# **Biosafety Clearing-House and the Cartagena Protocol on Biosafety**

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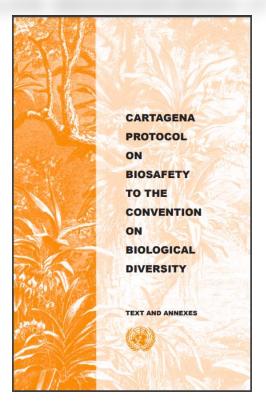


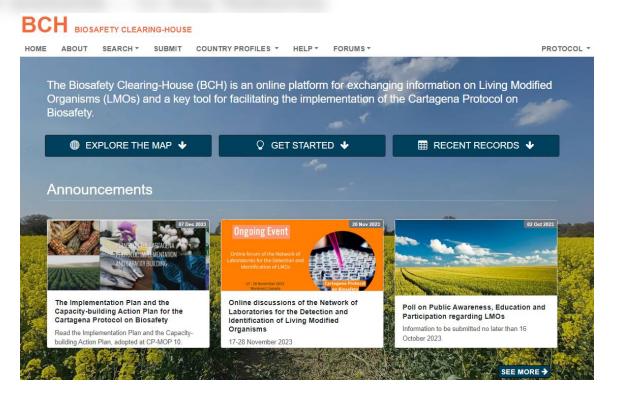


# **Objectives**

### Goal of this presentation:

- 1. Provide a brief **history** of the Biosafety Clearing-House (BCH) and overview of the Cartagena Protocol Parties' **obligations** relevant to the BCH
- 2. Live demonstration of the BCH website its key features





# What is the Biosafety Clearing-House?

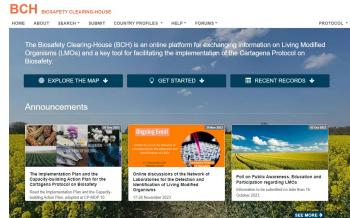
The Biosafety Clearing-House (BCH) was established further to **Article 20** of the Cartagena Protocol on Biosafety in order to:

- Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms (LMOs);
- > Assist Parties to implement the Protocol.

**The Biosafety Clearing-House (BCH)** is an **information exchange mechanism** that was set up by the Cartagena Protocol on Biosafety to facilitate the exchange of information on LMOs and to assist

Parties to better comply with their obligations under the Protocol.

BCH has been developed as a website: <a href="http://bch.cbd.int">http://bch.cbd.int</a> Access is free and BCH is available in all 6 UN languages.



CARTAGENA

PROTOCOL ON BIOSAFETY

TO THE
CONVENTION
ON
BIOLOGICAL
DIVERSITY

# The Biosafety Clearing-House: History

### **Article 20** – Information sharing and the Biosafety Clearing-House

Each Party shall make available to the BCH any information required under the Protocol:

- a) Any existing <u>laws</u>, <u>regulations and guidelines</u> for implementation of the Protocol
- b) Any bilateral, regional and multilateral agreements and arrangements
- c) Summaries of its <u>risk assessments</u> or environmental reviews of LMOs generated by its regulatory process, and carried out in accordance with Article 15
- d) Its final <u>decisions</u> regarding the importation or release of LMOs
- e) Reports submitted by it pursuant to Article 33

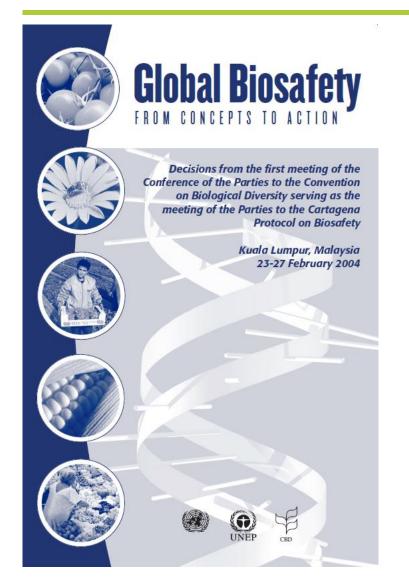


**Article 33** 

**Monitoring and Reporting** 

**Each Party shall monitor the implementation of its obligations under this Protocol**, and shall, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, **report** to the Conference of the Parties serving as the meeting of the Parties to this Protocol **on measures that it has taken to implement the Protocol**.

# Modalities of Operation of the Biosafety Clearing-House (COP-MOP Decision BS-I/3)



- Outlines the role, characteristics and administration of the BCH. This includes:
  - Its role in providing access to information
  - It is guided by principles of inclusiveness and transparency
  - It is developed by the Secretariat in a manner to ensure it is accessible, user-friendly, searchable and understandable.



BCH has been developed as a website: <a href="http://bch.cbd.int">http://bch.cbd.int</a>

## Types of information in the BCH



<u>Parties to the Protocol are required to publish</u> certain information in the BCH including:

- Laws and regulations to implement the Protocol
- Reports of risk assessments carried out to evaluate potential adverse effects of living modified organisms
- Decisions on living modified organisms
- Contact information for national focal points and competent national authorities

### **Reference Records:**



### **Other categories of information** in the BCH include:

- LMO, organism and gene registries
- Capacity development initiatives
- Biosafety Virtual Library Resources
- Biosafety Organizations
- Labs for detection and identification of LMOs
- Biosafety news

BCH also hosts a number of online **forums** and discussions on different biosafety-related topics:









### Why is the BCH important?

The BCH is an important repository of information on LMOs and biosafety that can assist decision-makers in countries around the world as well as civil society and the biotechnology industry.

The BCH fosters transparency:

- by <u>allowing easy and open access to information about the national decisions and risk assessments of Parties and non-Parties</u> relating to specific LMOs
- by providing <u>easy access to vital information relevant to imports and exports</u>, including details of national contacts, relevant laws, regulations and guidelines governing the use and handling of LMOs
- > by providing access to a variety of scientific, technical, environmental, legal and capacity-building information
- by ensuring that the relevant authorities in other <u>countries can quickly find out whom to inform in the event of an accidental movement of LMOs</u> into their territory
- by providing a <u>dynamic platform where information is registered by users and where it can be easily searched and retrieved</u>, thus allowing users to contribute to or access biosafety-related information
- > by facilitating effective participation of the public and non-government organizations in the decision-making process

### The BCH is for everyone

- Governments and risk assessors
- Civil society
- Scientists and academics
- Industry

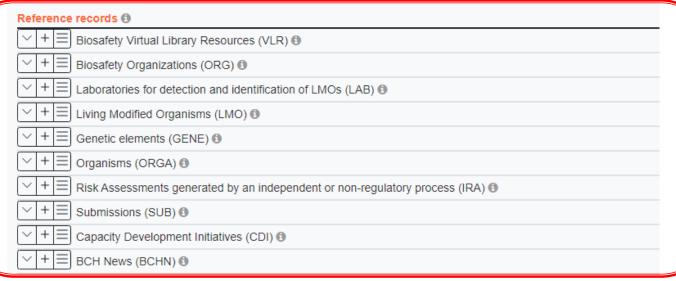


#### Types of record in the BCH

#### **National Records**



#### **Reference Records**





National Records are records that Parties to the Cartagena Protocol have the obligation to submit in accordance with the Protocol as well as other national information relevant to the implementation of the Protocol.

<u>National Records</u> **are owned by the Government**. They can be managed by are 3 types of *national users*:

- 1. BCH National Focal Points (BCH-NFPs)
- 2. Cartagena Protocol on Biosafety National Focal Points (CPB-NFPs)
- 3. National Authorized Users (NAUs)

National records 6				
V + ■ National Focal Point (NFP) 1				
✓ +  ☐ Competent National Authorities (CNA) ⑤				
Supplementary Protocol Competent Authorities (SPCA)   Supplementary Protocol Competent Authorities (SPCA)				
+ Biosafety Laws, Regulations, Guidelines and Agreements (LAW) 1				
Countries' Decisions or any other Communications (DEC) 1				
Risk Assessments generated by a regulatory process (RA) 1				
∀ +      ■ National Biosafety Websites or Databases (NDB)      ●				
Fourth National Reports on the Implementation of the Cartagena Protocol on Biosafety (NR4)				
Third National Reports on the Implementation of the Cartagena Protocol on Biosafety (NR3) 1				
Second National Reports on the Implementation of the Cartagena Protocol on Biosafety (NR2) 1				
First National Reports on the Implementation of the Cartagena Protocol on Biosafety (NR1) 1				
Biosafety Experts (EXP) 1				
Country Profiles for Biosafety Clearing-House (BCP)   Country Profiles for Biosafety Clearing-House (BCP)				

In <u>decision CP-9/15</u>, Parties to the NKLSP were requested **to designate a competent authority** to perform the functions set out in <u>Article 5</u> of the NKLSP, and to make the contact information of its competent authority available in the BCH.

Same decision also requested the Executive Secretary to create the appropriate **common format** in the BCH to enable Parties to share the contact information of their competent authorities pursuant to <u>Article 5</u> of the Supplementary Protocol.



National records 1			
National Focal Point (NFP) 1			
✓ + = Competent National Authorities (CNA) <b>1</b>			
Supplementary Protocol Competent Authorities (SPCA) 1			
Biosafety Laws, Regulations, Guidelines and Agreements (LAW) 1			
Countries become or any other communications (BEG) o			
Risk Assessments generated by a regulatory process (RA)			
National Biosafety Websites or Databases (NDB) 1			
Fourth National Reports on the Implementation of the Cartagena Protocol on Biosafety (NR4)			
Third National Reports on the Implementation of the Cartagena Protocol on Biosafety (NR3) (1)			
Second National Reports on the Implementation of the Cartagena Protocol on Biosafety (NR2) 1			
First National Reports on the Implementation of the Cartagena Protocol on Biosafety (NR1) 1			
Biosafety Experts (EXP) 1			
Country Profiles for Biosafety Clearing-House (BCP)   Country Profiles for Biosafety Clearing-House			

National websites or databases include publicly searchable internet sites on biosafety that are maintained by governments or national institutions.

### **Article 23 (Public Awareness and Participation)**

#### Parties shall:

- Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs
- Endeavor to ensure that public awareness and education encompass access to information on LMOs

National records (1)				
National Focal Point (NFP) 1				
Biosafety Laws, Regulations, Guidelines and Agreements (LAW) 1				
Countries' Decisions or any other Communications (DEC)				
∀ +				
∀ +      ■ National Biosafety Websites or Databases (NDB)      ①				
Fourth National Reports on the Implementation of the Cartagena Protocol on Biosafety (NR4)				
Third National Reports on the Implementation of the Cartagena Protocol on Biosafety (NR3) 1				
Second National Reports on the Implementation of the Cartagena Protocol on Biosafety (NR2) (1)				
First National Reports on the Implementation of the Cartagena Protocol on Biosafety (NR1) 1				
Biosafety Experts (EXP) 1				
Country Profiles for Biosafety Clearing-House (BCP) 1				

The <u>roster of biosafety experts was established by ExCOP-1 Decision EM-I/3</u> and aims to:

"provide advice and other support, as appropriate and upon request, to developing country Parties and Parties with economies in transition, to conduct risk assessment, make informed decisions, develop national human resources and promote institutional strengthening, associated with the transboundary movements of LMOs."

### Decision BS-IV/4 sets out:

- the criteria and minimum requirements for experts to be nominated to the roster of experts (Annex I)
- guidelines for the roster of experts (Annex II)

Scientific records



<u>Reference Records</u> include various biosafety-related resources and scientific information that can be submitted by any registered user. <u>Any registered BCH user</u> can create, edit, delete the records but it is the <u>Secretariat</u> who validates and publishes those records or approves modification or deletion of a record.

# Numbers at a glance to-date (as at 12 January 2024):

### **National records**

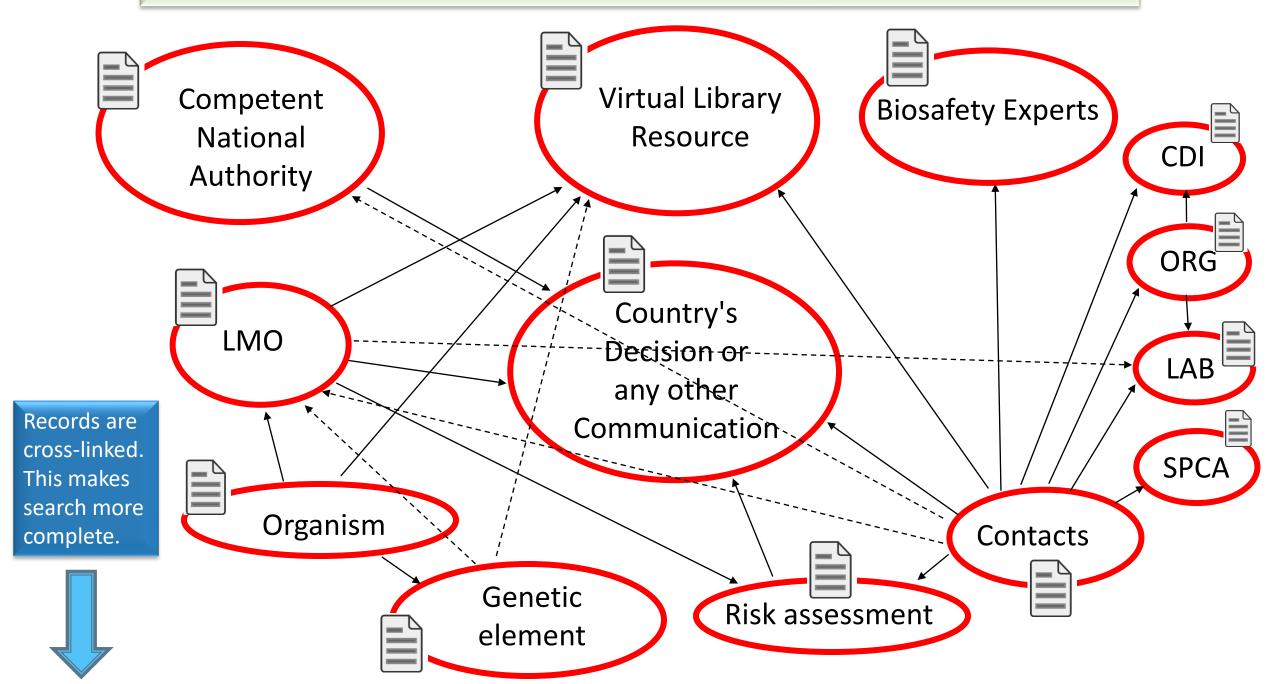
- 344 national focal points
- 401 competent national authorities
- 15 supplementary protocol competent authorit
- 1147 laws and legislations
- 2761 decisions by 56 countries
- 2644 risk assessments
- 151 websites and databases
- 366 experts

### **Reference records**

- 2093 LMOs (960), genes (861) and organisms (272)
- 1575 biosafety virtual library resources
- 423 capacity development initiatives
- 383 biosafety organizations
- 78 laboratories
- 32 independent risk assessments
- 558 biosafety news



# Example of inter-relationship between various record types in the BCH



### ☐ Decisions on the LMO ☐ Risk Assessments

LAST UPDATED: 24 MAY 2013

#### 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.

https://bch.cbd.int/database/record?documentID=14750







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

Name

YieldGard™ maize

EN

Transformation event

MON810

Does this LMO have a unique identifier?

Unique identifier

MON-ØØ81Ø-6

Yes

#### Developer(s)

- ORGANIZATION: MONSANTO | BCH-CON-SCBD-14925-3 [7]

#### ORGANIZATION:

Monsanto

800 North Lindbergh Blvd.

St. Louis, MO

63167, United States of America

Phone: + 1 314 694-1000 Fax: +1 314 694-3080

Website: http://www.monsanto.com

#### Description

Insect-resistant maize produced by inserting the cry1Ab gene from Bacillus thuringiensis subsp. kurstaki HD-1. The genetic modification affords resistance to attack by the European corn borer (ECB), Ostrinia nubilalis.

EN

#### Recipient Organism or Parental Organisms

The term "Recipient organism" refers to an organism (either already modified or non-modified) that was subjected to genetic modification, whereas "Parental organisms" refers to those that were involved in cross breeding or cell fusion.



BCH-ORGA-SCBD-246-6 Organism Zea mays (Maize, Corn, MAIZE)

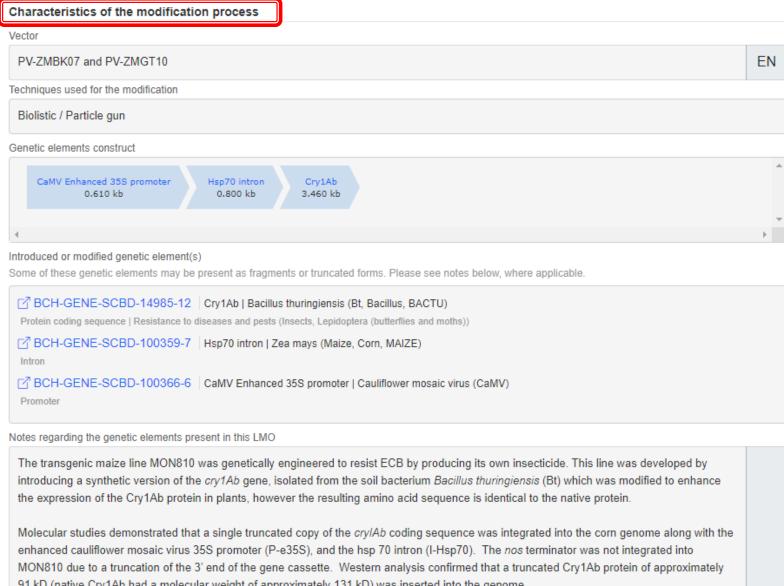
Crops

#### Related LMO(s)



☑ BCH-LMO-SCBD-14779-7 PH-MON8Ø9-2 - Insect-resistant maize MON809 | Monsanto, Pioneer Hi-Bred International Inc. | Resistance to antibiotics (Kanamycin), Resistance to diseases and pests (Insects, Lepidoptera (butterflies and moths), European corn borer (Ostrinia nubilalis)), Resistance to herbicides (Glyphosate)

☑ BCH-LMO-SCBD-15410-7 Insect Resistant Maize MON801 | Monsanto | Resistance to antibiotics (Kanamycin), Resistance to diseases and pests (Insects, Lepidoptera (butterflies and moths), European corn borer (Ostrinia nubilalis))



91 kD (native Cry1Ab had a molecular weight of approximately 131 kD) was inserted into the genome.

ΕN

Corn event MON 810 was produced by microprojectile bombardment of embryogenic corn tissue with plasmids PVZMBK07 and PV-ZMGT10. However plasmid vector PV-ZMGT10 was not integrated into the plant genome. Further Southern blot analysis indicated that the genes for glyphosate tolerance (CP4 EPSPS) and antibiotic resistance (neo) were not transferred to line MON 810 and the absence of the CP4 EPSPS and gox gene products was also confirmed by Western blotting. The CP4 EPSPS and GOX protein encoding genes were presumed to have been inserted into the initial transformant at a separate genetic loci from the cry1Ab gene and then subsequently lost through segregation during the crossing events leading to line MON810.

#### LMO characteristics

Modified traits

Resistance to diseases and pests

Insects

Lepidoptera (butterflies and moths)

European corn borer (Ostrinia nubilalis)

Common use(s) of the LMO

Food

Feed

Biofuel

#### Detection method(s)

External link(s)

% MON-ØØ81Ø-6 - EU Reference Laboratory for GM Food and Feed (EURL-GMFF) [ English ]

% MON-ØØ81Ø-6 - CropLife International Detection Methods Database [ English ]

% MON-ØØ81Ø-6 - EU Reference Laboratory for GM Food and Feed (EURL-GMFF) ( JRC ) [ English ]

% MON-ØØ81Ø-6 - CropLife International Detection Methods Database ( CropLife ) [ English ]

#### Additional Information

Other relevant website addresses and/or attached documents

% MON810 - OECD Biotrack Product Database [ English ]

% MON810 - CERA GM Database [ English ]

Safety Assessment of YieldGard Insect-Protected Corn Event MON 810 [ English ]

BATS (2003) Genetically Modified (GM) Crops: molecular and regulatory details, v.2.pdf [ English ]

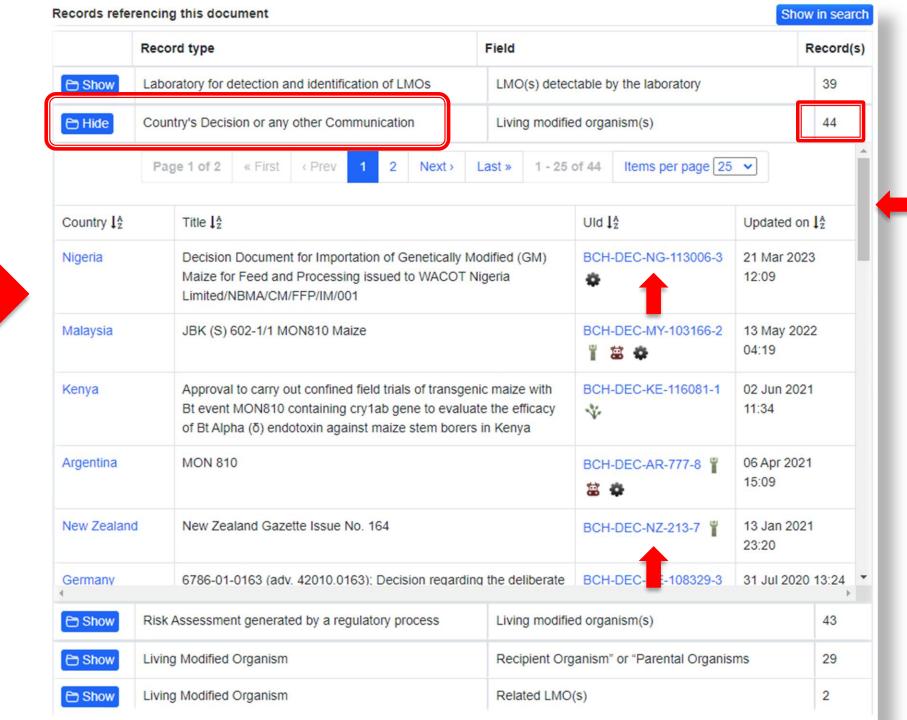
MON810 - Monsanto.pdf [ English ]



# Records referencing this document

# Show in search

	Record type	Field	Record(s)
<b>⊜</b> Show	Laboratory for detection and identification of LMOs	LMO(s) detectable by the laboratory	39
<b>⊜</b> Show	Country's Decision or any other Communication	Living modified organism(s)	44
Show	Risk Assessment generated by a regulatory process	Living modified organism(s)	43
Show	Living Modified Organism	Recipient Organism" or "Parental Organisms	29
<b>⊜</b> Show	Living Modified Organism	Related LMO(s)	2





LAST UPDATED: 24 MAY 2013

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Name

YieldGard™ maize

ΕN

Transformation event

MON810

Does this LMO have a unique identifier?

Yes

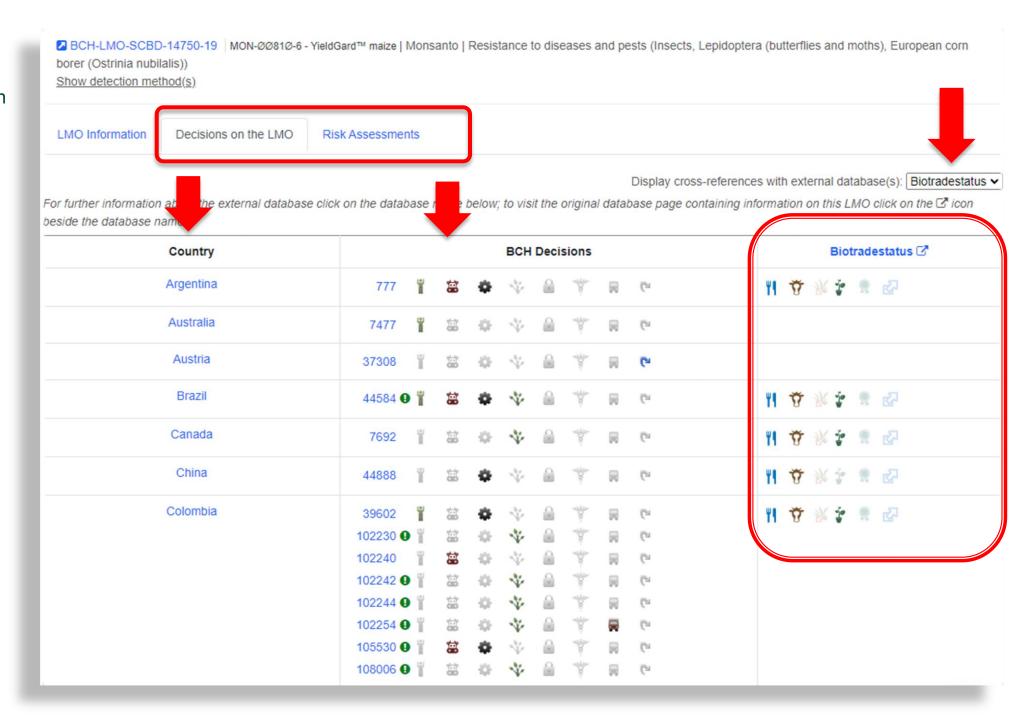
Unique identifier

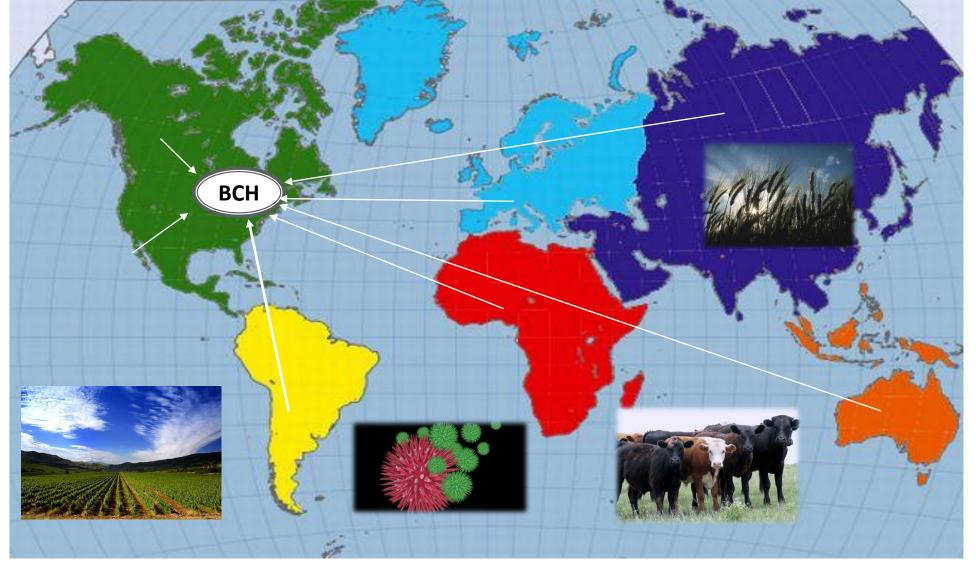
MON-ØØ81Ø-6

#### You can find:

- Information on decisions other countries have taken on a specific LMO and for what uses
- **Risk assessment** reports from other countries

You can also cross-check information on decisions against the information in the **Biotradestatus** database maintained by CropLife International.

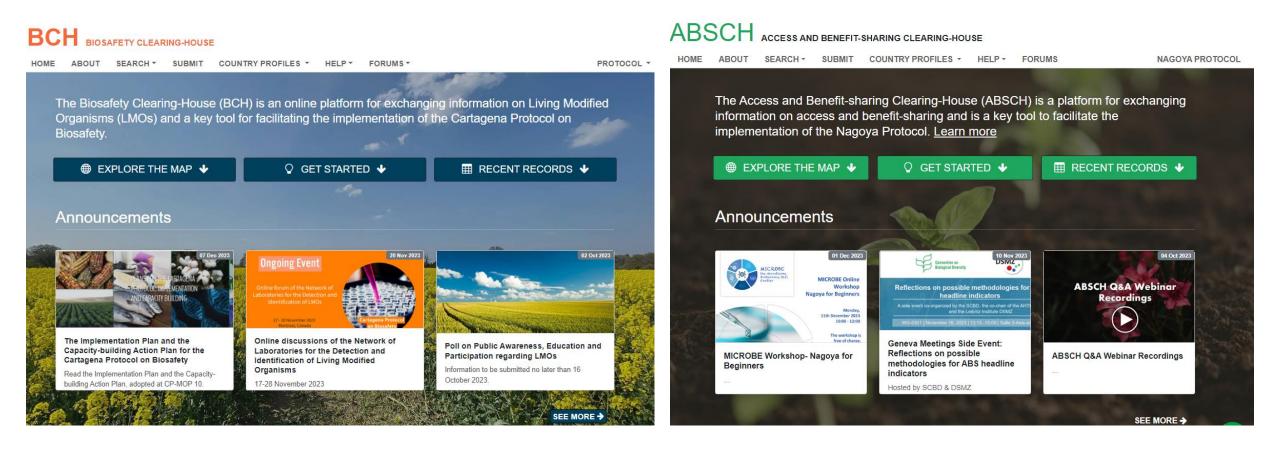




BCH is among the most important resources world-wide offering information on LMOs. In addition to the information submitted by Governments, it offers the most complete description of all LMOs commercialized as of today and the largest virtual library on biosafety. BCH is a **key tool** for information-sharing, capacity-building and facilitating the implementation of the Cartagena Protocol on Biosafety.

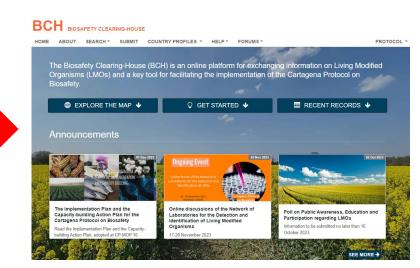
## New BCH Platform went officially live on 29 November 2021!

The new BCH user interface has been developed to resemble, both in appearance and functionalities, the user interface of the Access and Benefit-sharing Clearing-House (ABS CH) with a view to ensuring coherence and integration between the clearing-houses.



### **Migration: Key Points**





### Migration involved:

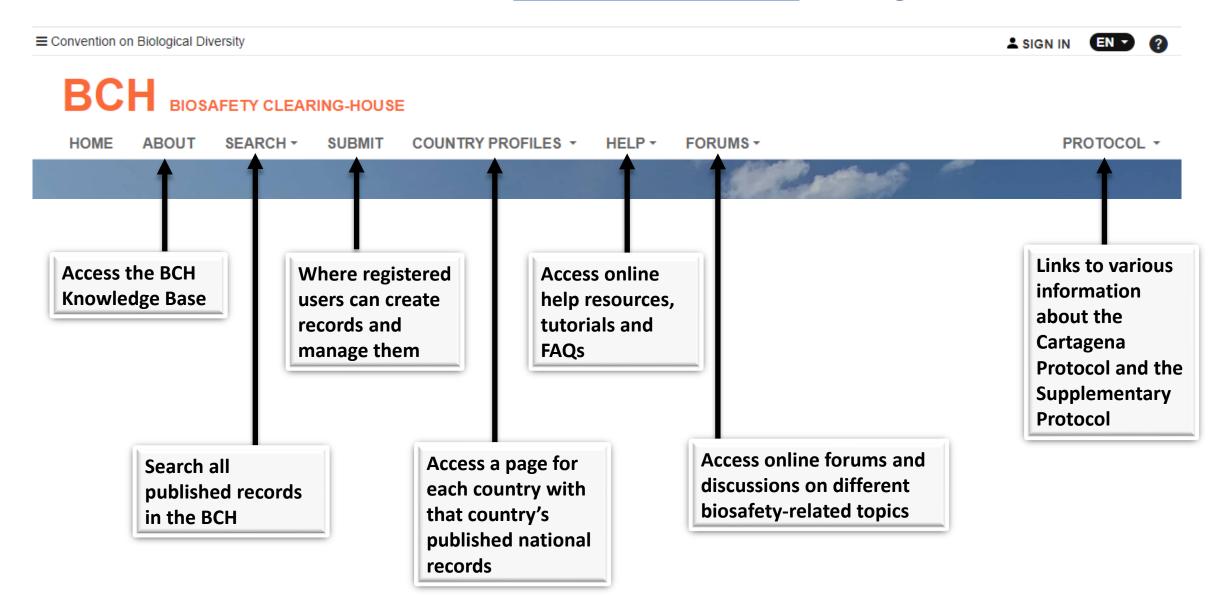


- --Building a new 'house' for the BCH
- --Designing that house in a similar style to other clearing-houses while maintaining specific functionalities required for the BCH and the Protocol
- --Moving the data from the old house to the new house

#### **New BCH:**

- Is built on a modern platform with a modern look
- Is more user-friendly, including easier procedures for publishing records
- Has a new search interface while preserving the multi-level search capability of the previous BCH it is the most advanced SEARCH ever built by the Secretariat
- Has more tools for displaying and analysis of search results

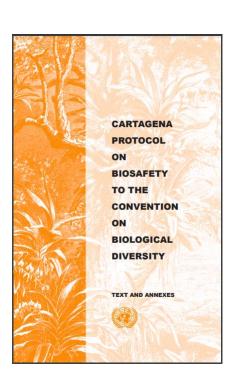
# Access the BCH at: <a href="https://bch.cbd.int/">https://bch.cbd.int/</a> Let's go LIVE!

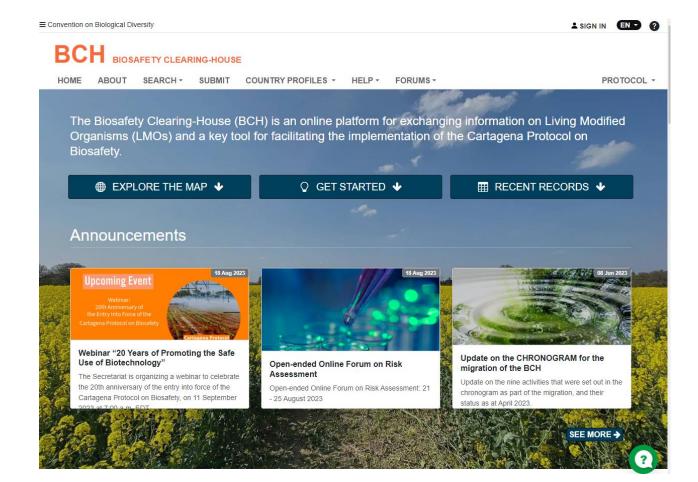


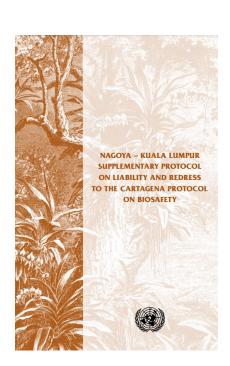
# The Biosafety Clearing-House

### Conclusion

The BCH is the core of the Cartagena Protocol on Biosafety and is key to its implementation.







# Thank you!

# For more information on the BCH:





"BCH on BCH Forum": <a href="https://bch.cbd.int/en/portals/bch-on-bch">https://bch.cbd.int/en/portals/bch-on-bch</a>

