Business & Industry



Biosafety Clearing-House

Who can register information?

	NATIONAL RECORDS (decisions, law, risk assessment*, etc)	REFERENCE RECORDS (LMO, gene, organism, risk assessment**, etc)
National Focal Points	☑	☑
Registered users	☒	☑

* Risk assessment generated by regulatory process

** Risk assessment generated by independent or non-regulatory process

Biosafety Clearing-House

Numbers at a glance

National records

- 841 national biosafety contacts
- 826 laws and legislations
- 1265 decisions by 43 countries
- 961 risk assessments
- 157 experts

Reference records

- 374 LMOs
- 417 genetic elements
- 195 organisms
- 420 capacity building initiatives & country ne
- 292 organizations
- 1430 publications

Biosafety Clearing-House

Country Profile

Profile information and status	
Country	**Brazil**
Date of signature	-
Date of ratification	2003-11-24
Date of entry into force	2004-02-22
Profile revision	-
Profile status	**Published**
Profile last updated on	-

Type of document	Number of records
Biosafety Expert	17
Capacity Building Needs and Priorities	0
Competent National Authority	7
Country's Decision or any other Communication	45
Law, Regulation or Guideline	22
National Database or Website	1
National Focal Point	2
News	0
Report on Assignment	0
Risk Assessment	42
Reports on Implementation of the Protocol	2
Total number of records	**138**

- ✓ National experts
- ✓ National Authorities
- ✓ Decisions
- ✓ Law & regulations
- ✓ Guidelines
- ✓ National Focal Points
- ✓ Risk Assessment
- ✓ National reports

Biosafety Clearing-House

Modified Organism

MON-ØØ81Ø-6 - YieldGard™ maize

LMO Information | Decisions on the LMO | Risk Assessments

Record information and status

Record ID	14750
Status	Published
Date of creation	2006-06-05 14:39 UTC (kirsty.mclean.consultant@cbd.int)
Date of last update	2013-05-24 18:43 UTC (dina.abdelhakim@cbd.int)

Living Modified Organism identity

The image below identifies the LMO through its unique identifier, trade name and a link to this page of the BCH. Click on it to download a larger image on your computer. For help on how to use it go to the LMO quick-links page.

CBD

MON-ØØ81Ø-6
YieldGard™ maize

http://bch.cbd.int/database/record.shtml?documentid=14750

Read barcode or type above URL into internet browser to access information on this LMO in the Biosafety Clearing-House © SCBD 2012

Other International Biosafety-related Bodies

- Food and Agriculture Organisation
- International Plant Protection Convention
- Codex Alimentarius Commission
- World Organisation for Animal Health
- World Trade Organization
- Organisation for Economic Cooperation and Development
- Bilateral, regional and multilateral agreements

Food and Agriculture Organization

Food and Agriculture Organization of the United Nations

for a world without hunger

Google™ Custom Search

- FAO Home
- Food safety and quality
- GM Foods Platform
- Browse information by
  - OECD Unique Identifier
  - Commodity
  - Trait
  - Country
- Resources
- Global outlook
- FAQ for visitors
- Login

FAO GM Foods Platform

Welcome to the FAO GM Foods Platform

A platform for all

The FAO GM Foods Platform is a simple online platform to share information on safety assessment of foods derived from recombinant-DNA plants authorized in accordance with the Codex "Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants (CAC/GL 45-2003, annex III adopted in 2008) ". This Platform also facilitates the effective utilization of food safety assessment in situations of Low Level Presence (LLP) of r-DNA plant materials in food.

How it works

The FAO GM Foods Platform is freely accessible for those who want to browse the information. Registration is required for those who need to upload information. Only officially nominated Focal Points can register to the Platform.

Contact us

If you need help, please first visit the "FAQ for visitors" page. There you'll find answers to many common questions. If you're unable to find what you're looking for, contact us at GM-Platform@fao.org

Food Safety at FAO Highlight: FAO GM Foods Platform September 2015

Latest Newsletter

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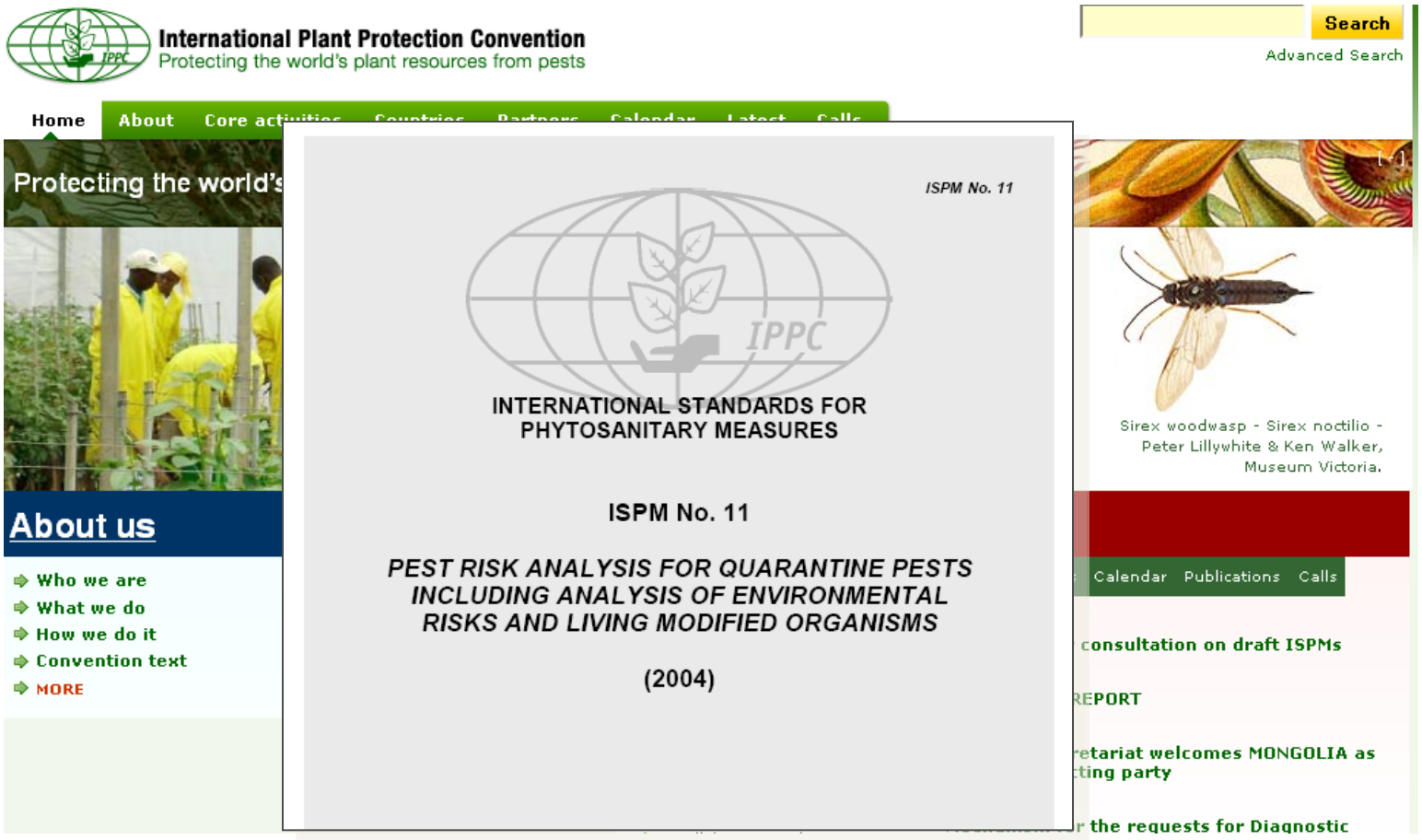
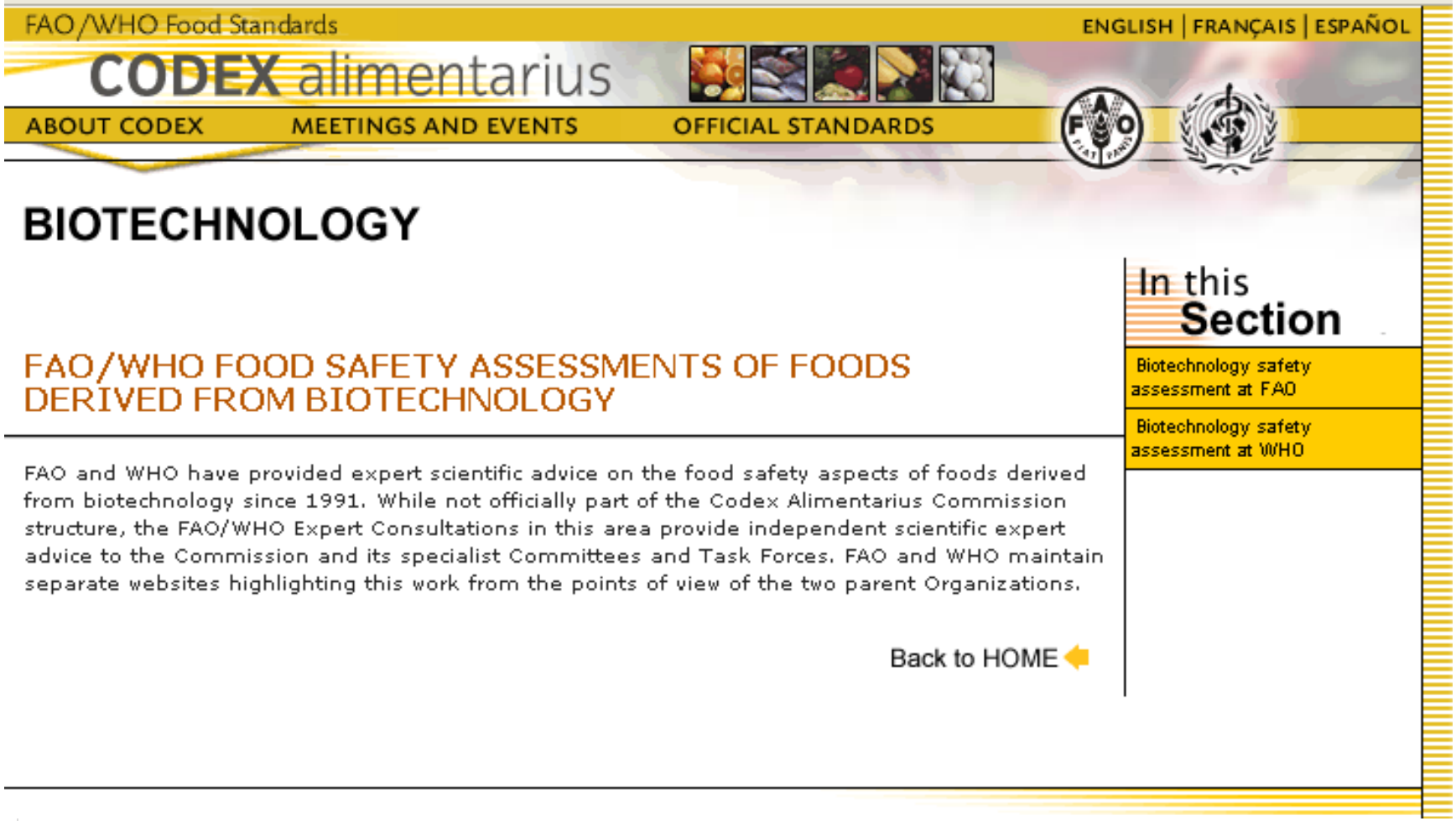
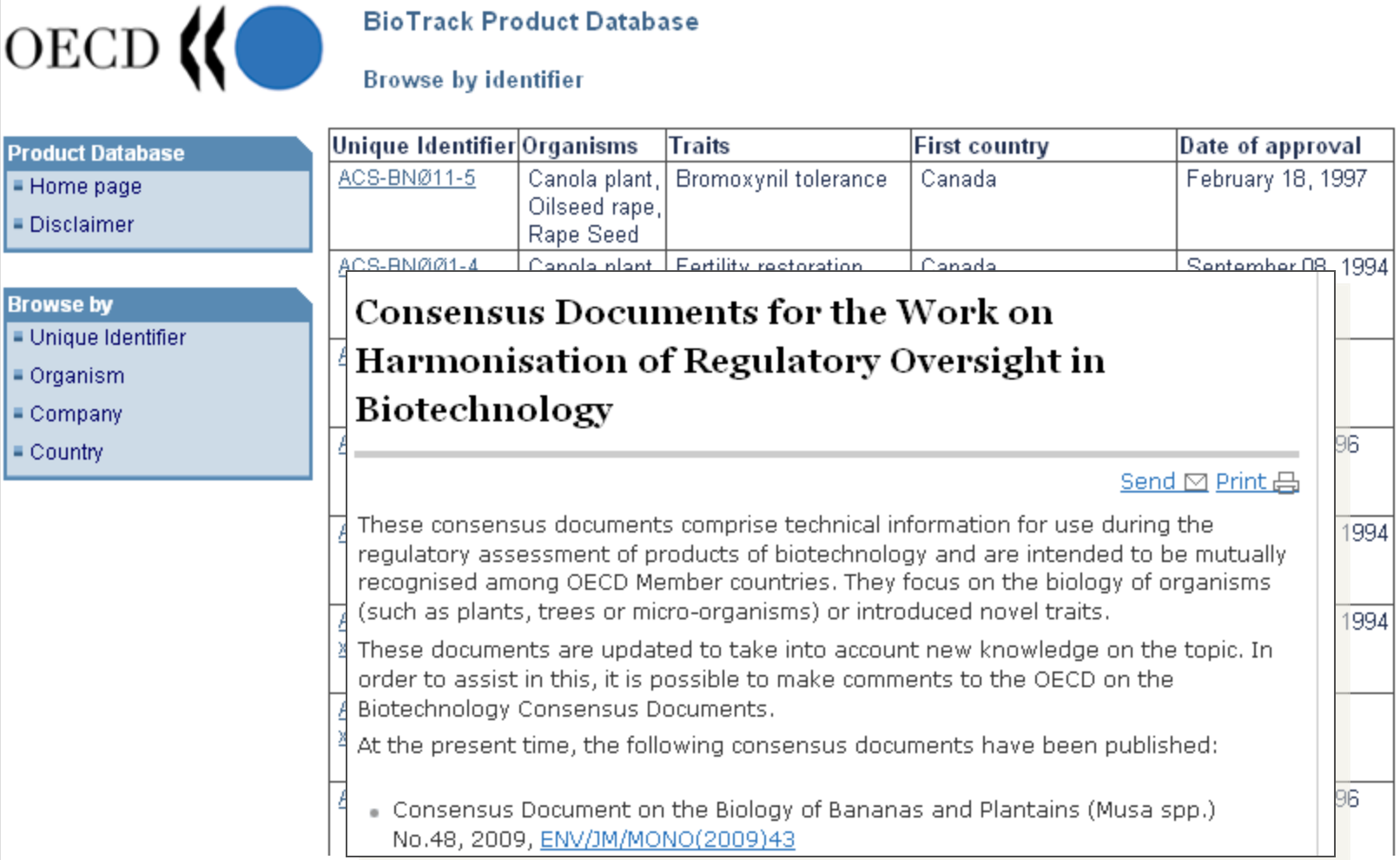
International Plant Protection Convention



Codex Alimentarius Commission



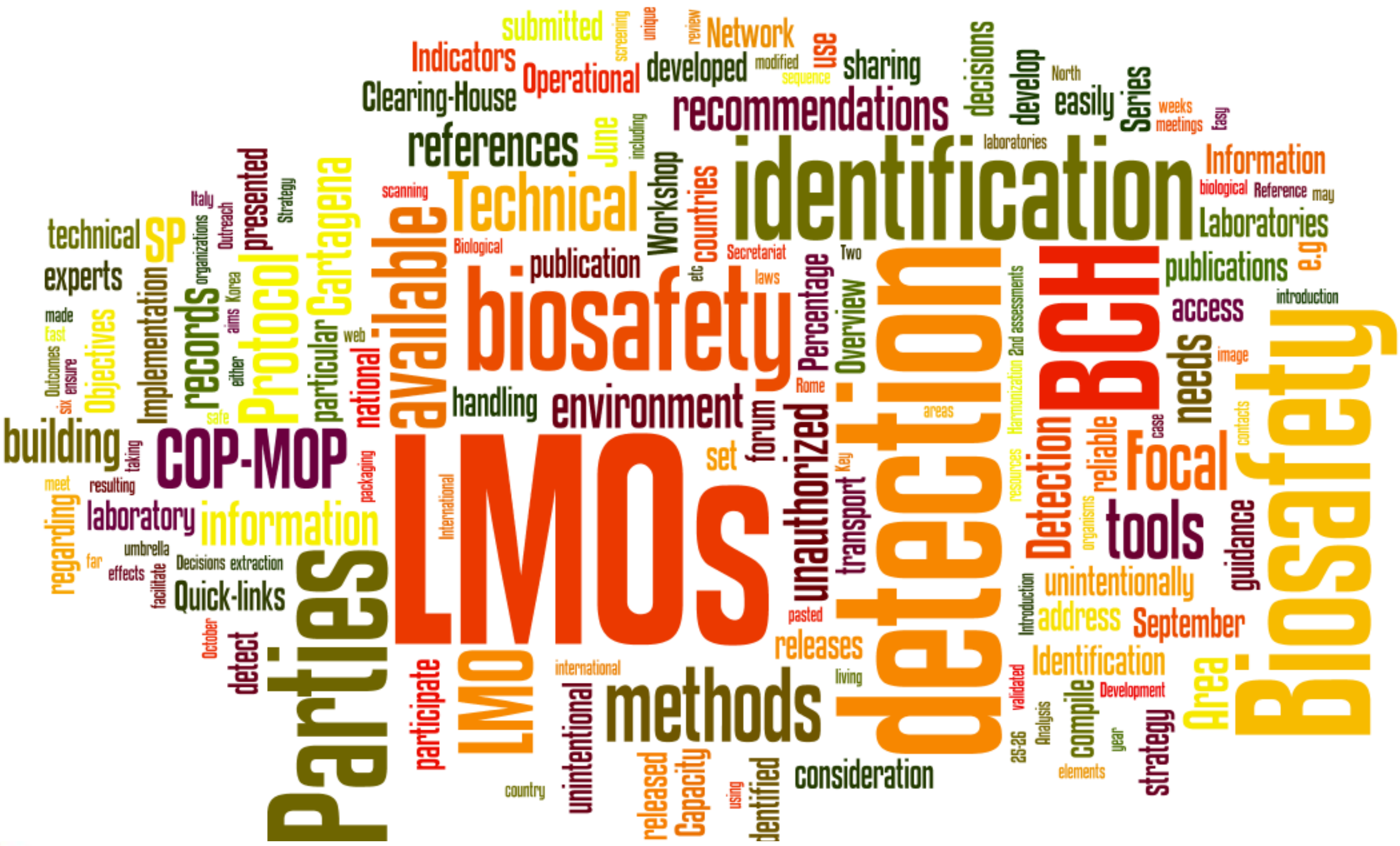
Organisation for Economic Cooperation and Development



World Organisation for Animal Health

World Trade Organization

Thank you!


LMOs
detection
identification
biosafety
Biosafety
BCH
Parties
methods
COP-MOP
Technical
references
recommendations
available
Protocol
Cartagena
information
environment
handling
unauthorized
Detection
tools
Focal
needs
Information
Laboratories
publications
access
publication
Clearing-House
Indicators
Operational
submitted
Network
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decisions
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Series
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Percentage
Overview
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consideration
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strategy
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Decisions
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Development
Harmonization
Introduction
validated
Analysis
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introduction
Reference
biological
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Biosafety Clearing-House

Modified Organism

MON-ØØ81Ø-6 - YieldGard™ maize

Characteristics of the transformation process

Vector

PV-ZMBK07 and PV-ZMGT10

Techniques used for the modification

- Biolistic / Particle gun

Genetic elements construct

CaMV Enhanced 35S promoter	Hsp70 intron	Cry1Ab
#100366	#100359	#14985
0.61 Kb	0.80 Kb	3.46 Kb

Further details

Notes regarding the genetic elements introduced or modified in this LMO

The transgenic maize line MON810 was genetically engineered to resist ECB by producing its own insecticide. This line was developed by introducing a synthetic version of the *cry1Ab* gene, isolated from the soil bacterium *Bacillus thuringiensis* (Bt) which was modified to enhance the expression of the Cry1Ab protein in plants, however the resulting amino acid sequence is identical to the native protein.

Biosafety Clearing-House

Modified Organism

MON-ØØ81Ø-6 - YieldGard™ maize

Detection method(s)

External link(s)

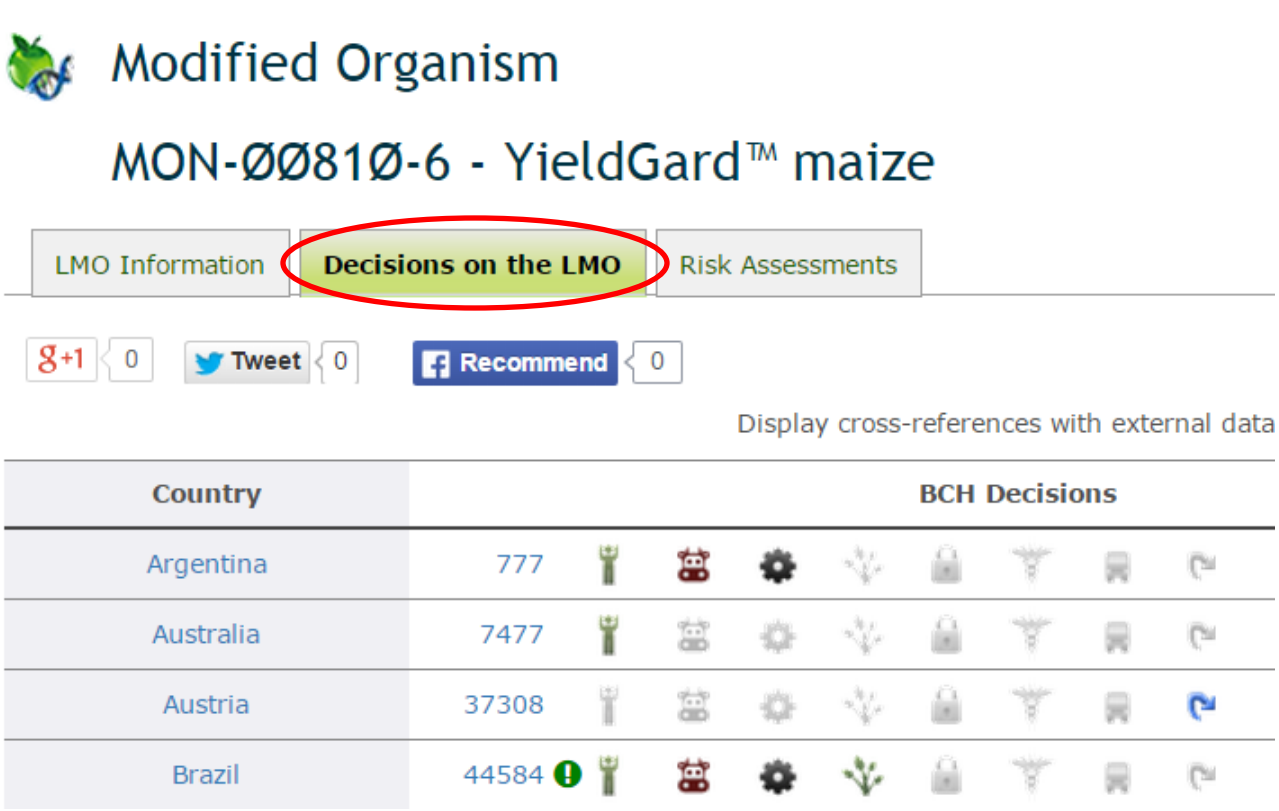
- MON-ØØ81Ø-6 - EU Reference Laboratory for GM Food and Feed (EURL-GMFF)
- MON-ØØ81Ø-6 - CropLife International Detection Methods Database

Additional Information

Other relevant website address or attached documents

- MON810 - OECD Biotrack Product Database
- MON810 - CERA GM Database
- Safety Assessment of YieldGard Insect-Protected Corn Event MON 810
- BATS (2003) Genetically Modified (GM) Crops: molecular and regulatory details, v.2.pdf
- MON810 - Monsanto.pdf

Biosafety Clearing-House



Biosafety Clearing-House

Modified Organism

MON-ØØ81Ø-6 - YieldGard™ maize

LMO Information | **Decisions on the LMO** | Risk Assessments

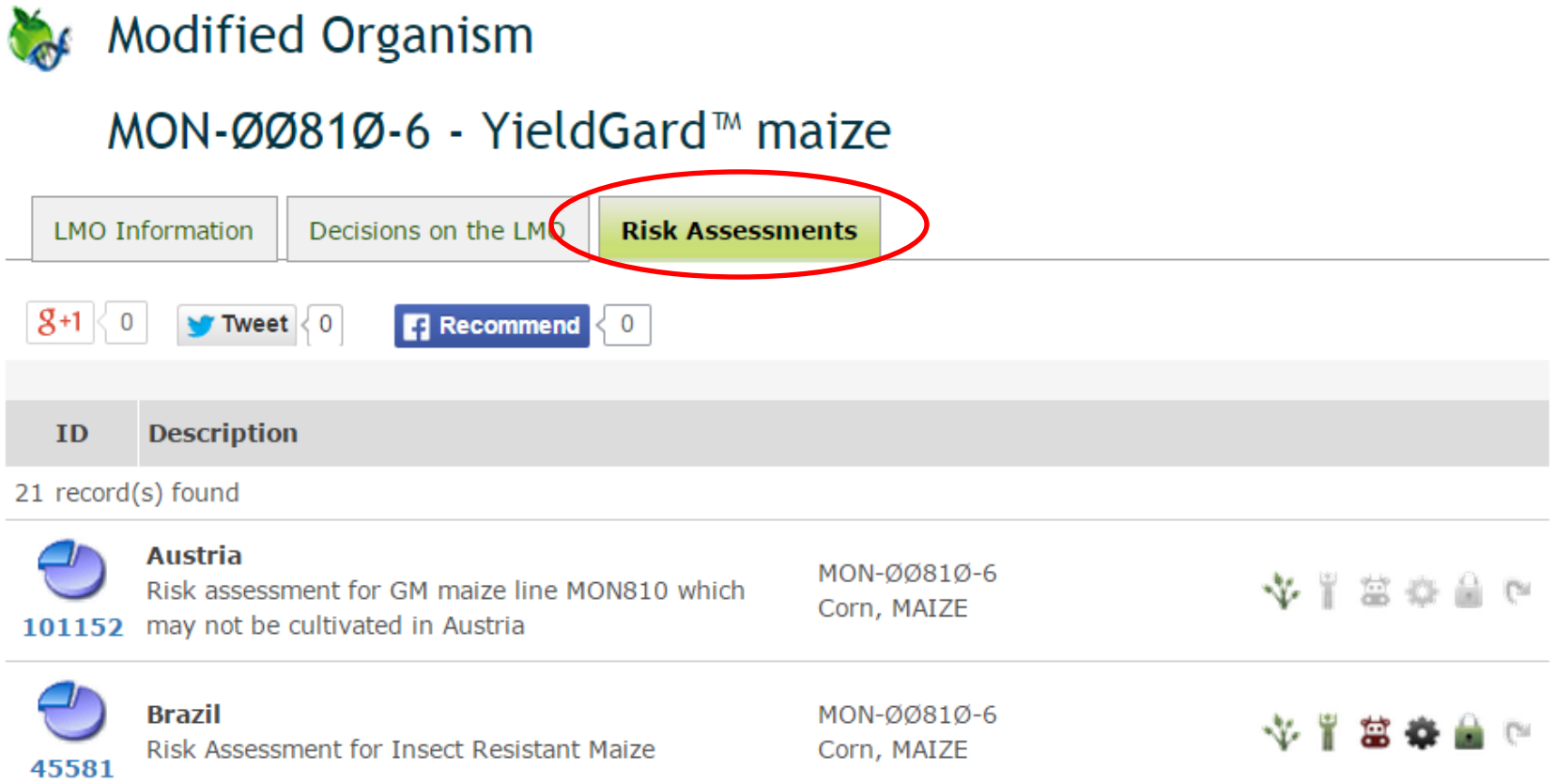
Display cross-references with external database(s): Biotradestatus

For further information about the external database click on the database name below; to visit the original database page containing information on this LMO click on the icon beside the database name

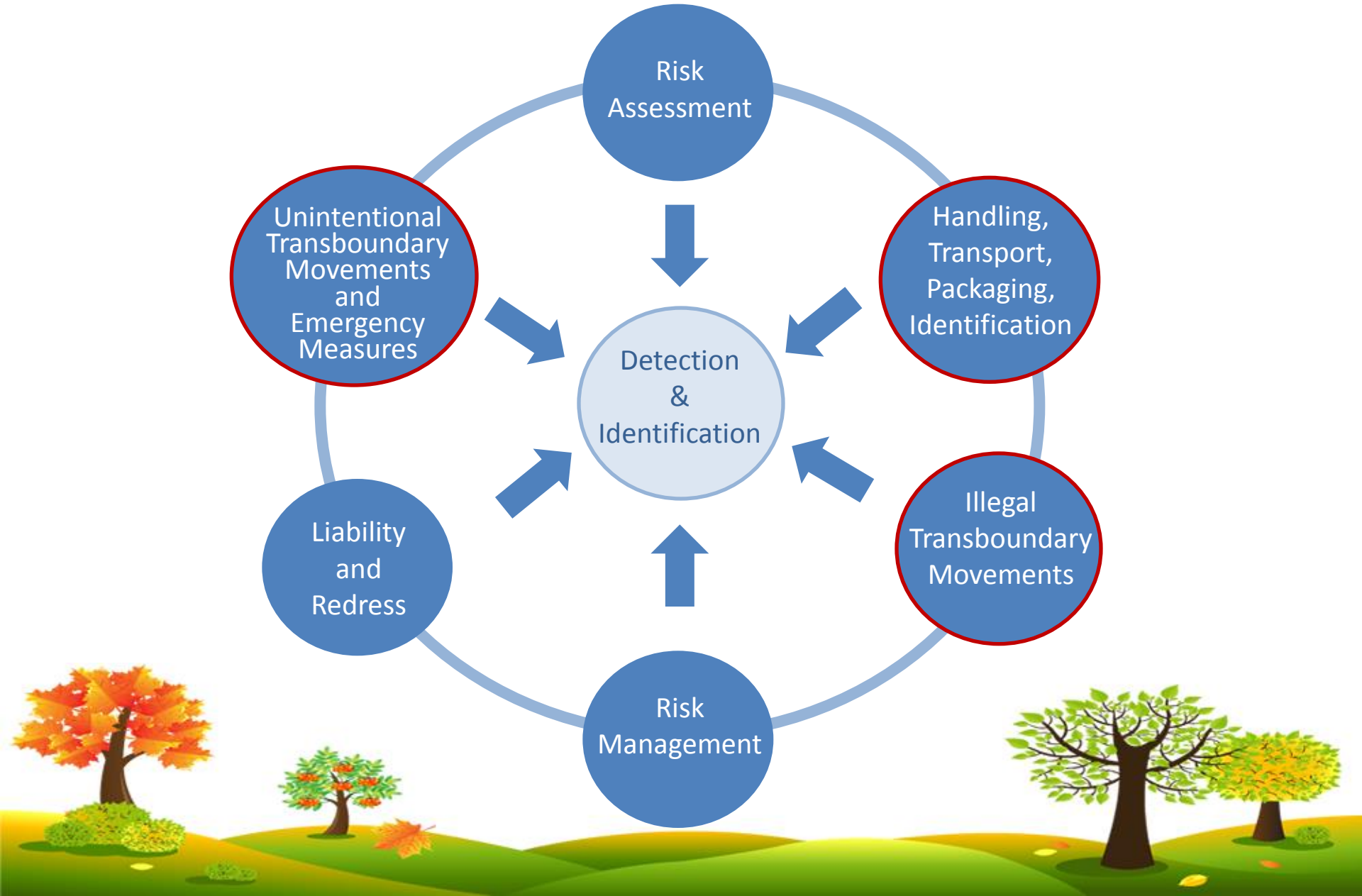
Country	BCH Decisions	Biostradestatus
Argentina	777	
Australia	7477	
Austria	37308	
Brazil	44584	

- Biotradestatus (CropLife International)
- GM Foods Platform (FAO)
- BioTrack Product Database (OECD)

Biosafety Clearing-House



Network of Laboratories



Network of Laboratories

Border officers
&
field inspectors

Laws
&
Regulations

Competent National Authorities

Detection labs

Civil society

Detect and alert relevant authorities about unauthorized LMOs and unintentional releases

Network of Laboratories

Focal areas of the Strategic Plan (2011-2020):

1. Implementation of biosafety systems
2. Capacity building
3. Compliance and review
4. Information sharing
5. Outreach and cooperation

Network of Laboratories

Open to all interested participants from LMO detection laboratories

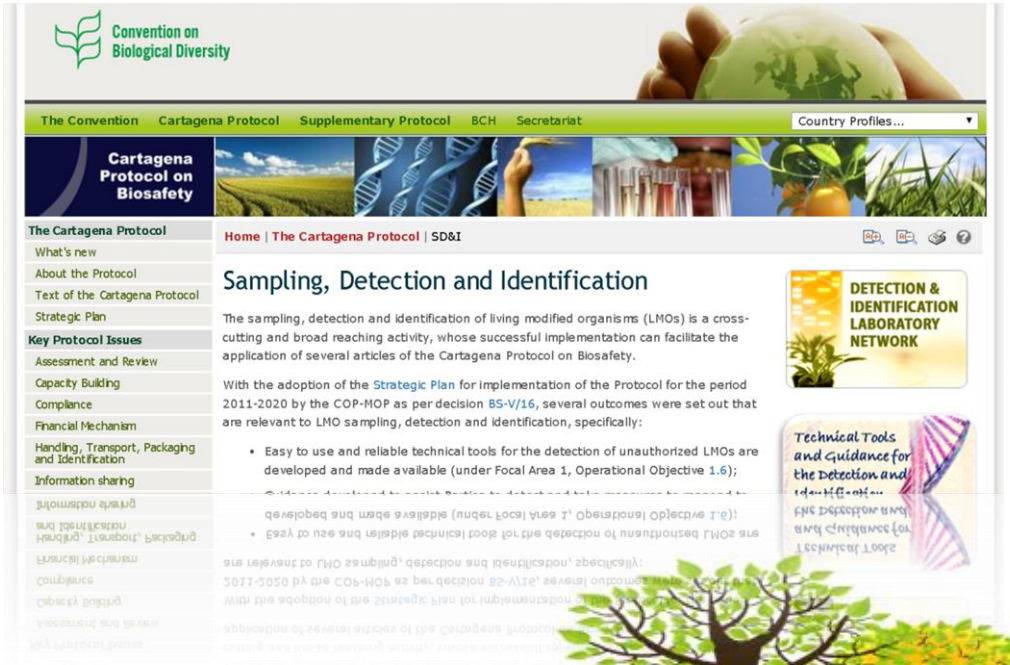
They must be registered in the Network in order to contribute to the online discussions

http://bch.cbd.int/onlineconferences/portal_detection/info_participants.shtml

Network of Laboratories

- ✓ Technical Tools and Guidance for the Detection and Identification of LMOs
  http://bch.cbd.int/protocol/cpb_detection/toolsandguidance.shtml

- ✓ Portal for the Sampling, Detection and Identification of LMOs
  http://bch.cbd.int/protocol/cpb_detection.shtml



Network of Laboratories

COP-MOP-7

Decision BS-VII/10:

✓Positive feedback

✓Support for additional activities of the Network of Laboratories for detection and identification of LMOs

✓Request the SCBD to organize training on sampling, detection and identification of LMOs

Network of Laboratories

Recommendations to COP-MOP-8

Workshop of the Network of Laboratories for the Detection and Identification of LMOs
9 - 11 June 2015, Ispra, Italy

- Conduct needs assessment
- Encourage Parties to support laboratories and networks for the detection and identification of LMOs, submit information on methods to the BCH
- Request the SCBD to:

i. Continue organizing online discussions of the Network of Laboratories

ii. Convene capacity-building activities

iii. Improve the user interface of the Technical Tools and Guidance for the Detection and Identification of LMOs

iv. Regularly update the Technical Tools and Guidance for the Detection and Identification of LMOs and training materials