

# 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



# Cartagena Protocol on Biosafety

## 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.



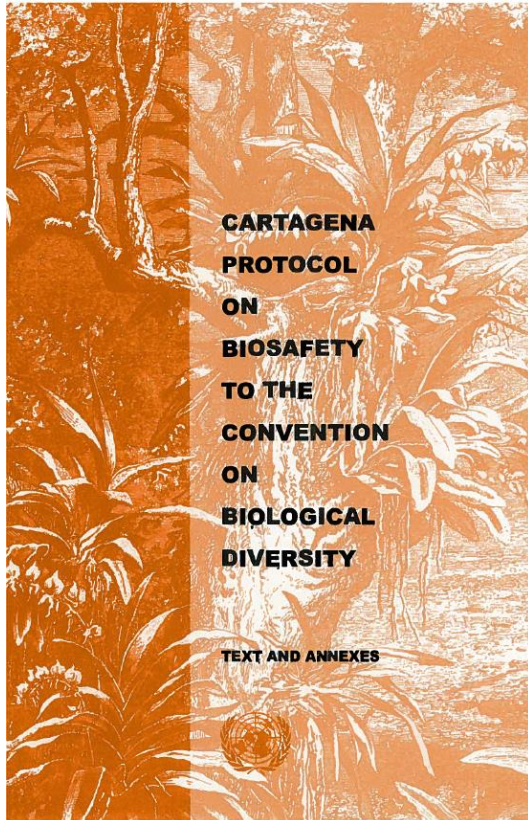
# What is a Protocol?

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

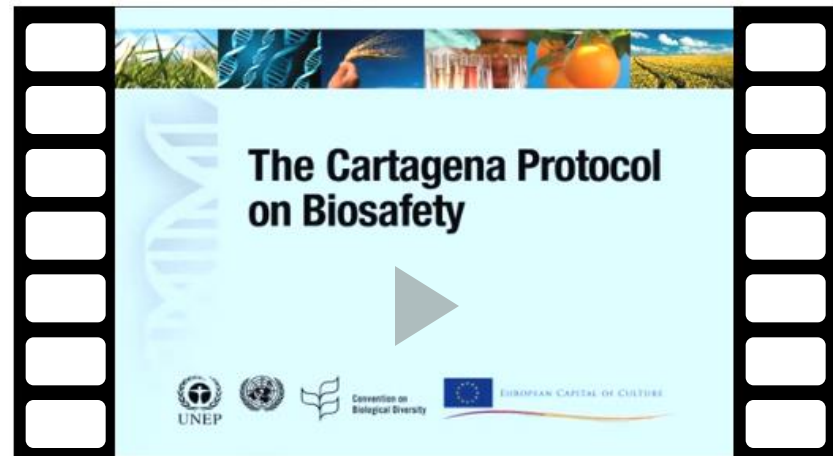
The Cartagena Protocol on Biosafety is under the Convention on Biological Diversity



# 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

**Biosafety Clearing-House** Convention on Biological Diversity

Home The BCH The Protocol Finding Information Registering Information Resources Help Country Profiles...

### Welcome to the BCH Central Portal

The Biosafety Clearing-House (BCH) is a mechanism set up by the Cartagena Protocol on Biosafety to facilitate the exchange of information on Living Modified Organisms (LMOs) and assist the Parties to better comply with their obligations under the Protocol. Global access to a variety of scientific, technical, environmental, legal and capacity building information is provided in the six official languages of the UN.

BCH account holders can create and manage records in the BCH by signing in through the Management Centre (Registering Information) section.

#### Latest news

- 2015-05-20 Republic of Korea - LMO Workshop for Bhutan Officials on Biosafety and Safety Management by Korea Biosafety Capacity Building Initiative...
- 2015-04-07 Malaysia - Consultation Workshop for the Final Draft Report of the Study on the Establishment of a Regulatory Framework for Liability and Redress for Damage Caused by LMOs, Kuala Lumpur, Malaysia, 31 March 2015...
- 2015-03-20 Mexico - PARTICIPANTES - SEGUNDO CURSO REGIONAL PARA EL FORTALECIMIENTO DE CAPACIDADES EN BIOSEGURIDAD DE ORGANISMOS GENÉTICAMENTE MODIFICADOS 2015...
- 2015-03-19 Iran (Islamic Republic of) - Theoretical and practical Workshop on BCH Capacity building...
- 2015-03-16 Republic of Korea - Announcement of LMOs Statistics for 2014, Korea...
- 2015-03-10 7th meeting of the IOBC-WPRS working group "GMO's in Integrated Plant Production" in Sofia, 1-3 June 2015...
- 2015-03-07 PERU - Simposio Latinoamericano: "Domesticación y manejo de recursos genéticos"...
- 2015-02-23 Guatemala - TALLER DIVERSIDAD GENÉTICA DE MAÍZ EN GUATEMALA: Estado de su conocimiento y su actualización...

More news...

#### Latest Additions [More additions...]

- 2015-05-21 Republic of Korea - Country's Decision or any other Communication
- 2015-05-21 Republic of Korea - Risk Assessment
- 2015-05-20 Kenya - Submissions from Parties, other Governments or relevant organizations
- 2015-05-20 Philippines - Submissions from Parties, other Governments or relevant organizations
- 2015-05-20 Pakistan - Submissions from Parties, other Governments or relevant organizations

#### Latest updates

- 2015-05-20 Mexico - National Focal Point
- 2015-05-15 Philippines - National Focal Point
- 2015-05-15 Botswana - National Focal Point
- 2015-05-15 Biosafety Information Resource
- 2015-05-15 Lithuania - Law, Regulation or Guideline

**COP-MOP 7**  
29 Sep - 3 Oct 2014

**Final Report:** **NEW**  
Ar | En | Es | Fr | Ru | Zh

[Webpage](#) | [Documents](#)







**Online discussions**  
Socio-economic Considerations **NEW**

**Open-ended** **NEW**  
Online Forum on Synthetic Biology

<http://bch.cbd.int>



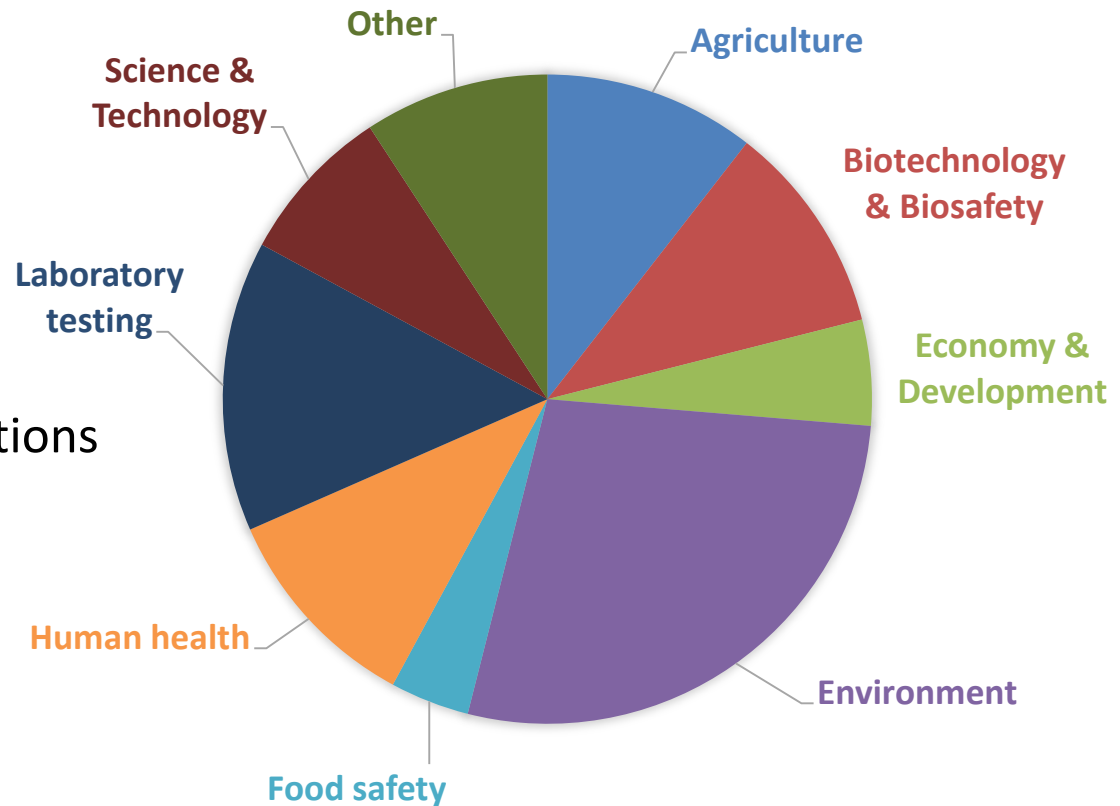
# Biosafety Clearing-House

- **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	<b>Brazil</b>
Date of signature	-
Date of ratification	2003-11-24
Date of entry into force	2004-02-22
Profile revision	-
Profile status	 <b>Published</b>
Profile last updated on	-

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

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



# Biosafety Clearing-House



Modified Organism

MON-00810-6 - 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)

 +1 0

 Tweet 0

 Recommend 2

## 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.



MON-00810-6  
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

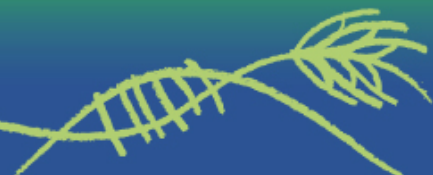
Browse information by

- 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](mailto:GM-Platform@fao.org)

[Start browsing](#)



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

[Latest Newsletter](#)

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# International Plant Protection Convention



**International Plant Protection Convention**  
Protecting the world's plant resources from pests

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Protecting the world's



## About us

- Who we are
- What we do
- How we do it
- Convention text
- [MORE](#)



ISPM No. 11

INTERNATIONAL STANDARDS FOR  
PHYTOSANITARY MEASURES

ISPM No. 11

**PEST RISK ANALYSIS FOR QUARANTINE PESTS  
INCLUDING ANALYSIS OF ENVIRONMENTAL  
RISKS AND LIVING MODIFIED ORGANISMS**

(2004)

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Sirex woodwasp - *Sirex noctilio* -  
Peter Lillywhite & Ken Walker,  
Museum Victoria.

[Calendar](#) [Publications](#) [Calls](#)

[consultation on draft ISPMs](#)

[REPORT](#)

[Secretariat welcomes MONGOLIA as  
acting party](#)

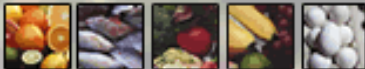
[for the requests for Diagnostic](#)

# Codex Alimentarius Commission

FAO/WHO Food Standards

ENGLISH | FRANÇAIS | ESPAÑOL

**CODEX** alimentarius



ABOUT CODEX

MEETINGS AND EVENTS

OFFICIAL STANDARDS



## BIOTECHNOLOGY

### FAO/WHO FOOD SAFETY ASSESSMENTS OF FOODS DERIVED FROM BIOTECHNOLOGY

FAO and WHO have provided expert scientific advice on the food safety aspects of foods derived from biotechnology since 1991. While not officially part of the Codex Alimentarius Commission structure, the FAO/WHO Expert Consultations in this area provide independent scientific expert advice to the Commission and its specialist Committees and Task Forces. FAO and WHO maintain separate websites highlighting this work from the points of view of the two parent Organizations.

[Back to HOME](#) ◀

#### In this Section

[Biotechnology safety assessment at FAO](#)

[Biotechnology safety assessment at WHO](#)

# Organisation for Economic Cooperation and Development



## BioTrack Product Database

Browse by identifier

### Product Database

- Home page
- Disclaimer

### Browse by

- Unique Identifier
- Organism
- Company
- Country

Unique Identifier	Organisms	Traits	First country	Date of approval
<a href="#">ACS-BN011-5</a>	Canola plant, Oilseed rape, Rape Seed	Bromoxynil tolerance	Canada	February 18, 1997
<a href="#">ACS-BN001-4</a>	Canola plant	Fertility restoration	Canada	September 08, 1994
<div> <h3>Consensus Documents for the Work on Harmonisation of Regulatory Oversight in Biotechnology</h3> <p><a href="#">Send</a> <a href="#">✉</a> <a href="#">Print</a> <a href="#">🖨</a></p> <p>These consensus documents comprise technical information for use during the regulatory assessment of products of biotechnology and are intended to be mutually recognised among OECD Member countries. They focus on the biology of organisms (such as plants, trees or micro-organisms) or introduced novel traits.</p> <p>These documents are updated to take into account new knowledge on the topic. In order to assist in this, it is possible to make comments to the OECD on the Biotechnology Consensus Documents.</p> <p>At the present time, the following consensus documents have been published:</p> <ul style="list-style-type: none"> <li>■ Consensus Document on the Biology of Bananas and Plantains (Musa spp.) No.48, 2009, <a href="#">ENV/JM/MONO(2009)43</a></li> </ul> </div>				

# World Organisation for Animal Health



Organisation  
Mondiale  
de la Santé  
Animale

World  
Organisation  
for Animal  
Health

Organización  
Mundial  
de Sanidad  
Animal

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- [The OIE](#)
- [The Veterinary Services](#)
- [Press releases/Editorials](#)
- [International meetings](#)
- [World animal health situation](#)
- [Official country disease status](#)
- [Animal diseases data](#)
- [OIE Expertise](#)
- [Certification of diagnostic assays](#)
- [Health standards](#)
- [Publications and Documentation](#)
- [Jobs/Internships/Services](#)
- [Links](#)

## Alerts - Disease Information

[Newcastle disease in Japan - Reassortment of swine H1N1 virus with pandemic H1N1](#)

 [Latest news on animal diseases](#) 

 [Update on avian influenza in animals](#)

 [World Animal Health Information Database](#)

## Highlights

[23/06/10](#) [Second Global Conference of the OIE's 227 Reference Laboratories and Collaborating Centres](#)

[17/06/10](#) [The OIE enters the final stage before official confirmation of global rinderpest eradication](#)

[23/05/10](#) [78th General Session of the OIE](#)

[previous press releases ...](#)

## OIE Conferences

 [First OIE Global Conference on Veterinary Legislation](#)  
[Djerba \(Tunisia\), 7-9 December 2010](#)

# World Trade Organization



## WHAT IS THE WTO?

- > Introduction
- > 153 members
- > WTO structure
- > Legal texts



## DIRECTOR-GENERAL

- > Pascal Lamy
- > Speeches
- > Schedule

## RESOURCES FOR...

- > Students
- > Journalists
- > NGOs
- > Parliamentarians
- > Research
- > Statistics
- > Distance learning

## WTO issues panel report on Airbus dispute

The WTO, on 30 June 2010, issued the report of a panel that had examined a complaint by the Certain Member States – Measures Affecting Trade in Large Civil Aircraft” (DS316). 30/06/2010

### See also:

- > Rapid Doha conclusion will help us achieve Millennium Declaration Goals – Lamy 29/06/2010
- > Lamy stresses importance of concluding the Round to G20 business leaders 26/06/2010
- > DG Lamy receives Kiel Institute's 2010 Global Economy Prize 20/06/2010
- > More WTO news

## DOHA ROUND STOCKTAKING, 26 March 2010



- > Report by Pascal Lamy
- > Press conference
- > Highlights from the press conference

## UPCOMING PUBLIC



## CURRENT WORK

### Negotiations and more

#### Doha Development Agenda



- > What is the DDA?
- > DDA main page
- > Trade Negotiations Committee
- > The July 2008 package

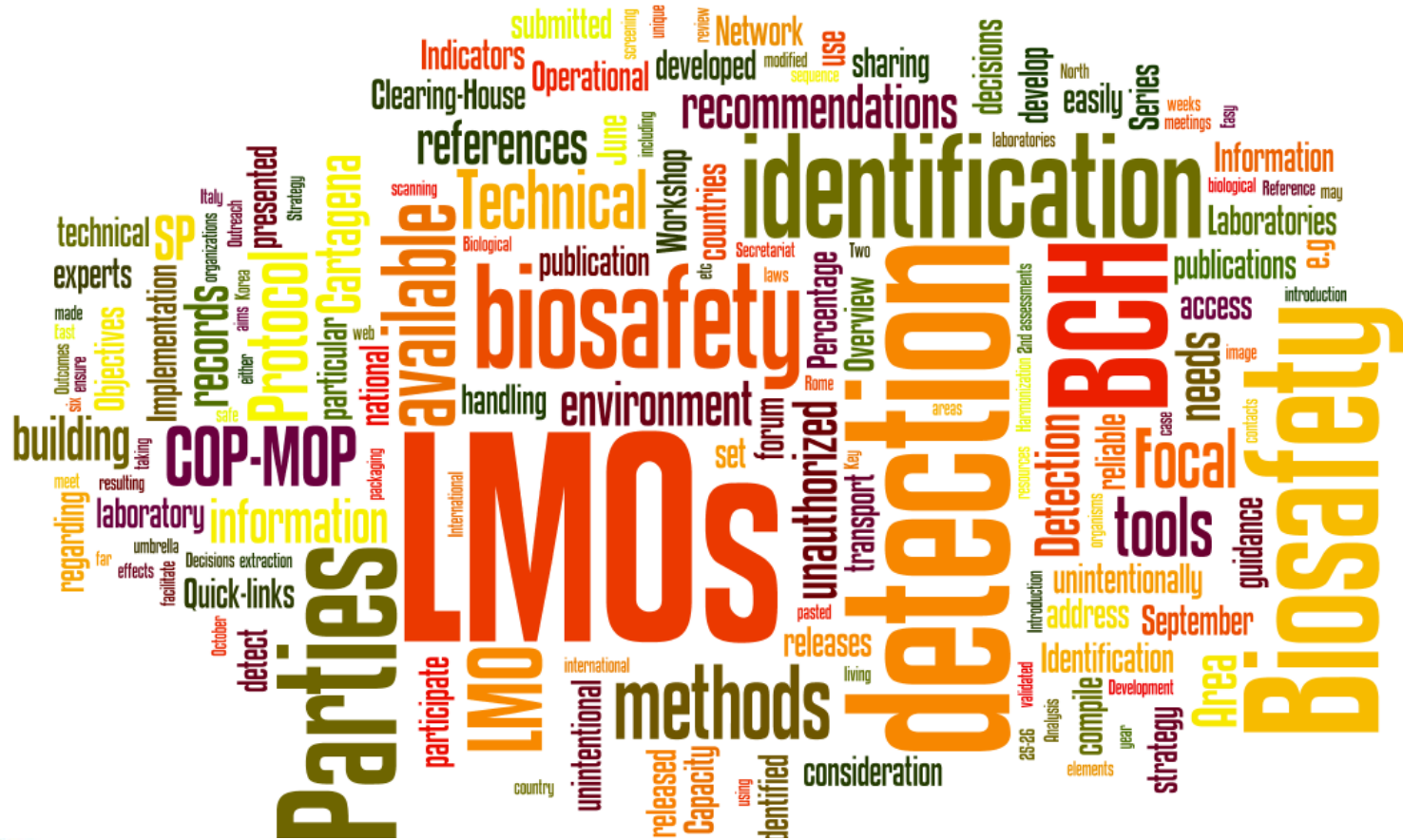
### Other work

Disputes Trade Policy Reviews Negotiating membership Aid for Trade

All other work is in

**TRADE TOPICS**

# Thank you!



# 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  
[#100366](#)  
0.61 Kb

Hsp70 intron  
[#100359](#)  
0.80 Kb

Cry1Ab  
[#14985](#)  
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

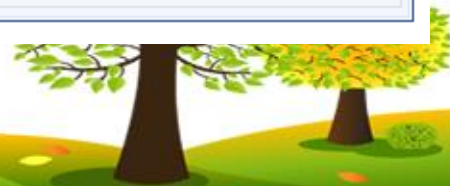
 [MON810 - OECD Biotrack Product Database](#)

 [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



Modified Organism

MON-00810-6 - YieldGard™ maize

LMO Information

Decisions on the LMO

Risk Assessments



0



Tweet

0



Recommend

0

Display cross-references with external data

Country	BCH Decisions									
Argentina	777									
Australia	7477									
Austria	37308									
Brazil	44584									



# 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	<a href="#">Biostradestatus</a>
<a href="#">Argentina</a>	<a href="#">777</a>	
<a href="#">Australia</a>	<a href="#">7477</a>	
<a href="#">Austria</a>	<a href="#">37308</a>	
<a href="#">Brazil</a>	<a href="#">44584</a>	

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



# Biosafety Clearing-House



Modified Organism

MON-ØØ81Ø-6 - YieldGard™ maize

LMO Information

Decisions on the LMO

**Risk Assessments**

g+1

0



Tweet

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Recommend

0

ID

Description

21 record(s) found



101152

**Austria**

Risk assessment for GM maize line MON810 which may not be cultivated in Austria

MON-ØØ81Ø-6  
Corn, MAIZE



45581

**Brazil**

Risk Assessment for Insect Resistant Maize

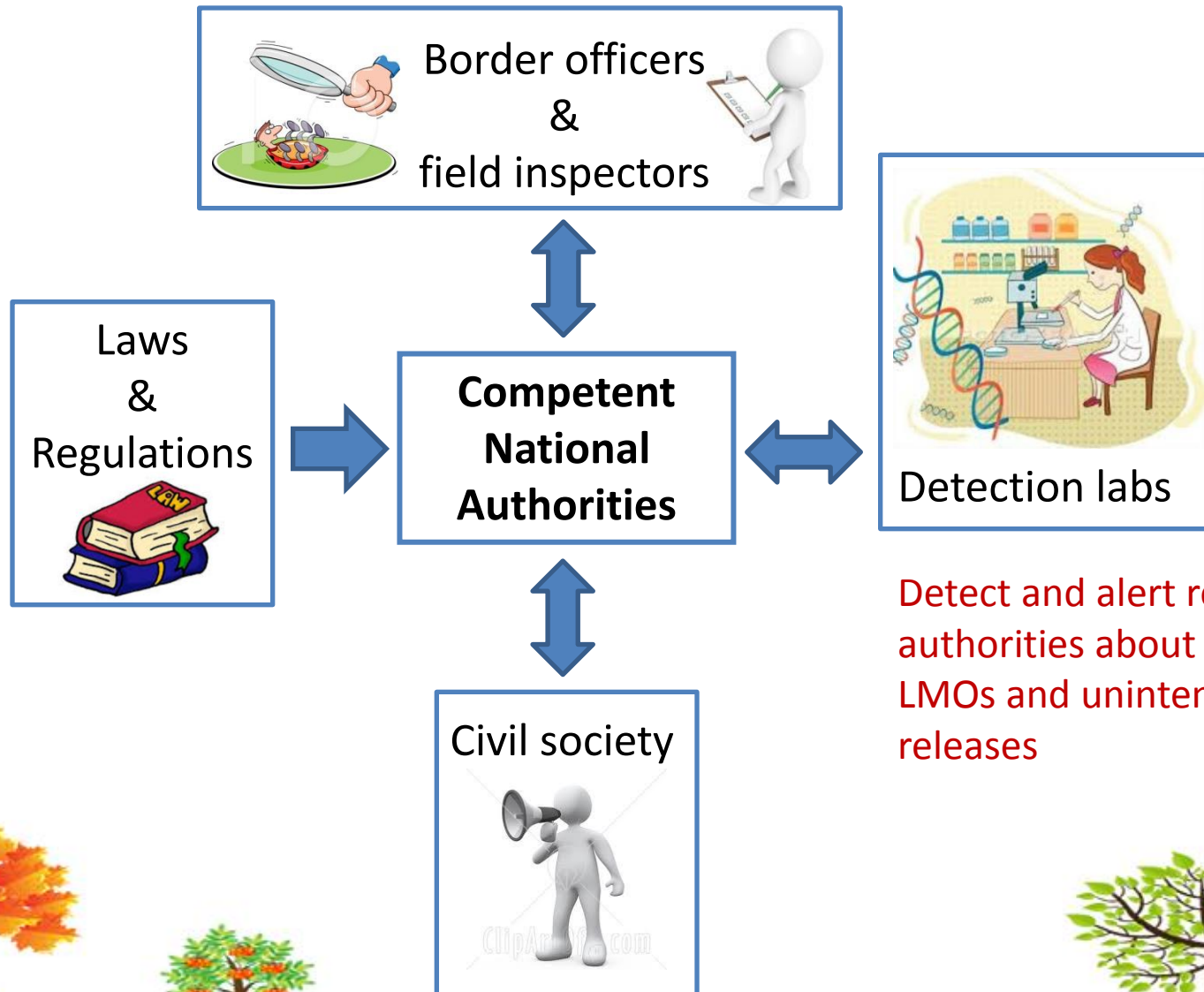
MON-ØØ81Ø-6  
Corn, MAIZE



# Network of Laboratories



# Network of Laboratories



# 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](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](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](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

