

### The Biosafety Clearing-House

Austein McLoughlin Associate Programme Management Officer 16 March 2023





# What is the Biosafety-Clearing House?

- The Biosafety Clearing-House (BCH) was established:
  - By Article 20 of the Cartagena Protocol on Biosafety
  - As part of the Clearing-House mechanism under Article 18, paragraph 3, of the Convention on Biological Diversity
- The BCH is the instrument that allows Parties to exchange information on living modified organisms (LMOs) and therefore plays a fundamental role in facilitating the implementation of the Cartagena Protocol









# Why is the BCH important?

- The BCH fosters transparency:
  - In the regulation of LMOs  $\rightarrow$  what rules apply and who to contact for more information
  - In decisions taken on LMOs  $\rightarrow$  what LMOs have been approved or prohibited, for what uses, and where
  - Access to information on LMOs
- The BCH is for everyone:
  - Governments that are not Parties to the Protocol are also encouraged to publish information in the BCH
  - A large number of decisions in the BCH have been published by non-Parties
  - Other stakeholders can also publish some types of information in the BCH and the BCH is freely accessible to everyone





# What information exists in the BCH?

- National records are published by governments and include information Parties are obliged to provide in accordance with the Protocol as well as other national information relevant to the implementation of the Protocol
- Reference records include a number of biosafetyrelated resources and information that can be submitted by any registered user and are validated by the Secretariat prior to their publication





### The BCH at its core







# How does the BCH contribute to the field of detection and identification of LMOs?

- Database of information related to biosafety and LMOs (scientific records, resource records, experts)
- User-friendly search and cross-referencing between records
- Linkages to other databases
- Network of Laboratories







## What type of scientific records are on the BCH?

- Living modified organisms
- Genetic elements
- Organisms
- Biosafety Virtual Library Resources
- Laboratories for detection and identification of LMOs
- Risk assessments generated by an independent or non-regulatory process

### Reference

- Risk assessment generated by a regulatory process
- Biosafety experts

### National







# Snapshot of the BCH

- 17,400+ records published
  - 940+ LMOs
  - 840+ genetic elements
  - 260+ organisms
  - 70+ laboratories
  - 1570+ virtual library resources
  - 2600+ risk assessments
  - 360+ biosafety experts





### What does a BCH record look like: Living Modified Organisms

IVING MODIFIED ORGANISM (LMO)	🗹 BCH-LMO-SCBD-15168-16   🗋 PDF   🖨 Print	t   🚀 Share   🥲 Compare 🝷   🗹 E
C Decisions on the LMO C Risk Assessme	nts	LAST UPDATED: 25 SEP 202
Living Modified Organism identity		
The image below identifies the LMO through its uni	que identifier, trade name and a link to this page of the BCH. Click or	n it to download a larger image on your compute
	For help on how to use it go to the LMO quick-links page.	
MON-88913-8 Roundup Ready <sup>™</sup> Flex <sup>™</sup> cot Read barcode or type above URL into internet bro	ton wser to access information on this LMO in the Biosafety Clearing-House © SCBD 2012	
Roundup Ready™ Flex™ cotton		EN
Transformation event		
MON88913 (88913)		
Does this LMO have a unique identifier?		
Yes		
Unique identifier		
MON-88913-8		

Convention on Biological Diversity Developer(s)

#### - ORGANIZATION: MONSANTO | BCH-CON-SCBD-14925-3

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

Roundup Ready® Flex cotton (MON 88913) was developed to allow the use of glyphosate, the active ingredient in the herbicide Roundup®, as a weed control option in cotton production. This genetically engineered cotton contains a novel form of the plant enzyme 5enolpyruvylshikimate-3-phosphate synthase (EPSPS) that allows MON 88913 to survive otherwise lethal applications of glyphosate. The *epsps* gene introduced into MON 88913 was isolated from a strain of the common soil bacterium *Agrobacterium tumefaciens* strain CP4; the EPSPS enzyme expressed by this gene is tolerant to glyphosate. MON 88913 cotton contains two copies of the EPSPS gene to confer tolerance to glyphosate later in the growing season, specifically after the fifth true leaf stage.

#### 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-12080-6 ORGANISM GOSSYPIUM HIRSUTUM (COTTON)

Crops

Point of collection or acquisition of the recipient organism or parental organisms

Variety: 'Coker 312'

EN



#### Characteristics of the modification process

#### Vector

PV-GHGT35

Techniques used for the modification

Agrobacterium-mediated DNA transfer

#### Genetic elements construct

	FMV 35S Enhancer 0.000 kb	Elongation factor EF-1 1.039 k	alpha promoter b	Elongati	ion	factor EF-1alpha Lead 0.045 kb	ler	Elongation factor EF-1alph 0.621 kb	na Intron 1	<b>^</b>	hlor	•
	CaMV 35S Enhancer 0.000 kb	Actin 8 promoter 1.174 kb	Actin 8 Leader 0.140	r sequence kb		Actin 8 Intron 1 0.472 kb		Chloroplast transit peptide 2 0.227 kb	5-enolp	yruvyls	hikir	
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#### Introduced or modified genetic element(s)

Some of these genetic elements may be present as fragments or truncated forms. Please see notes below, where applicable.

### C BCH-GENE-SCBD-14979-7 5-ENOLPYRUVYLSHIKIMATE-3-PHOSPHATE SYNTHASE GENE | AGROBACTERIUM TUMEFACIENS (AGROBACTERIUM)

Protein coding sequence | Resistance to herbicides (Glyphosate)

BCH-GENE-SCBD-103903-1 ELONGATION FACTOR EF-1ALPHA PROMOTER | ARABIDOPSIS THALIANA (THALE CRESS, MOUSE-EAR CRESS, ARABIDOPSIS, ARATH)

Promoter

BCH-GENE-SCBD-103904-1 ELONGATION FACTOR EF-1ALPHA LEADER | ARABIDOPSIS THALIANA (THALE CRESS, MOUSE-EAR CRESS, ARABIDOPSIS, ARATH)

Leader

BCH-GENE-SCBD-103905-1 ELONGATION FACTOR EF-1ALPHA INTRON 1 | ARABIDOPSIS THALIANA (THALE CRESS, MOUSE-EAR CRESS, ARABIDOPSIS, ARATH)

Intron

BCH-GENE-SCBD-100365-6 CHLOROPLAST TRANSIT PEPTIDE 2 | ARABIDOPSIS THALIANA (THALE CRESS, MOUSE-EAR CRESS, ARABIDOPSIS,



BCH-GENE-SCBD-105196-2 FMV 35S ENHANCER | FIGWORT MOSAIC VIRUS (FIGWORT MOTTLE VIRUS, FMV, CMOVB) Leader

#### BCH-GENE-SCBD-105197-2 CAMV 35S ENHANCER | CAULIFLOWER MOSAIC VIRUS (CAMV)

Leader

Notes regarding the genetic elements present in this LMO

#### Information on the inserted DNA sequences

The transforming plasmid PV-GHGT35 carried a transfer DNA sequence comprising of two codon-optimised Agrobacterium tumefaciens 5enolpyruvylshikimate-3-phosphate synthase (epsps) cassettes:

(1) the first *epsps* coding sequence under the regulation of a chimeric transcriptional promoter (*Figwort mosaic virus* 35S promoter enhancer and *Arabidopsis thaliana* elongation factor EF-1 alpha (*tsf1*) promoter), *tsf1* leader and intron sequences, an *A. thaliana* chloroplast transit peptide 2 sequence and a *Pisum sativum* ribulose-1,5-bisphosphate carboxylase/oxygenase (rubisco) E9 transcript termination and polyadenylation sequence (T-E9).

(2) the second *epsps* coding sequence regulated by another chimeric transcriptional promoter (*Cauliflower mosaic virus* 35S enhancer and *A. thaliana* actin 8 (*act8*) promoter), *act8* leader and intron sequences, *A. thaliana* chloroplast targeting peptide 2 and T-E9.

High levels of transcription are expected from both cassettes due to the presence of viral enhancer sequences. The EPSPS protein is expected to accumulate in the chloroplast due to the transit signal peptide.

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#### Vector information

Monsanto constructed the double border, binary plasmid vector PV-GHGT35 for the transformation of cotton variety Coker 312. The plasmid contains a single copy of two *epsps* expression cassettes within the T-DNA region. The T-DNA region of PV-GHGT35 was incorporated into the target cotton genome using *Agrobacterium*-mediated transformation. Plasmid PV-GHGT35 also contains several genes from the plasmid backbone necessary for maintenance and selection of the plasmid that are not ultimately incorporated into the plant genome. Plasmid PV-GHGT35 contains both vegetative and bacterial origins of replication that allow replication of the plasmid in both A. tumefaciens and Escherichia coli. The plasmid contains the *aad* gene encoding the Tn7 adenyltransferase that provides resistance to spectinomycin and streptomycin. The plasmid also contains a sequence, known as *rop*, which represses the formation of RNA primer thereby allowing maintenance and copy number control of the plasmid in *Escherichia coli*.

#### Note on genetic element sizes:

The promoter for both genetic constructs are chimeric promoters containing viral enhancer sequences. Thus, the size of the promoters (Elongation factor 1 alpha and Actin 8) in the 'Genetic elements construct' reflects the size of chimeric promoters (FMV 35S enhancer + Elongation factor 1 alpha promoter; CaMV 35S enhancer + Actin 8 promoter).



### What does a BCH record look like: Living Modified Organisms

Modified traits		
Resistance to herbicides		
Glyphosate		
Common use(s) of the LMO	<del></del>	
Fiber/textile	EURI	
Detection method(s)	European Union Reference Laborator	ry
External link(s)	for GM Food & Feed	
Sector MON-88913-8 - EU Reference Laboratory f	or GM Food and Feed (EURL-GMFF) ( JRC ) [ English ]	
Source Mon-88913-8 - CropLife International Dete	ction Methods Database ( CropLife ) [ English ]	
	CropLife	
	Meeting challenges in a growing word Home About Us Crop Protection Plant Biotechnology Resources Contact Us	AL

#### Background

Genetically modified (GM) crops were first introduced in 1994 and have now been adopted by farmers in more

#### Convention on Biological Diversity

#### Additional Information

Additional Information

The EPSPS enzyme is part of the shikimate pathway, an important biochemical pathway in plants involved in the production of aromatic amino acids and other aromatic compounds. When conventional plants are treated with glyphosate, the plants cannot produce the aromatic amino acids needed for growth and survival. EPSPS is present in all plants, bacteria, and fungi. It is not present in animals, since these organisms are unable to synthesize their own aromatic amino acids. Because the aromatic amino acid pathway is not present in mammals, birds, or aquatic life forms, glyphosate has little, if any, toxicity for these organisms. The EPSPS enzyme is naturally present in foods derived from plant and microbial sources.

Other relevant website addresses and/or attached documents

MON 88913-8 - APHIS [English]

#### Records referencing this document

Show in search

EN

	Record type	Field	Record(s)
🕒 Show	Living Modified Organism	Recipient Organism" or "Parental Organisms	10
C Show	Risk Assessment generated by a regulatory process	Living modified organism(s)	43
C Show	Country's Decision or any other Communication	Living modified organism(s)	47
C Show	Laboratory for detection and identification of LMOs	LMO(s) detectable by the laboratory	6

#### ☐ BCH-LMO-SCBD-15168-16



### What does a BCH record look like: Living Modified Organisms

Records refere	ncing this document					Show in search
	Record type	Field				Record(s)
C Show	Living Modified Organism	Recipie	nt Organism'	° or "Parental Organisms		11
C Show	Risk Assessment generated by a regulatory process	Living r	nodified orga	nism(s)		43
C Show	Country's Decision or any other Communication	Living r	nodified orga	inism(s)		47
C Hide	Laboratory for detection and identification of LMOs	LMO(s	detectable b	by the laboratory		6
Title ↓ <sup>A</sup>			Uld ‡∄		Updated on ${\downarrow}^{\mathbb{A}}_{\mathbb{Z}}$	A
LAB - Executiv	ve Environment Agency (ExEA)		BCH-LAB-	SCBD-250602-2	29 Mar 2021 18:13	
LAB - Nationa	I Bureau of Plant Genetic Resources, New Delhi (NBPGR)		BCH-LAB-	SCBD-250645-6	29 Mar 2021 15:26	
LAB - Europea	an Union Reference Laboratory for Genetically Modified Food and Feed (EU-RL	GMFF)	BCH-LAB-	SCBD-250649-4	29 Mar 2021 15:20	
LAB - Comisió	ón Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificad	os (CIBIOGEM)	BCH-LAB-	SCBD-250671-15	29 Mar 2021 15:13	
LAB - Wagenin Wageningen U	ngen Food Safety Research (WFSR), Wageningen University & Research (Form University & Research) (WFSR)	ely RIKILT	BCH-LAB-	SCBD-250647-9	15 Jun 2020 13:25	
LAB - Centre of	de Recerca en Agrigenòmica (CRAG)		BCH-LAB-	SCBD-250661-2	03 Aug 2012 19:38	-
4						- F

### Where can you find detection-related information on the BCH?

- Living modified organisms (LMO)
  - Detection methods field (automated links)
  - Characteristics of the modification process section
  - Sequence information, regulatory documents and/or related journal publications in the additional information field
- Genetic elements (GENE)
  - GMO Genetic Elements Thesaurus (with EUginius)
  - Sequence information in the additional information field (if available)
- Organisms (ORGA)

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 Sequence information in the additional information field (if available)







### Where can you find detection-related information on the BCH?

- Biosafety Virtual Library Resources (VLR)
  - Scientific publications related to the field of detection and identification of LMOs
  - Detection is a "Biosafety Thematic Area"
- Laboratories for detection and identification of LMOs (LAB)
  - Information on services performed, methods used, types of LMOs analyzed, LMOs, genetic elements, accreditation
- Risk assessments (regulatory and non-regulatory; RA & IRA)
  - Risk assessment summary or report
  - LMO detection and identification methods proposed
- Biosafety experts (EXP)
  - Sampling and detection of LMOs is an Area of Expertise















### How do I search for information related to detection?

- 1. Go to http://bch.cbd.int
- 2. Click "Search" and select "Records"
- 3. Select specific types of records under "Record types"

Convention on Biological Diversity Austein McLoughlin \* EN -AFETY CLEARING-HOUSE HOME ABOUT SEARCH \* SUBMIT COUNTRY PROFILES \* HELP -FORUMS \* PROTOCOL \* Records Registries Clearing-House (BCH) is an online platform for exchanging information on Living Modified Organisms LMO a key tool for facilitating the implementation of the Cartagena Protocol on Biosafety. Organism Gene National Report Analyzer XPLORE THE MAP ♀ GET STARTED III RECENT RECORDS 🔸 Announcements 06 Feb 2023 23 Jan 2023 **QUESTION AND ANSWER WEBINAR** Webinar: New and improved clearing-house features

■ Convention on Biological Diversity	Austein McLoughlin 👻 💒 💽 👔
BCH BIOSAFETY CLEARING-HOUSE	
HOME ABOUT SEARCH SUBMIT COUNTRY PROFILES HELP FORUMS	PROTOCOL -
CBD / BCH / Search	
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GLOBAL FILTERS: Record types 🛞 Keywords 👻 Country 👻 Regions 👻 Date 👻 My saved searches 💌	
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National Records	Party Status
<ul> <li>National records are published by governments and include information Parties are obliged to provide in accordance with the Protocol as well as other national information relevant to the implementation of the Protocol.</li> <li>National Focal Points (344)</li> <li>Competent National Authorities (407)</li> <li>Supplementary Protocol Competent Authorities (13)</li> <li>Biosafety Laws, Regulations, Guidelines and Agreements (1139)</li> <li>Countries' Decisions or any other Communications (2710)</li> <li>Risk Assessments generated by a regulatory process (2597)</li> <li>National Biosafety Websites or Databases (151)</li> <li>Fourth National Reports on the Implementation of the Cartagena Protocol on Biosafety (135)</li> <li>Third National Reports on the Implementation of the Cartagena Protocol on Biosafety (160)</li> </ul>	<ul> <li>Party to the Cartagena Protocol on Biosafety</li> <li>Party to the Supplementary Protocol</li> <li>Ratified, not yet Party to the Cartagena Protocol on Biosafety</li> <li>Not a Party to the Cartagena Protocol on Biosafety</li> </ul>
Second National Reports on the Implementation of the Cartagena Protocol on Biosafety (156)	
Interim National Reports on the Implementation of the Cartagena Protocol on Biosafety (0) (0)	
Biosafety Experts (363) 1	
Country Profiles for Biosafety Clearing-House (168) 🕕	
Contacts (2460) ()	
Reference Records	
Reference records include a number of biosafety-related resources and information that can be submitted by any registered user and are validated by the Secretari	riat prior to their publication.
Biosafety Virtual Library Resources (1571) 🕕	
Biosafety Organizations (377)	
Laboratories for detection and identification of LMOs (74)	
Genetic elements (847) <sup>(1)</sup>	
Organisms (268) ()	
Risk Assessments generated by an independent or non-regulatory process (32)     Submissions (525)	
Capacity Development Initiatives (423) ()	(?)
BCH News (558) @	



### How do I refine my search: Laboratories for the detection and identification of LMOs

Search		
Laboratories for detection and identification of LMOs	re 	TAKE SEARCH TOUR
Search the Clearing-House	Q DEFAULT VIEW 🗸 🗄 SORT 🖈 SH	IARE 📥 EXPORT
GLOBAL FILTERS: Record types - Keywords - Cou	ountry - Regions - Date - My saved searches -	💭 Save this search
SUB-FILTERS	All records 74 National records 0 Reference records 72 SCBD records 0	
Laboratories for detection and identification of LMOs		
Free Text	Page 1 01 3 « First « Piev 1 2 3 ivext > Last » 1 - 25 01 74 items per page 25 •	
Search in Laboratories for detection and identification of LMC Q	LAB - The P.I "Central Phytosanitary Laboratory" of the NFSA of the Republic of Moldova Field sampling, Development of standard methods, Development of reference materials	ď
Services and activities performed	LABORATORY FOR DETECTION AND IDENTIFICATION OF LMOS   BCH-LAB-SCBD-263325-1   REPUBLIC OF MOLDOVA   24 FEB 2023	
Types of LMOs	LAB - Department of Chemistry Malaysia (DOC)	ď
Geographical region	Development of standard methods, Organization of inter-laboratory comparisons, Validation of third parties' results and methods, Capacity-building or training	
Types of detection/identification method(s) available for use in the		
	LAB - GMO Detection Laboratory in Shanghai Jiao long University (GMODL-SJTU)	6
LMO(s) detectable by the laboratory	LABORATORY FOR DETECTION AND IDENTIFICATION OF LMOS   BCH-LAB-SCBD-255921-1   CHINA   30 MAR 2022	
Genetic elements(s) detectable by the laboratory	LAB - Centre National de Recherches sur l'Environnement (CNRE)	2
	Field sampling. Development of reference materials. Supply of reference materials. Organization of inter-laboratory comparisons	
	LABORATORY FOR DETECTION AND IDENTIFICATION OF LMOS   BCH-LAB-SCBD-2559867-1   MADAGASCAR   23 MAR 2022	



### How do I refine the search: Laboratories for the detection and identification of LMOs

#### SUB-FILTERS

Laboratories for detection and identification of LMOs	<b>^</b>
Free Text	
Search in Laboratories for detection and identification of LMC	Q
Services and activities performed	>
Types of LMOs	>
Geographical region	>
Types of detection/identification method(s) available for use laboratory	in the
LMO(s) detectable by the laboratory	>
Genetic elements(s) detectable by the laboratory	>

- Sub-filters specific to the fields on the common format for each record type
- Improved functionality compared to previous version of the platform







### How do I refine the search: Laboratories for the detection and identification of LMOs

Search		
Laboratories for detection and identification of LMOs	r filters	TAKE SEARCH TOUR
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Search in Laboratories for detection and identificat Q	LAB - The P.I "Central Phytosanitary Laboratory" of the NFSA of the Republic of Moldova Field sampling, Development of standard methods, Development of reference materials	C
Services and activities performed	LABORATORY FOR DETECTION AND IDENTIFICATION OF LMOS   BCH-LAB-SCBD-263325-1   REPUBLIC OF MOLDOVA   24 FEB 2023	
Types of LMOs	LAB - Department of Chemistry Malaysia (DOC)	C
Geographical region	Development of standard methods, Organization of inter-laboratory comparisons, Validation of third parties' results and methods, Capacity-building or training LABORATORY FOR DETECTION AND IDENTIFICATION OF LMOS   BCH-LAB-SCBD-260243-1   MALAY \$\SLAP A C 27 APR 2022	
Types of detection/identification method(s) available		
for use in the laboratory	LAB - GMO Detection Laboratory in Shanghai Jiao Tong University (GMODL-SJTU)	C
Qualitative PCR (end-point PCR)	LABORATORY FOR DETECTION AND IDENTIFICATION OF LMOS   BOHLAR-SCED-3559314   CHINA   30 MAR 2022	
LMO(s) detectable by the laboratory		
Genetic elements(s) detectable by the laboratory	LAB - Centre National de Recherches sur l'Environnement (CNRE)	C.
	LABORATORY FOR DETECTION AND IDENTIFICATION OF LMOS   BCH-LAB-SCBD-255867-1   MADAGASCAR   23 MAR 2022	
	LAB - DNA Fingerprinting and Transgenic Crops Monitoring Lab (DETCM Lab)	12
	Field sampling, Field testing, Development of standard methods, Capacity-building or training	
	LABORATORY FOR DETECTION AND IDENTIFICATION OF LMOS   BCH-LAB-SCBD-250652-3   INDIA   25 MAR 2021	



### How do I refine the search: Laboratories for the detection and identification of LMOs

Search	
Clear filters	O TAKE SEARCH TOUR
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LABORATORY FOR DETECTION AND IDENTIFICATION OF LMOS   BCH-LAB-SCBD-255921-1   CHINA   30 MAR 2022	
Genetic elements(s) detectable by the laboratory Field sampling, Development of reference materials, Supply of reference materials, Organization of inter-laboratory comparisons LABORATORY FOR DETECTION AND IDENTIFICATION OF LMOS   BCH-LAB-SCBD-255867-1   MADAGASCAR   23 MAR 2022	C
LAB - DNA Fingerprinting and Transgenic Crops Monitoring Lab (DFTCM Lab)         Field sampling, Field testing, Development of standard methods, Capacity-building or training         LABORATORY FOR DETECTION AND IDENTIFICATION OF LMOS   BCH-LAB-SCBD-250652-3   INDIA   25 MAR 2021	C



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• Cross referencing between records in the BCH





# Other ways to find information

- Cross referencing between records in the BCH
- Through the use of the registries

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Compiled lists of all LMOs, genetic elements and organisms

#### Living Modified Organism (LMO) Registry

The LMO Registry provides summary information on all living modified organisms registered in the BCH, including transformation events, genetic modifications and the unique identification code (if available) for each record. Links to all decisions and risk assessment reports that refer to these organisms are accessible through the records in the registry.

#### Organism Registry

The Organism Registry includes summary information on those organisms that have been registered in the BCH as parental, recipient or donor organisms. The registry includes links to the records on each organism where further information about relevant biological characteristics, including information on taxonomic classification, common name, origin, centre of origin and centre of genetic diversity can be found. Links to records that reference the organism are provided at the bottom of each individual record.

#### Genetic Element Registry

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The Genetic Element Registry provides a summary of information on the genetic elements associated with the LMOs registered in the BCH, including information on the donor organism, conferred traits and biological function. The registry includes links to the records on each genetic element where more details may be found. LMOs containing the particular genetic element are referenced at the bottom of the individual record.

View registry

View registry

View registry





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# What is the Secretariat doing moving forward?

- Following the launch of the new platform in November, the Secretariat continues to improve the new BCH platform
- In decision CP-10/11, Parties are invited to submit information on their laboratories using the LAB common format
- Opportunities to explore further interlinkages and interoperability with other databases
  - Current: JRC GMOMethods + Croplife Detection methods database, FAO GM Foods platform, OECD BioTrack Product database





# How to engage with the BCH?

- Sign up for a BCH account (<u>http://bch.cbd.int</u>)
- Submit information
  - New publications or protocols
  - Information on your lab
- Provide feedback (<u>bch@cbd.int</u>)
- Get help:
  - Chat



- Training materials











# Thank you

# Secretariat of the Convention on Biological Diversity

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