Materials and data of the Biosafety Clearing-House and its key role in supporting laboratory detection

Austein McLoughlin
Associate Programme Management Officer
Secretariat of the Convention on Biological Diversity

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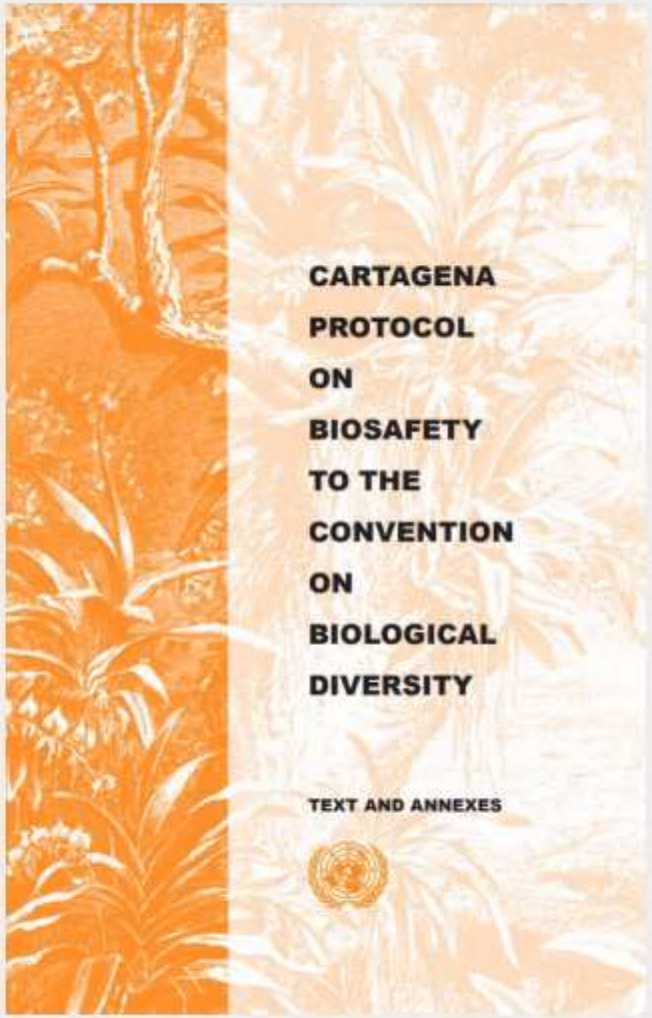
What is the Biosafety-Clearing House?

- 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**

* Also known as GMOs



Why is the Biosafety-Clearing House important?

- The BCH fosters transparency:
  - In the regulation of LMOs → what rules apply and who to contact for more information
  - In decisions taken on LMOs → 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 on the Biosafety Clearing-House?

- **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

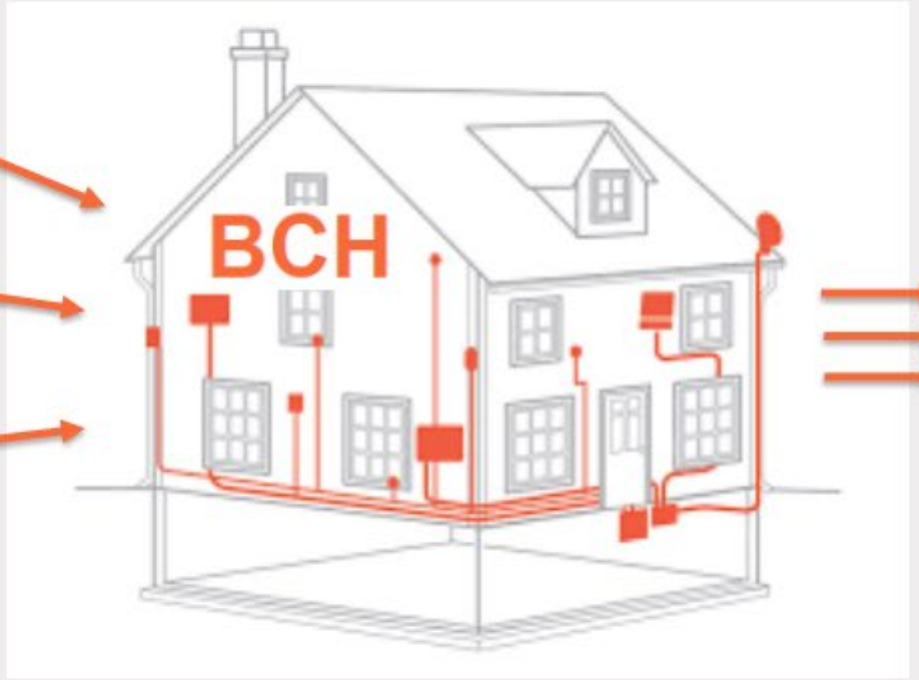
- **Reference records** include a number of biosafety-related resources and information that can be submitted by any registered user and are validated by the Secretariat prior to their publication

The Biosafety Clearing-House at its core?

Designated National Contacts

CBD Secretariat

Any registered user



All published information is publicly available

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 for the Detection and Identification of Living Modified Organisms

What type of scientific records are on the Biosafety Clearing-House?

- 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 Biosafety Clearing-House

17,000+ records published

- 950+ LMOs
- 850+ genetic elements
- 270+ organisms
- 70+ laboratories
- 1570+ virtual library resources
- 2650+ risk assessments
- 360+ biosafety experts

What does a BCH record look like: Living Modified Organisms

LIVING MODIFIED ORGANISM (LMO) | BCH-LMO-SCBD-15168-16 | PDF | Print | Share | Compare | Edit

Decisions on the LMO | Risk Assessments

LAST UPDATED: 25 SEP 2020

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=15168

CBD

MON-88913-8
Roundup Ready™ Flex™ cotton

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

Name

Roundup Ready™ Flex™ cotton | EN

Transformation event

MON88913 (88913)

Does this LMO have a unique identifier?

Yes

Unique identifier

MON-88913-8

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 5-enolpyruvylshikimate-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.

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-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

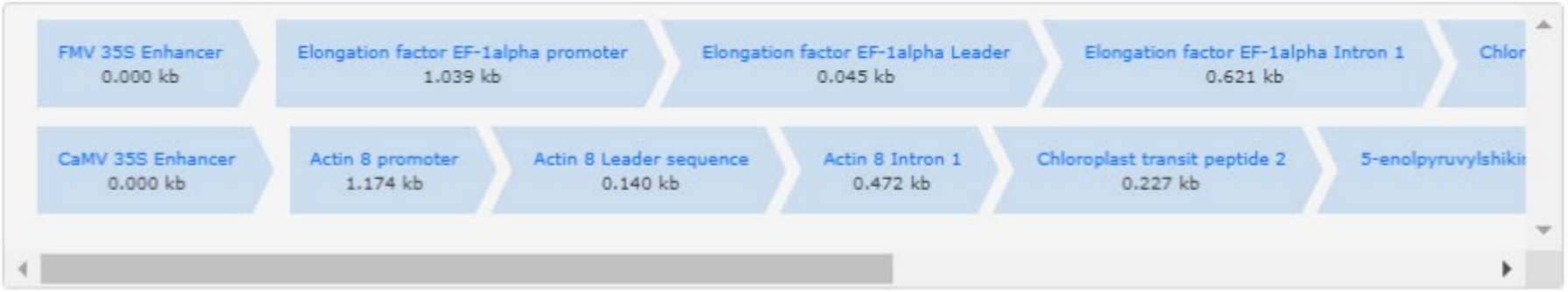
Vector

PV-GHGT35 EN

Techniques used for the modification

Agrobacterium-mediated DNA transfer

Genetic elements construct



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.

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* 5-enolpyruvylshikimate-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.

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).

EN

What does a BCH record look like: Living Modified Organisms

LMO characteristics

Modified traits

Resistance to herbicides

Glyphosate

Common use(s) of the LMO

Fiber/textile

Detection method(s)

External link(s)

MON-88913-8 - EU Reference Laboratory for GM Food and Feed (EURL-GMFF) (JRC) [English]

MON-88913-8 - CropLife International Detection Methods Database (CropLife) [English]

EURL

European Union Reference Laboratory

for GM Food & Feed

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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.	EN

Other relevant website addresses and/or attached documents

MON 88913-8 - APHIS *[English]*

Euginius: MON88913 *[English]*

Records referencing this document

Show in search

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

BCH-LMO-SCBD-15168-16

Report

What does a BCH record look like: Living Modified Organisms

Records referencing this document

Show in search

	Record type	Field	Record(s)
Show	Living Modified Organism	Recipient Organism" or "Parental Organisms	11
Show	Risk Assessment generated by a regulatory process	Living modified organism(s)	43
Show	Country's Decision or any other Communication	Living modified organism(s)	47
Hide	Laboratory for detection and identification of LMOs	LMO(s) detectable by the laboratory	6

Title	Uid	Updated on
LAB - Executive Environment Agency (ExEA)	BCH-LAB-SCBD-250602-2	29 Mar 2021 18:13
LAB - National Bureau of Plant Genetic Resources, New Delhi (NBPGR)	BCH-LAB-SCBD-250645-6	29 Mar 2021 15:26
LAB - European Union Reference Laboratory for Genetically Modified Food and Feed (EU-RL GMFF)	BCH-LAB-SCBD-250649-4	29 Mar 2021 15:20
LAB - Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados (CIBIOGEM)	BCH-LAB-SCBD-250671-15	29 Mar 2021 15:13
LAB - Wageningen Food Safety Research (WFSR), Wageningen University & Research (Formely RIKILT Wageningen University & Research) (WFSR)	BCH-LAB-SCBD-250647-9	15 Jun 2020 13:25
LAB - Centre de Recerca en Agrigenòmica (CRAG)	BCH-LAB-SCBD-250661-2	03 Aug 2012 19:38

BCH-LMO-SCBD-15168-16

Report

What information is available related to detection 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)

- Sequence information in the additional information field (if available)

What is the Biosafety-Clearing House?

Biosafety Virtual Library Resources (VLR)

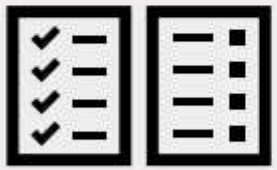
- Scientific publications related to the field of detection and identification of LMOs
- Detection is a "Biosafety Thematic Area"

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

What is the Biosafety-Clearing House?

Biosafety Virtual Library Res

- Scientific publications r
  identification of LMOs
- Detection is a "Biosafe

Laboratories for detection a

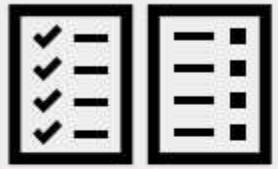
- Information on service
  LMOs analyzed, LMOs,

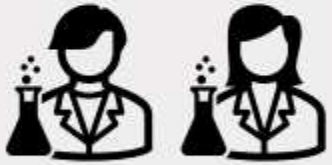
Risk assessments (regulator

- Risk assessment summ
- LMO detection and ide

Biosafety experts (EXP)

- Sampling and detectio





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Конвенция о биологическом разнообразии

ООН окружающая среда

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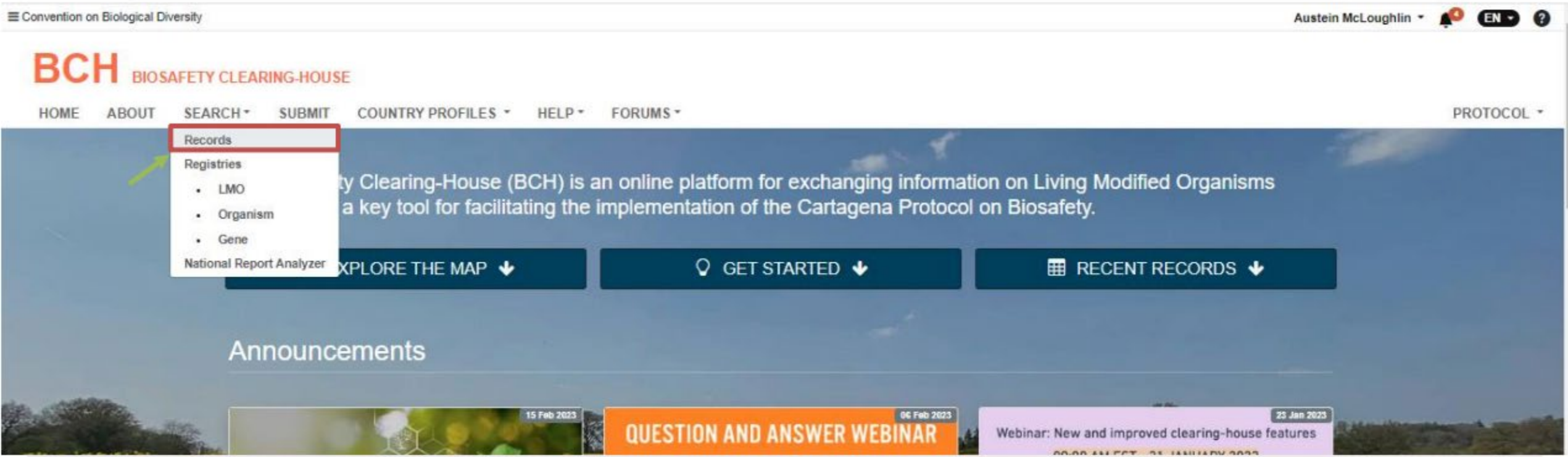
How do I search for information related to detection?

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



Search

TAKE SEARCH TOUR

Search the Clearing-House

DEFAULT VIEW SORT SHARE EXPORT

GLOBAL FILTERS: Record types Keywords Country Regions Date My saved searches

National Records

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.

- National Focal Points (344)
- Competent National Authorities (407)
- Supplementary Protocol Competent Authorities (13)
- Biosafety Laws, Regulations, Guidelines and Agreements (1139)
- Countries' Decisions or any other Communications (2710)
- Risk Assessments generated by a regulatory process (2597)
- National Biosafety Websites or Databases (151)
- Fourth National Reports on the Implementation of the Cartagena Protocol on Biosafety (135)
- Third National Reports on the Implementation of the Cartagena Protocol on Biosafety (160)
- Second National Reports on the Implementation of the Cartagena Protocol on Biosafety (156)
- First National Reports on the Implementation of the Cartagena Protocol on Biosafety (0)
- Interim National Reports on the Implementation of the Cartagena Protocol on Biosafety (0)
- Biosafety Experts (363)
- Country Profiles for Biosafety Clearing-House (168)

- Contacts (2460)

Party Status

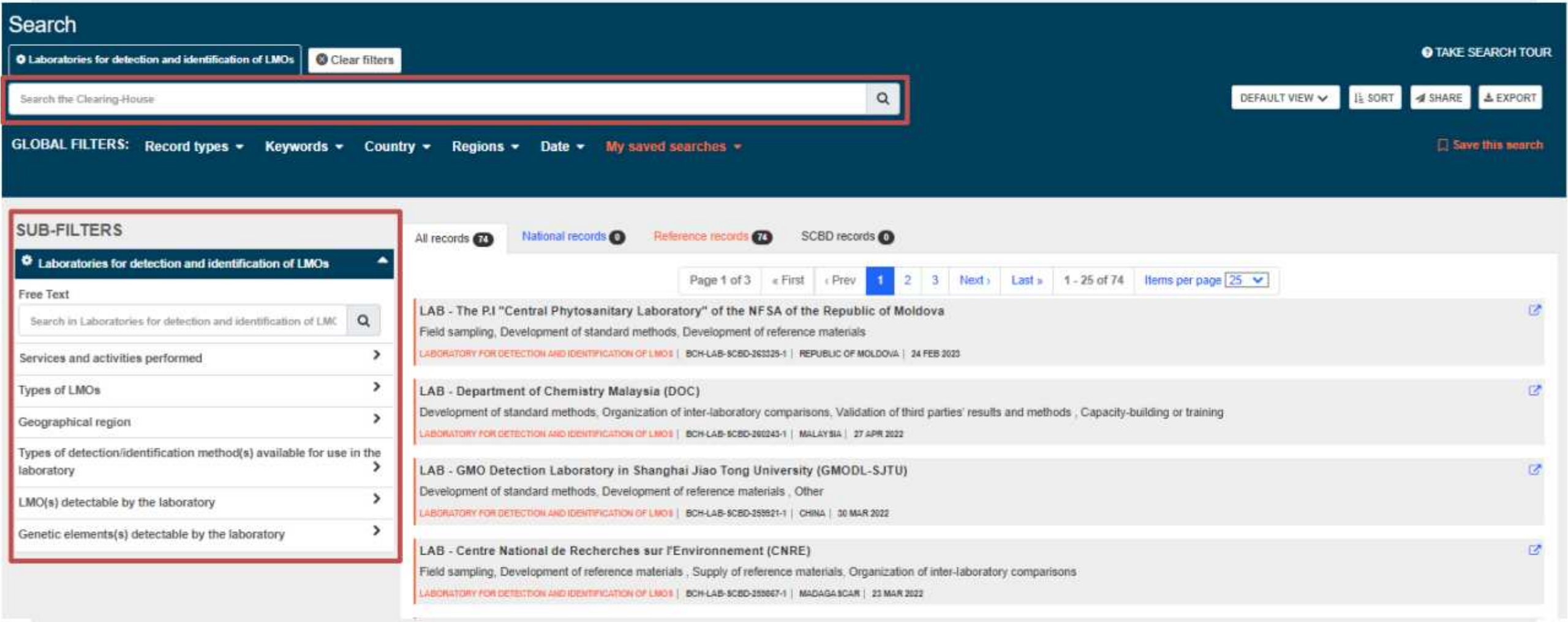
- Party to the Cartagena Protocol on Biosafety
- Party to the Supplementary Protocol
- Ratified, not yet Party to the Cartagena Protocol on Biosafety
- Not a Party to the Cartagena Protocol on Biosafety

Reference Records

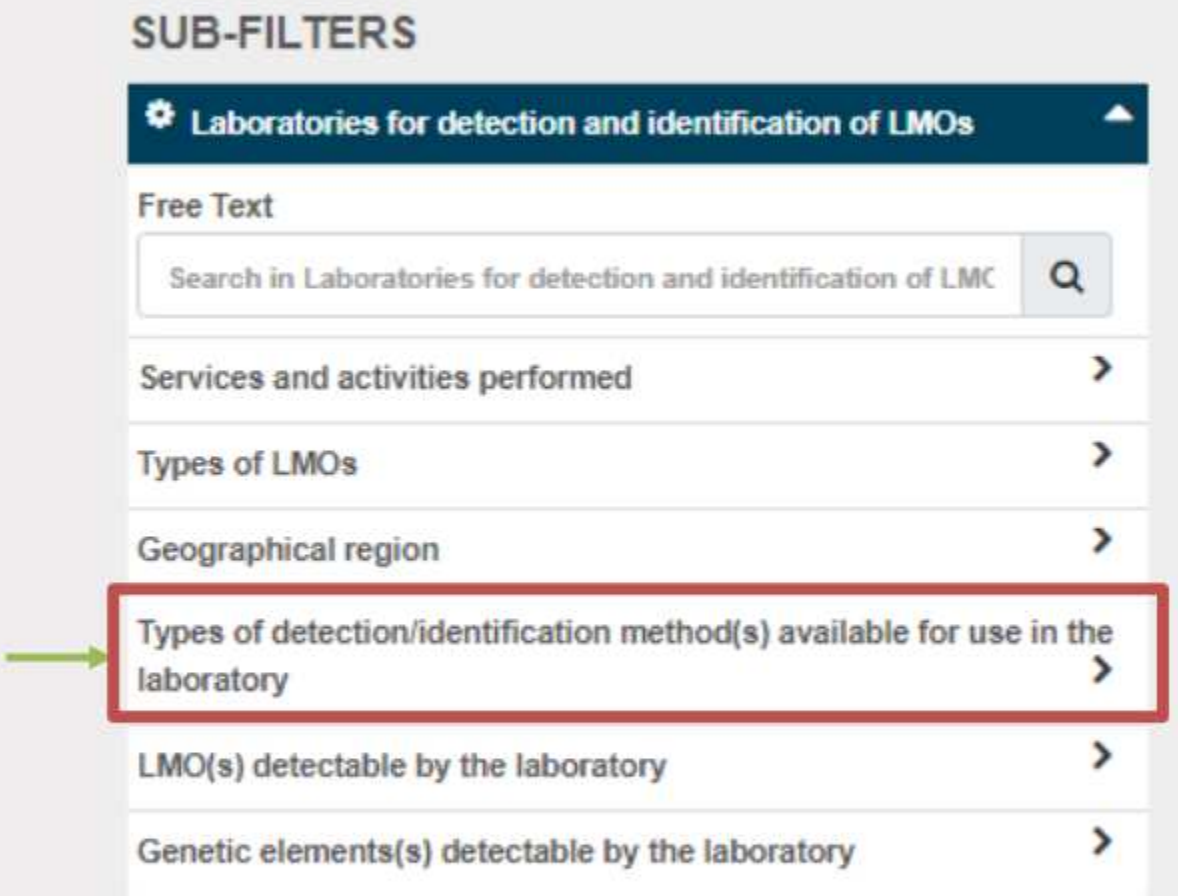
Reference records include a number of biosafety-related resources and information that can be submitted by any registered user and are validated by the Secretariat prior to their publication.

- Biosafety Virtual Library Resources (1571)
- Biosafety Organizations (377)
- Laboratories for detection and identification of LMOs (74)
- Living Modified Organisms (941)
- Genetic elements (847)
- 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 of LMOs

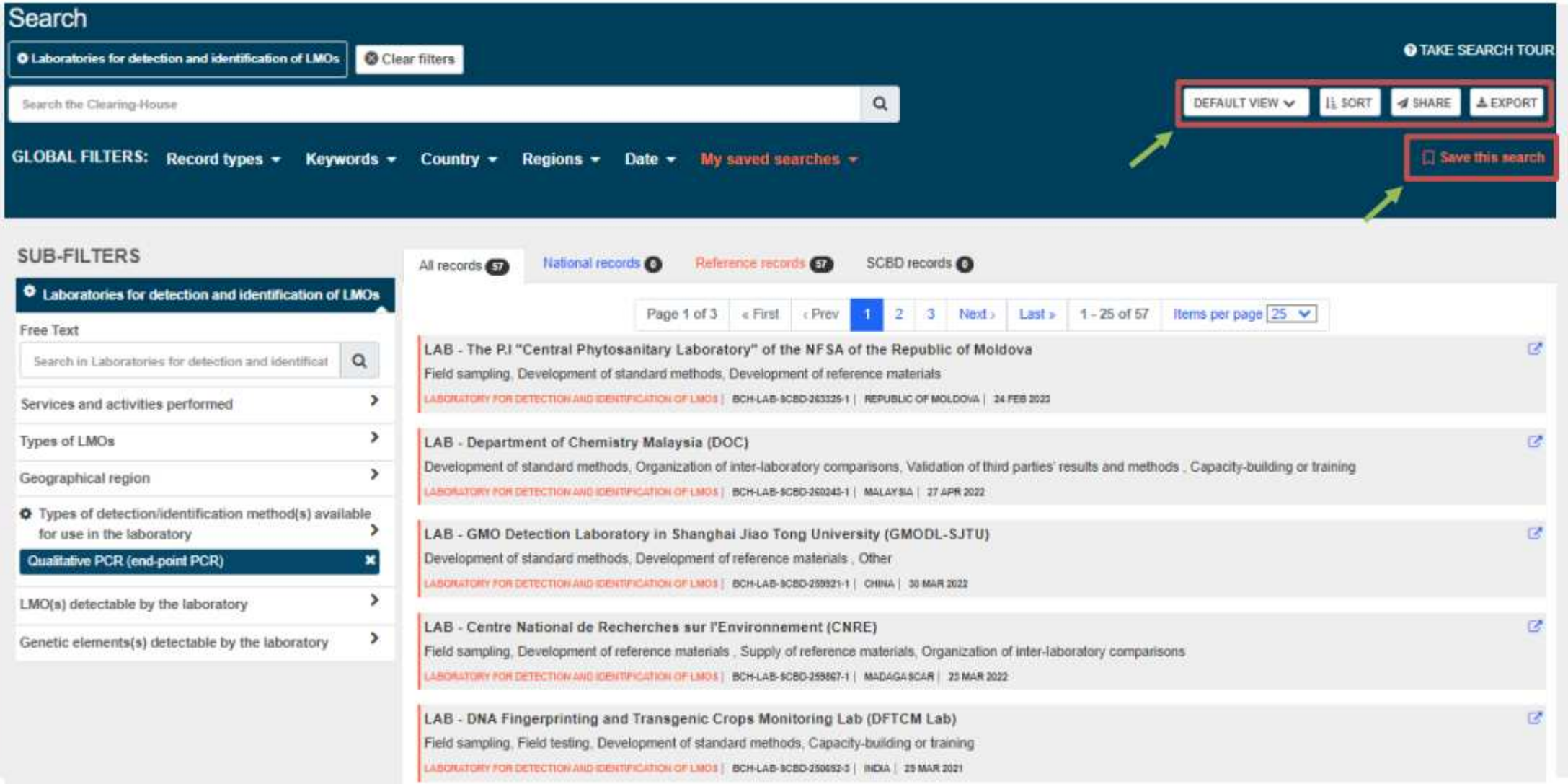


How do I refine my search: Laboratories for the detection of LMOs

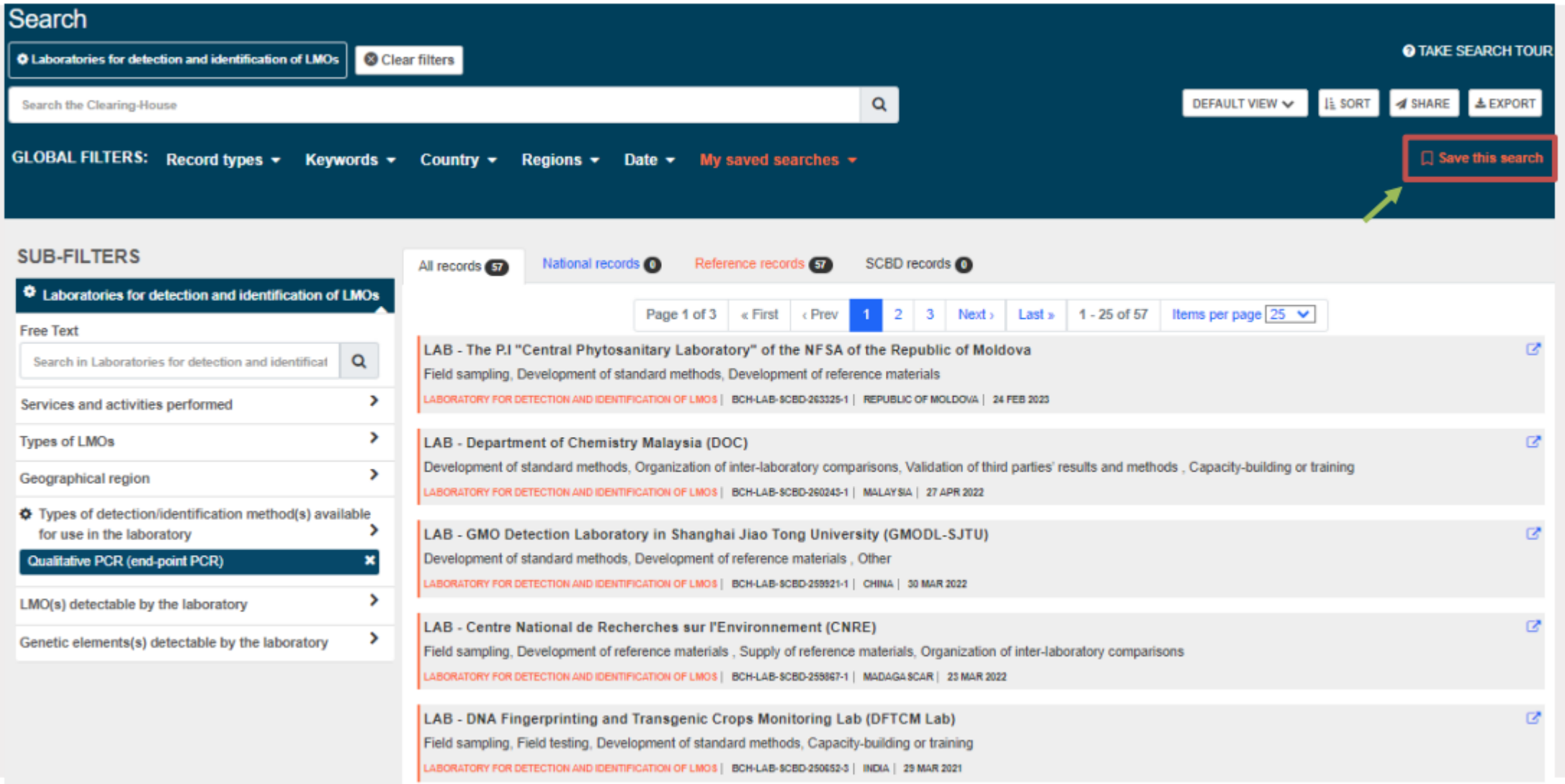


- Sub-filters specific to the fields on the common format for each record type
- Improved functionality compared to previous version of the platform

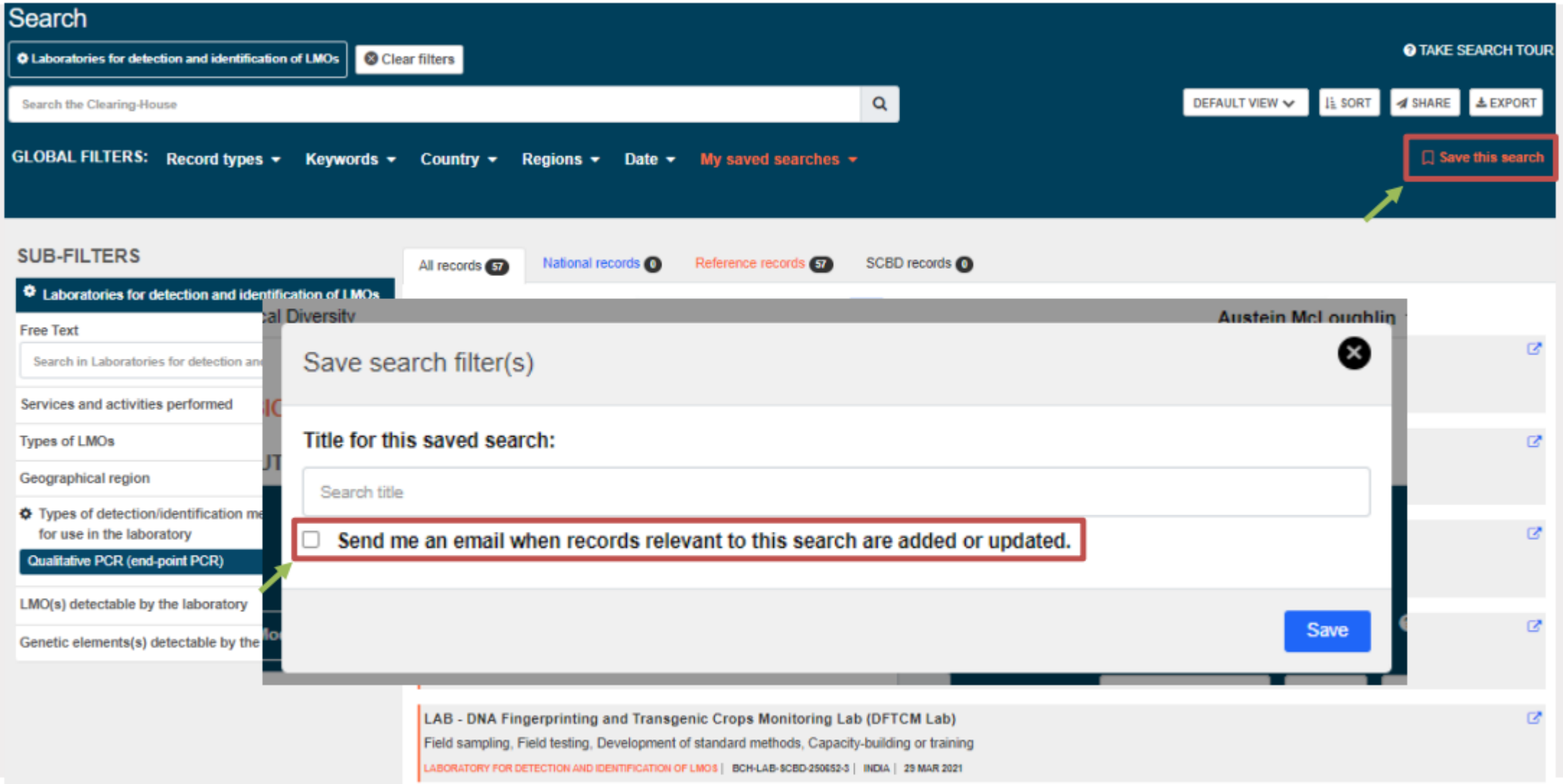
How do I refine my search: Laboratories for the detection of LMOs



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

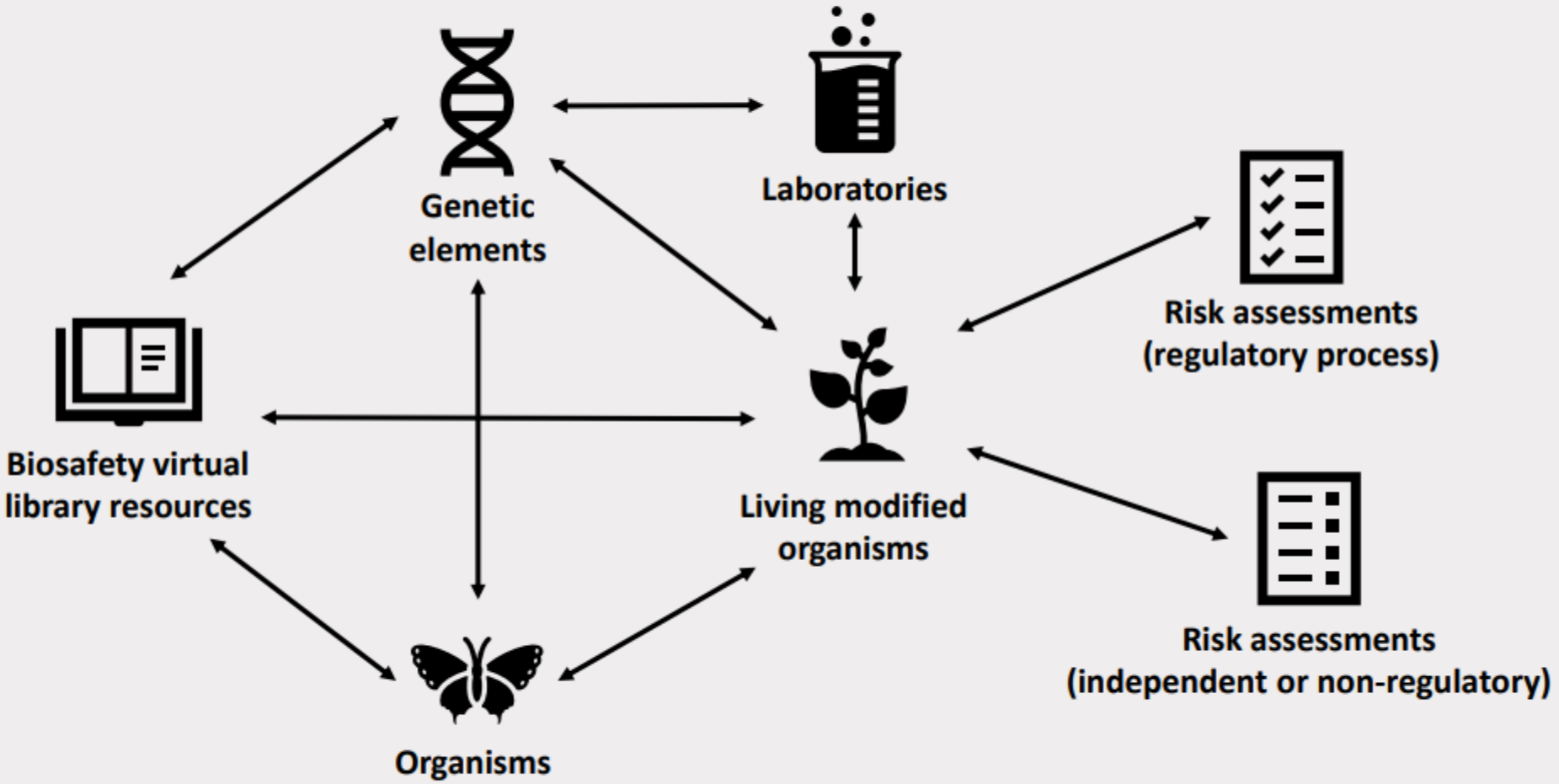


How do I refine my search: Laboratories for the detection of LMOs



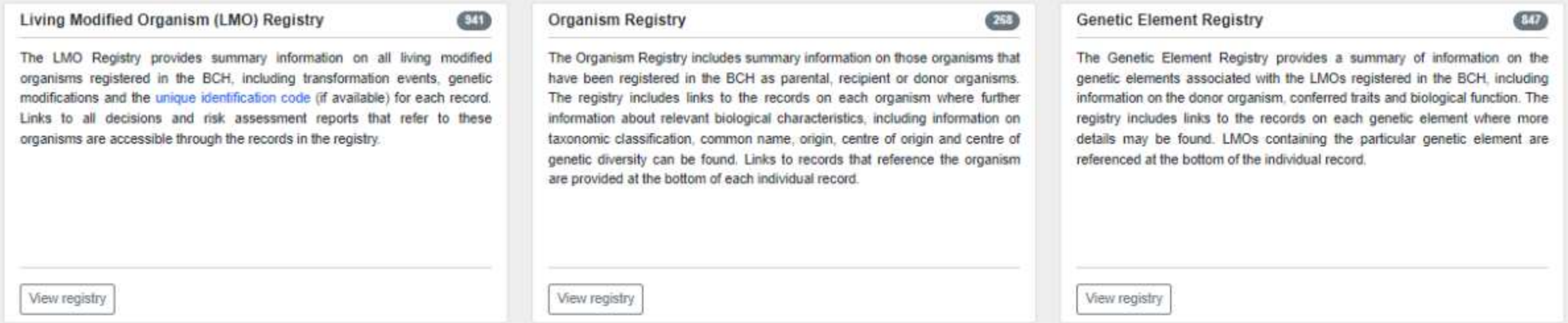
Other ways to find information

- Cross referencing between records in the BCH

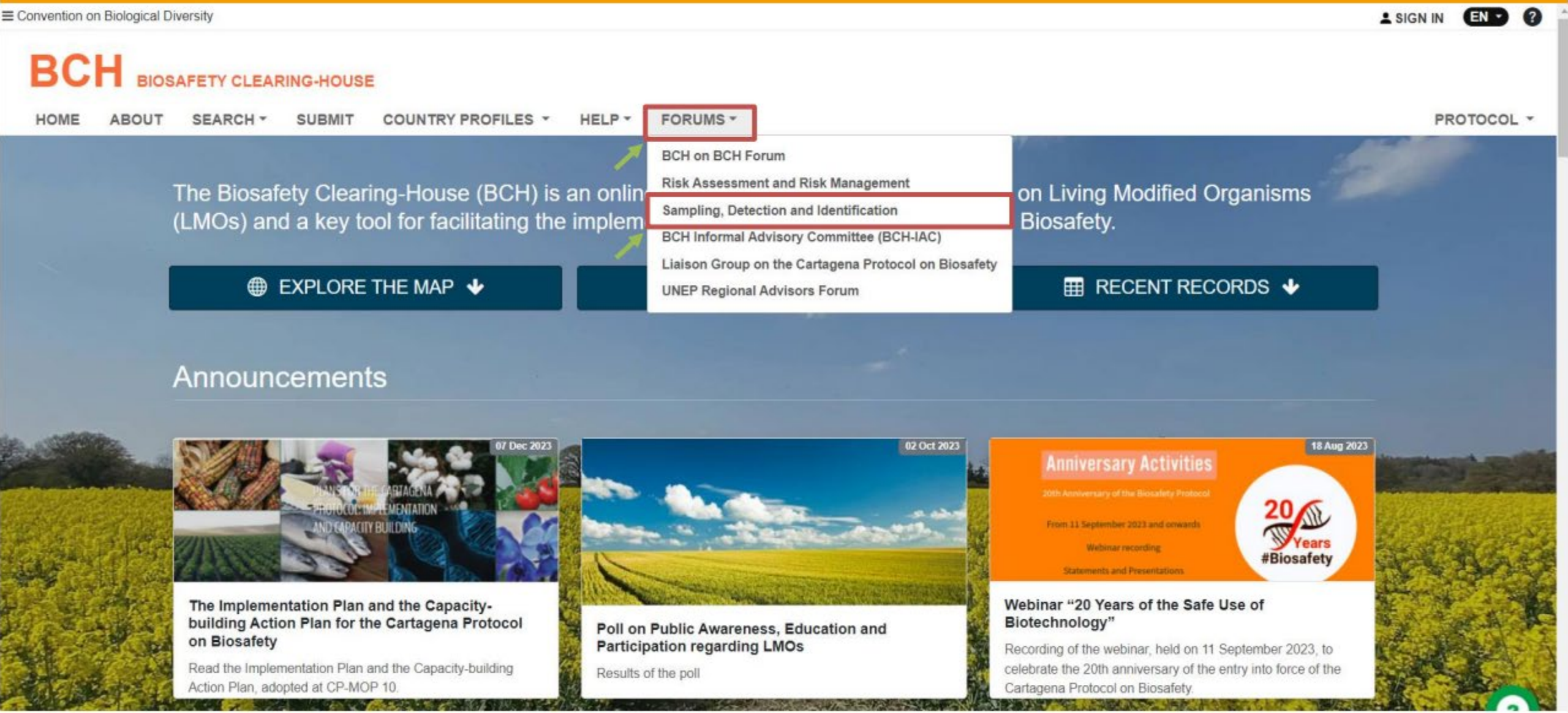


Other ways to find information

- Cross referencing between records in the BCH
- Through the use of the registries:
  - Compiled lists of all LMOs, genetic elements and organisms
- Forums



Network of Laboratories for the Detection and Identification of LMOs



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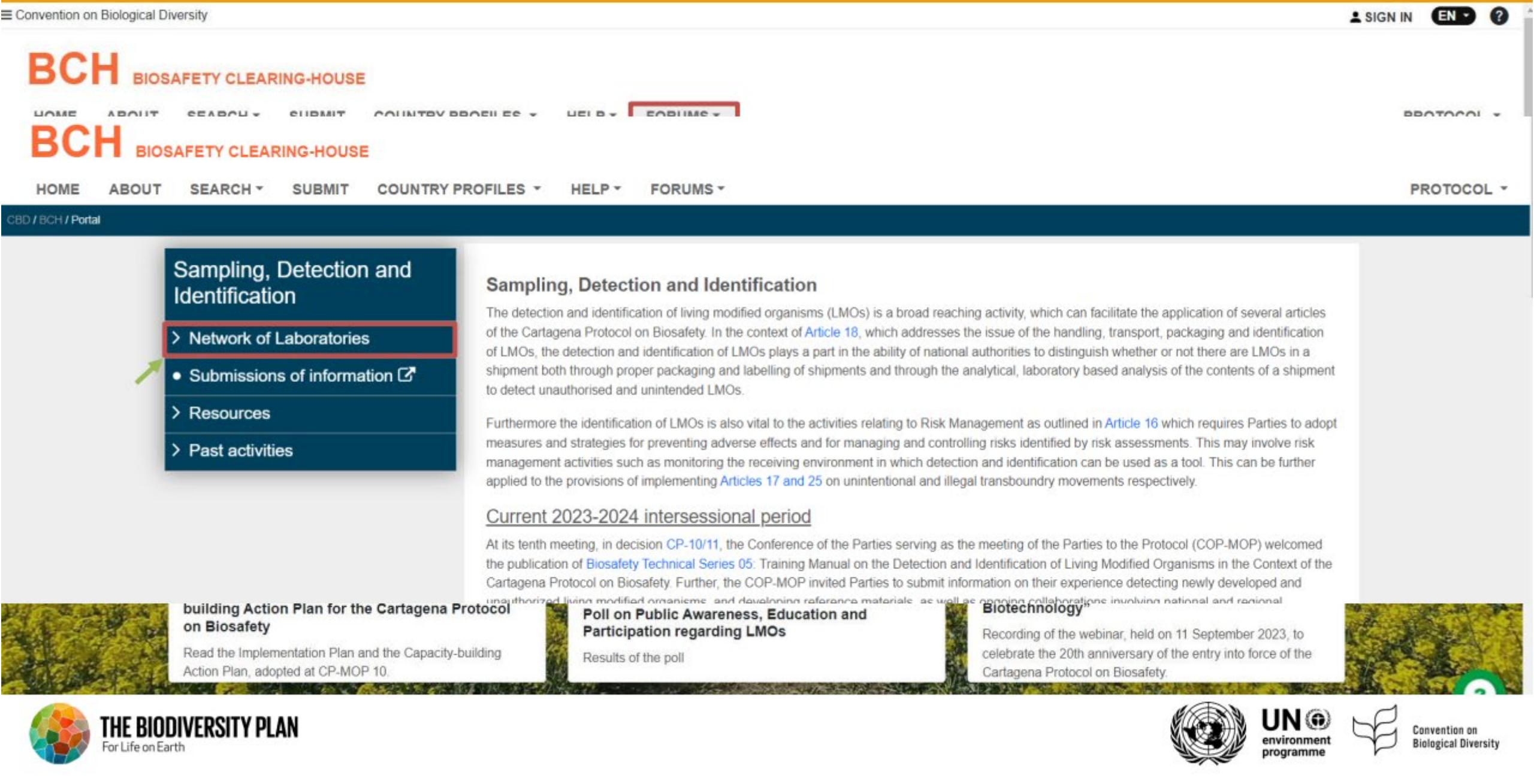
Network of Laboratories for the Detection and Identification of LMOs



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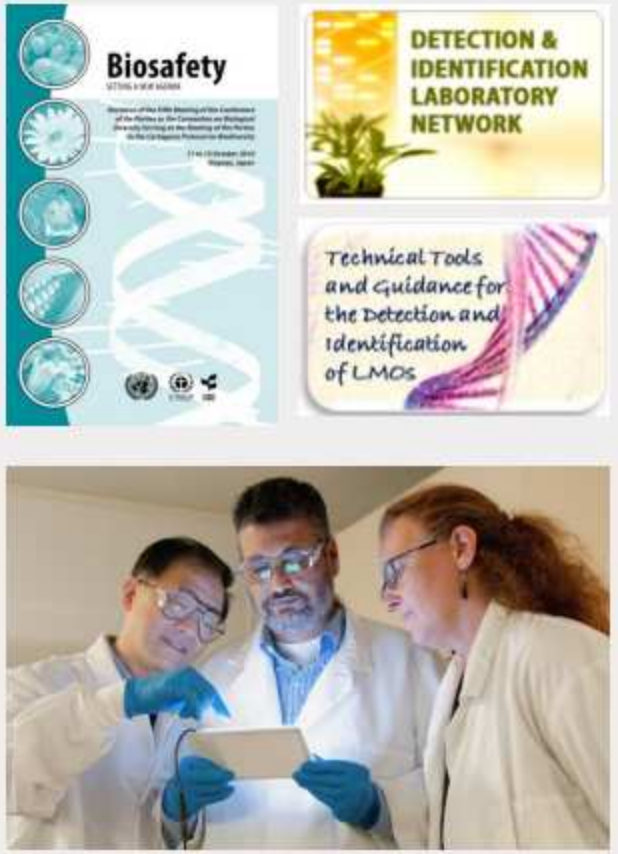
Network of Laboratories for the Detection and Identification of LMOs

- An electronic network of laboratories to facilitate the identification of LMOs as well as sharing of information and experiences (decision BS-V/9)
- Hosted on the Biosafety Clearing-House
- Supports the programme of work on detection
  - Assists with developing technical materials
  - Definitions (e.g., illegal vs. unintentional transboundary movements)
  - Online discussions to inform Parties
- 204 experts from all regions

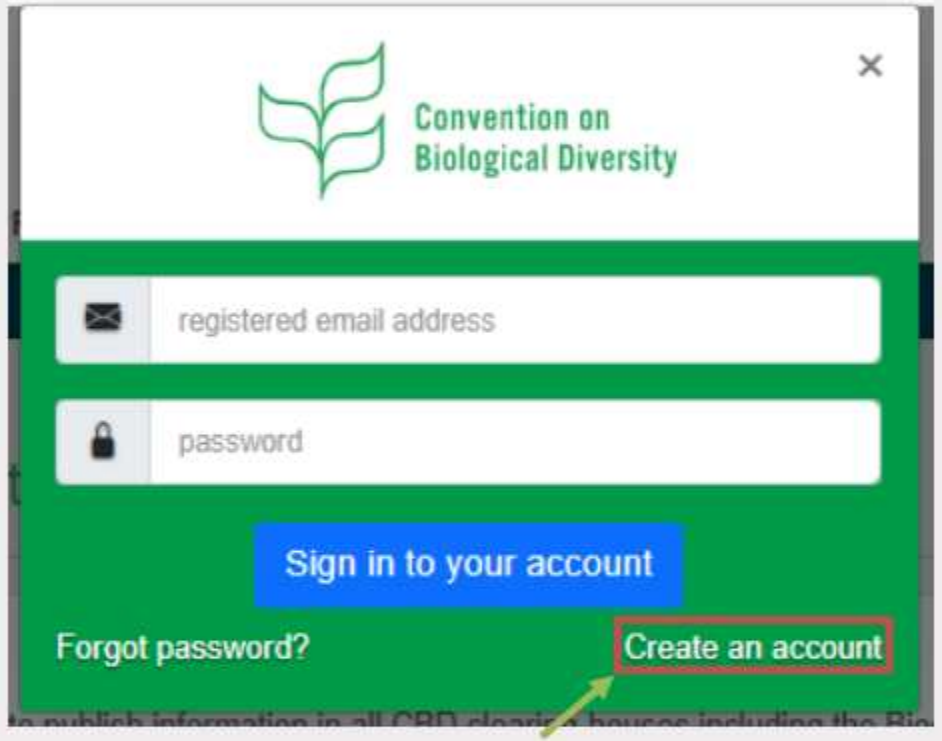


What is the Secretariat doing moving forward?

- Following the launch of the new platform, 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
- Continued enlargement of the Network of Laboratories

How to engage with the Biosafety Clearing-House?

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



Join the Network of Laboratories!

- How?
  - Send a nomination
    - Signed letter either:
      - National focal point to the Cartagena Protocol on Biosafety; or
      - Head of organization
    - CV with description of involvement in detection and identification activities

Thank you!

Secretariat of the Convention on Biological Diversity

413 St. Jacques Street, Suite 800
Montreal, Quebec, Canada H2Y 1N9
Tel. +1 514 288 2220

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