THE BCH III PROJECT

SCIENTIFIC INFORMATION in the Biosafety Clearing House

Prof Ossama AbdelKawy

2023

RECORDS

Introduced or modified genetic element(s)

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

BCH-GENE-SCBD-14972-12 PHOSPHINOTHRICIN N-ACETYLTRANSFERASE GENE

Protein coding sequence | Resistance to herbicides (Glufosinate)

BCH-GENE-SCBD-14985-12 CRY1AB | BACILLUS THURINGIENSIS - BT, BACILLUS, BACTU

Protein coding sequence | Resistance to diseases and pests (Insects, Lepidoptera (butterflies and moths))

BCH-GENE-SCBD-14975-5 BETA-LACTAMASE GENE | (BACTERIA)

Protein coding sequence | Resistance to antibiotics (Ampicillin)

BCH-GENE-SCBD-100287-7 CAMV 35S PROMOTER

Promoter

BCH-GENE-SCBD-100290-6 CAMV 35S TERMINATOR

Terminator

- Genetic element
- Promoter
- Terminator
- Marker gene
- Agrobacterium
- Coding sequence
- Truncated gene
- Unique identifier
- Transformation cassette
- Gene gun
- Risk Assessment
- Detection and identification

Description

This LMO contains two copies of a truncated synthetic version of the full length *cry1Ab* gene from *Bacillus thuringiensis* subsp. *kurstaki*. The synthetic truncated *cry1Ab* gene encodes a protein that corresponds to the first 648 amino acids of the N-terminal of the 1155 amino acid full length native Cry1Ab protein and includes the portion of the native protein that is necessary for insect control.

EN

- *Also note that the cassette has genetic elements belonging to corn to dupe the plant cell so that it does not recognize that*

Additional information concerning the *bla* gene insert in this LMO:

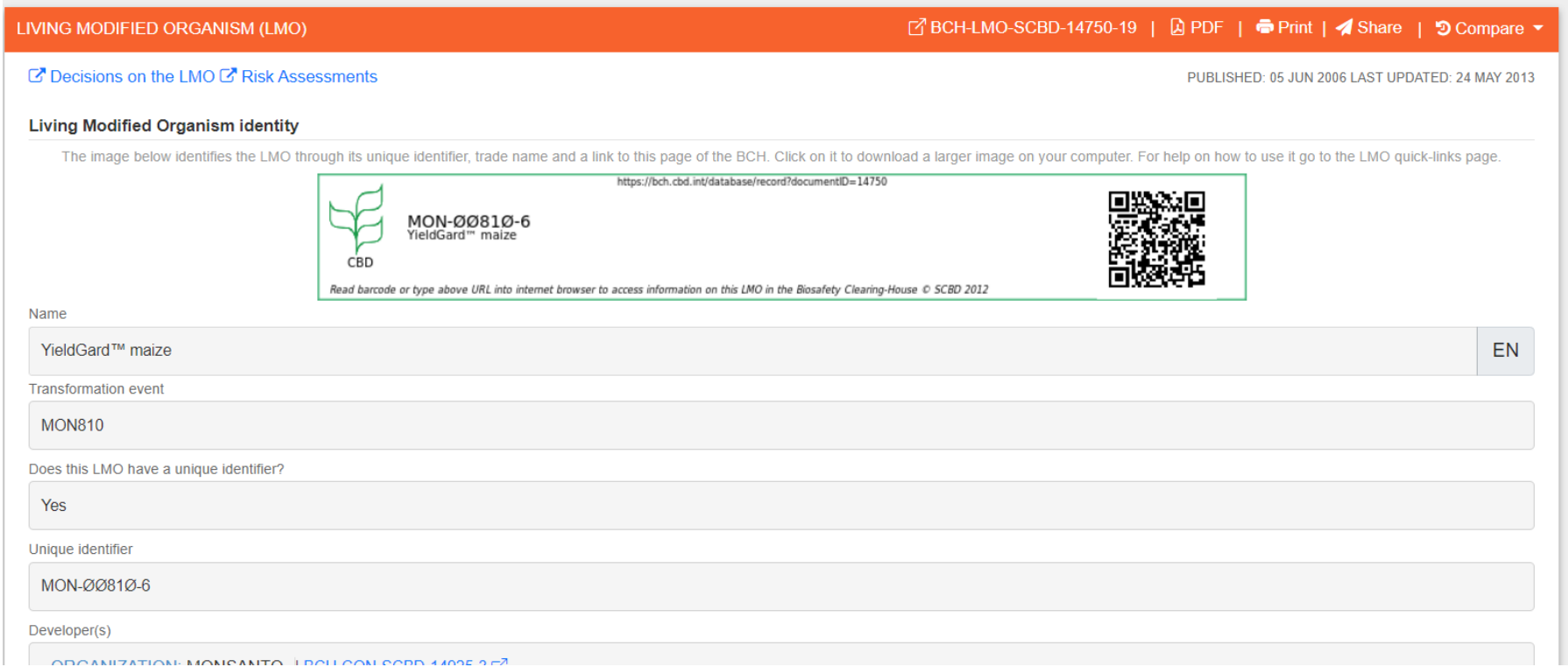
The *bla* gene from *Escherichia coli* is not expressed in plant cells, but was employed as a selectable trait for screening bacterial colonies for the presence of the plasmid vector.

Additional information on the inserted genetic material:

EN

LMO RECORD

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



LIVING MODIFIED ORGANISM (LMO)

BCH-LMO-SCBD-14750-19 | PDF | Print | Share | Compare

Decisions on the LMO Risk Assessments

PUBLISHED: 05 JUN 2006 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.

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CBD

MON-ØØ81Ø-6
YieldGard™ maize

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?

Yes

Unique identifier

MON-ØØ81Ø-6

Developer(s)

CPB. ART 3.

Use of Terms

For the purposes of this Protocol:

(g) "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

(i) "Modern biotechnology" means the application of:

a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family,

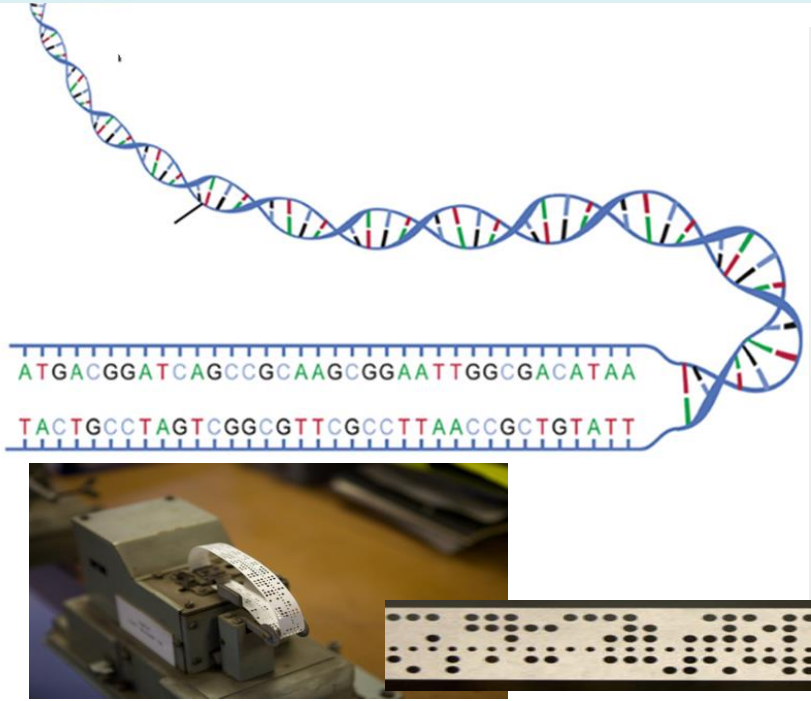
that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

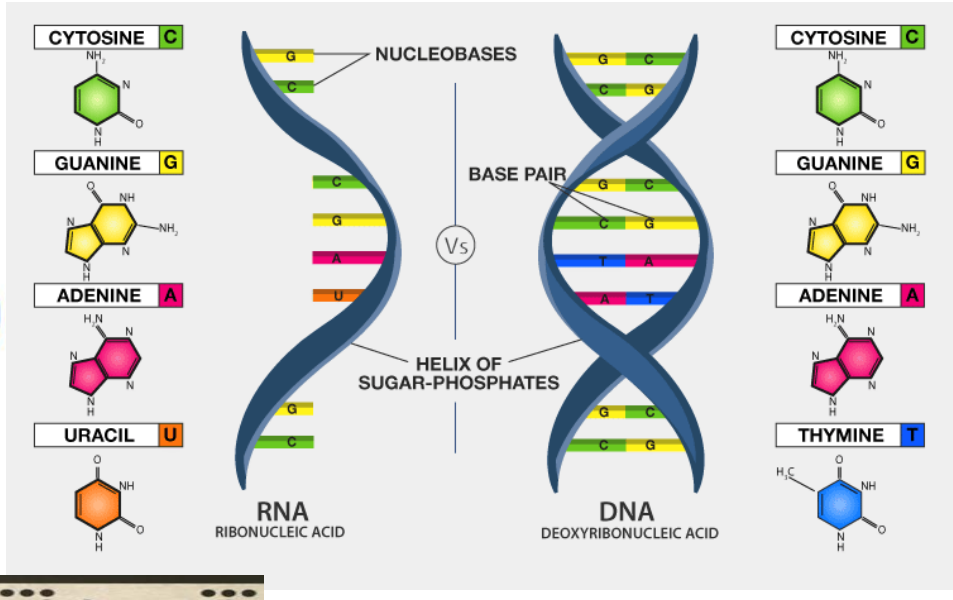
GENETIC MATERIALS?




the medium by which inherited characteristic of a living organism are transmitted from one generation to the next

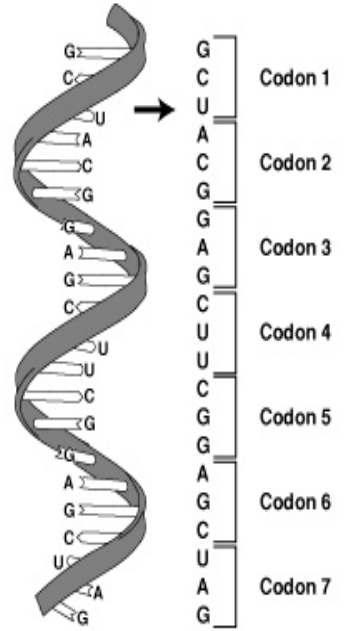
GENETIC CODE ?





Sequences of nucleic acids that contain instruction to direct and regulate the production of structural and functional proteins which are responsible for traits.

GENETIC CODE?



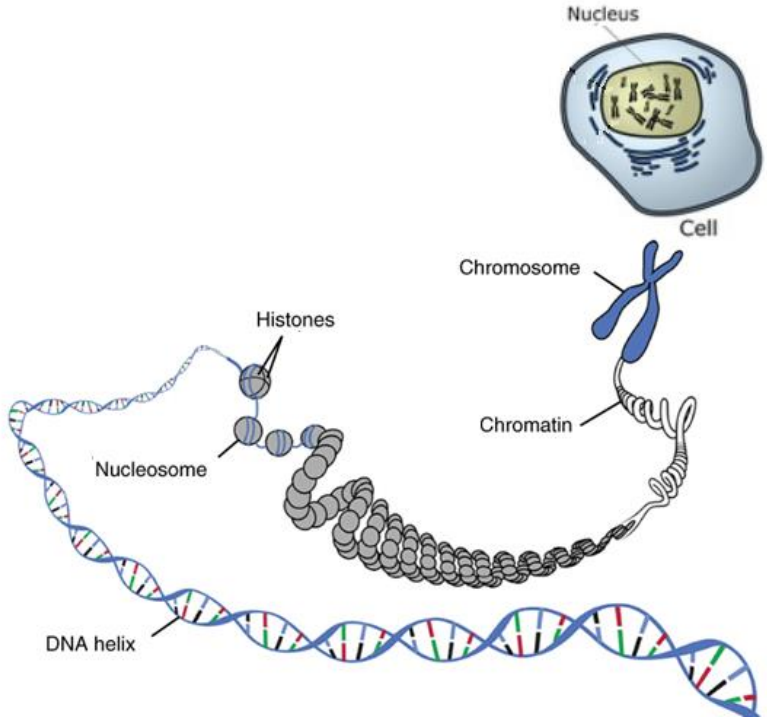
1st base

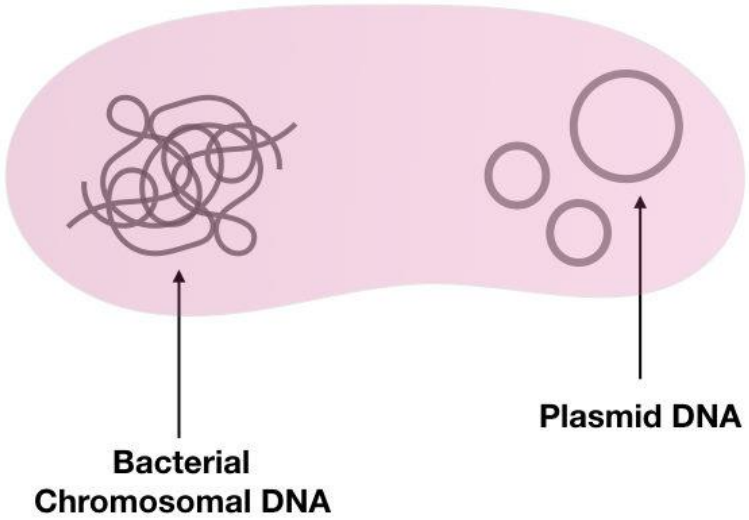
2nd base	U		C		A		G		3rd base
U	UUU	Phenylalanine	UCU	Serine	UAU	Tyrosine	UGU	Cysteine	U
	UUC	Phenylalanine	UCC	Serine	UAC	Tyrosine	UGC	Cysteine	C
	UUA	Leucine	UCA	Serine	UAA	Stop	UGA	Stop	A
	UUG	Leucine	UCG	Serine	UAG	Stop	UGG	Tryptophan	G
C	CUU	Leucine	CCU	Proline	CAU	Histidine	CGU	Arginine	U
	CUC	Leucine	CCC	Proline	CAC	Histidine	CGC	Arginine	C
	CUA	Leucine	CCA	Proline	CAA	Glutamine	CGA	Arginine	A
	CUG	Leucine	CCG	Proline	CAG	Glutamine	CGG	Arginine	G
A	AUU	Isoleucine	ACU	Threonine	AAU	Asparagine	AGU	Serine	U
	AUC	Isoleucine	ACC	Threonine	AAC	Asparagine	AGC	Serine	C
	AUA	Isoleucine	ACA	Threonine	AAA	Lysine	AGA	Arginine	A
	AUG	Methionine (Start)	ACG	Threonine	AAG	Lysine	AGG	Arginine	G
G	GUU	Valine	GCU	Alanine	GAU	Aspartic Acid	GGU	Glycine	U
	GUC	Valine	GCC	Alanine	GAC	Aspartic Acid	GGC	Glycine	C
	GUA	Valine	GCA	Alanine	GAA	Glutamic Acid	GGA	Glycine	A
	GUG	Valine	GCG	Alanine	GAG	Glutamic Acid	GGG	Glycine	G

Nonpolar, aliphatic Polar, uncharged Aromatic Positively charged Negatively charged

It is universal in all living organisms with a negligible exceptions. Three consecutive bases (codon) code for one amino acid

GENETIC MATERIALS?

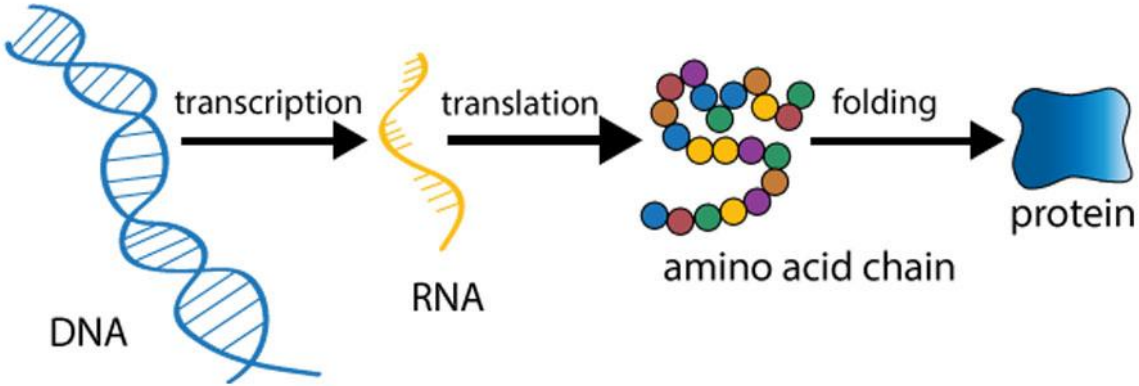




Within a cell, the genetic material is organized into smaller, discrete units called **genes** that are arranged on chromosomes and plasmids.

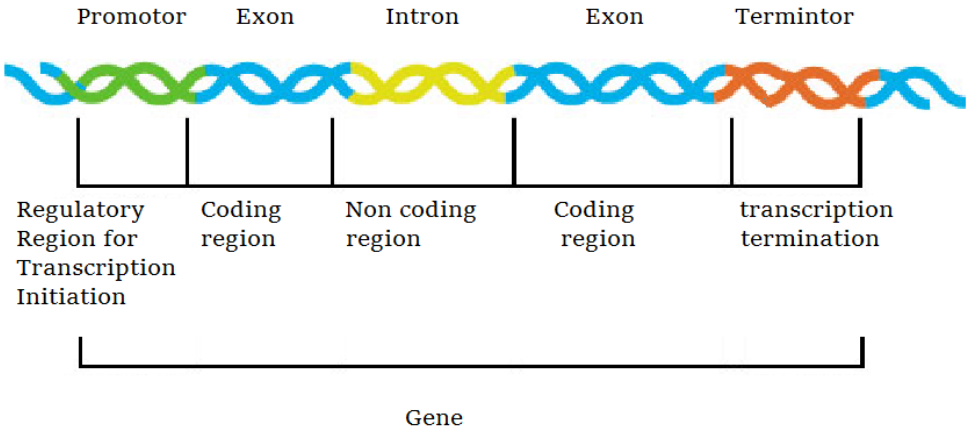
A **gene** is the basic physical and functional unit of heredity.

GENE EXPRESSION?



Is the synthesis of a specific protein with a sequence of amino acids that is encoded in the gene in a two steps process. The flow of genetic information to produce a messenger RNA (mRNA) molecule during the process of **transcription**. provides the information for the ribosome to catalyze protein synthesis in a process called **translation**.

GENE STRUCTURE



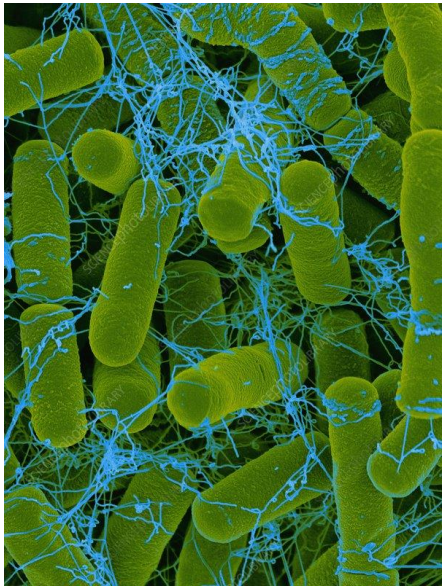
The process of transcription is initiated at the **promotor**. **Introns** are noncoding sections of an RNA transcript, or the DNA encoding it, that are spliced out before the mRNA molecule is translated into a protein. The sections of DNA (or RNA) that code for proteins are called **exons**. A **terminator** causes the transcription to stop.

SPECIES ?

- Is a group of living organisms consisting of similar individuals capable of exchanging genes or interbreeding to produce fertile offspring.

- Gene pool is the total genetic diversity found within a species.

GENETIC BARRIERS BETWEEN SPECIES

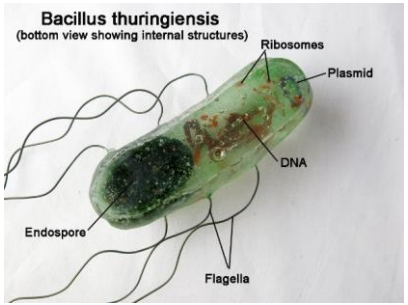


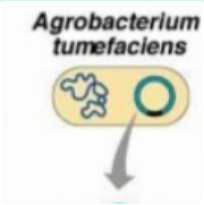
Each living cell is able to identify foreign genetic materials belonging to other species and would destroy it if it comes inside, which create **barriers** between species.

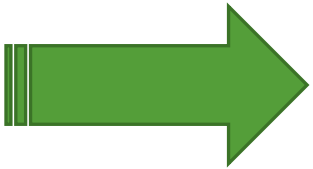
GENETIC ENGINEERING – MODERN BIOTECHNOLOGY

genetic material is altered or artificially introduced **in vitro** to induce a desirable new trait which **does not occur naturally** in the species. Inserted genes usually come from **a different species**.

GMO?





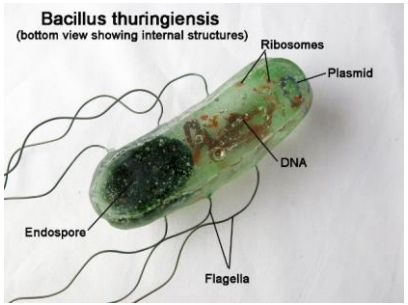


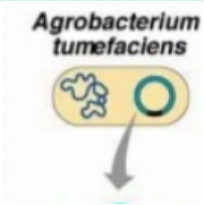
Bollgard

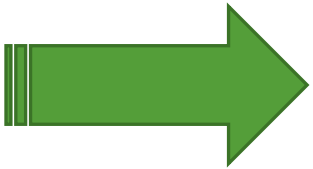
MON-ØØ531-6 - Bollgard™ cotton

An example is the genetically modified Cotton line MON531. It was genetically engineered to resist the bollwarms by producing its own insecticide. This line was developed by introducing the cry1Ac gene, isolated from the common soil bacterium Bacillus thuringiensis (Bt), into a cotton line by Agrobacterium-mediated transformation.

GMO?







Bollgard

MON-ØØ531-6 - Bollgard™ cotton

The **bollgard** possesses a novel combination of genetic material and in addition to the normal cotton genes it has genes inserted from a bacteria overcoming the natural physiological reproductive or recombination barriers

CPB. ART 3.

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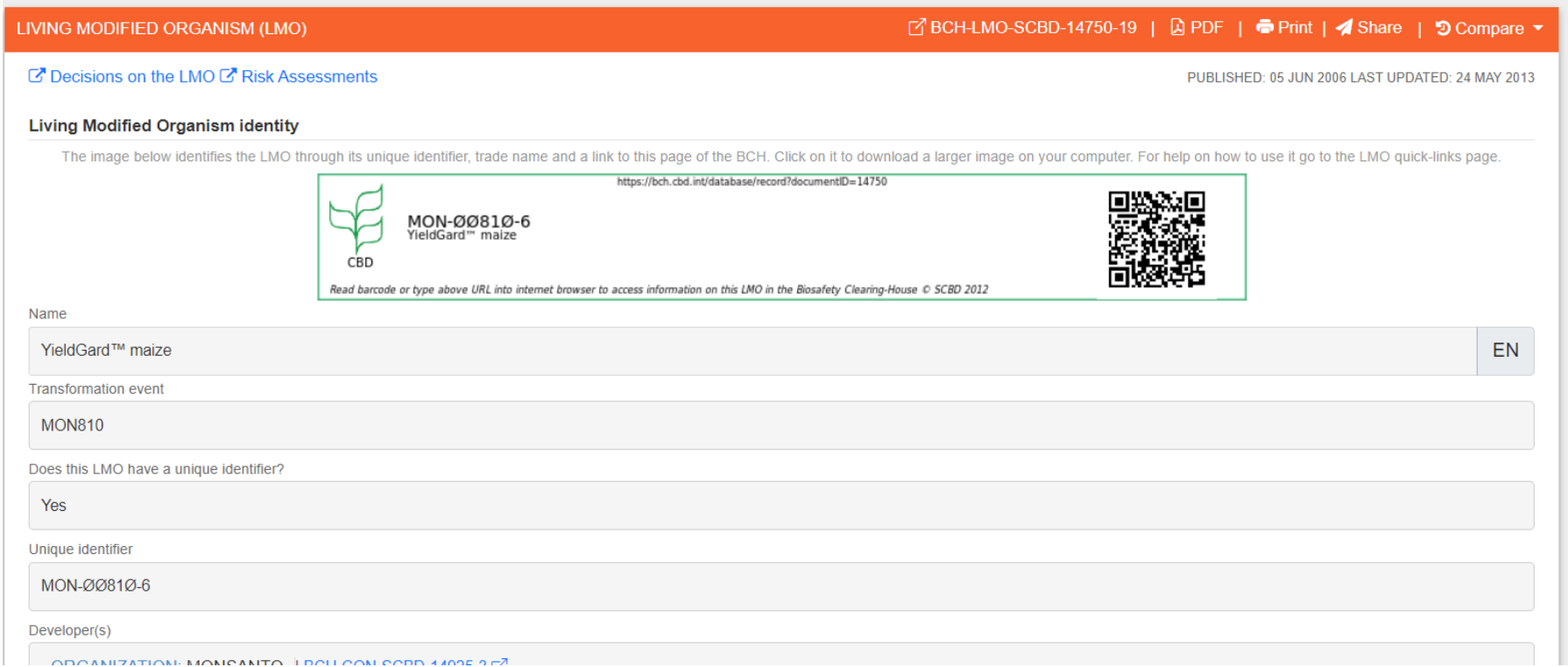

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CBD

MON-ØØ81Ø-6
YieldGard™ maize

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Name

YieldGard™ maize EN

Transformation event

MON810

Does this LMO have a unique identifier?

Yes

Unique identifier

MON-ØØ81Ø-6

Developer(s)

GENETIC ENGINEERING – MODERN BIOTECHNOLOGY

OVERVIEW ON THE PROCESS OF GENETIC ENGINEERING

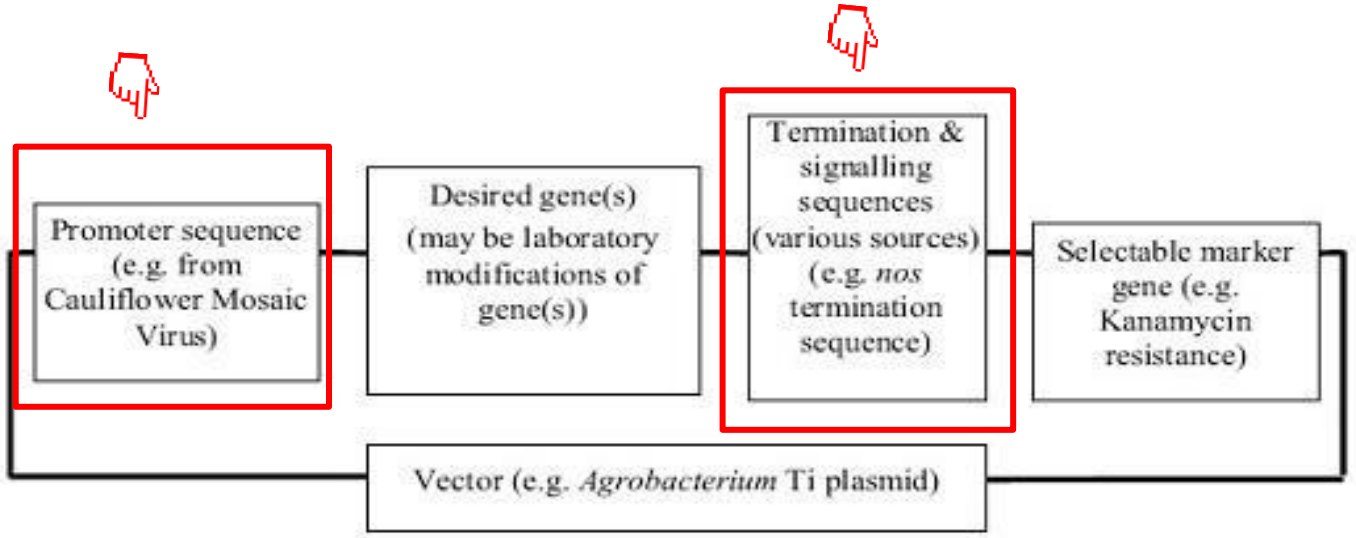
- A gene(s) of interest identified and isolated from a donor organism

- Then manipulated in the laboratory to enhance or modulate the expression of the gene once it is introduced into the intended recipient organism

- The manipulated gene of interest, as well as other nucleotide sequences needed for the proper functioning of the gene(s) of interest, may then be built in an orderly sequence into a “transformation cassette”

GENETIC ENGINEERING – MODERN BIOTECHNOLOGY

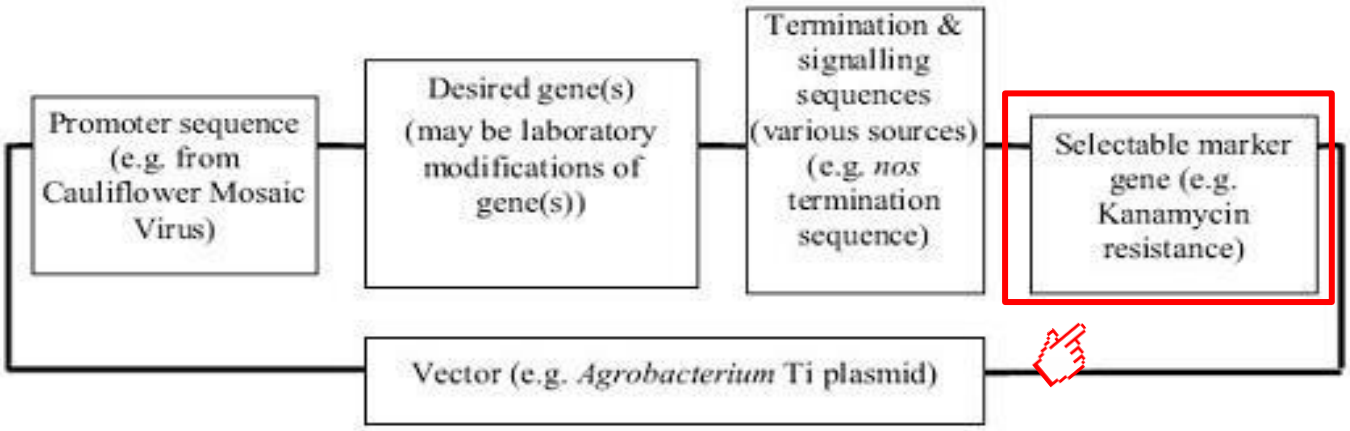
TRANSFORMATION CASSETTE



The transformation cassette typically includes a "promoter sequence" (regulate gene expression) and "termination sequence" which are necessary to ensure that the gene is expressed correctly in the recipient organism.

GENETIC ENGINEERING – MODERN BIOTECHNOLOGY

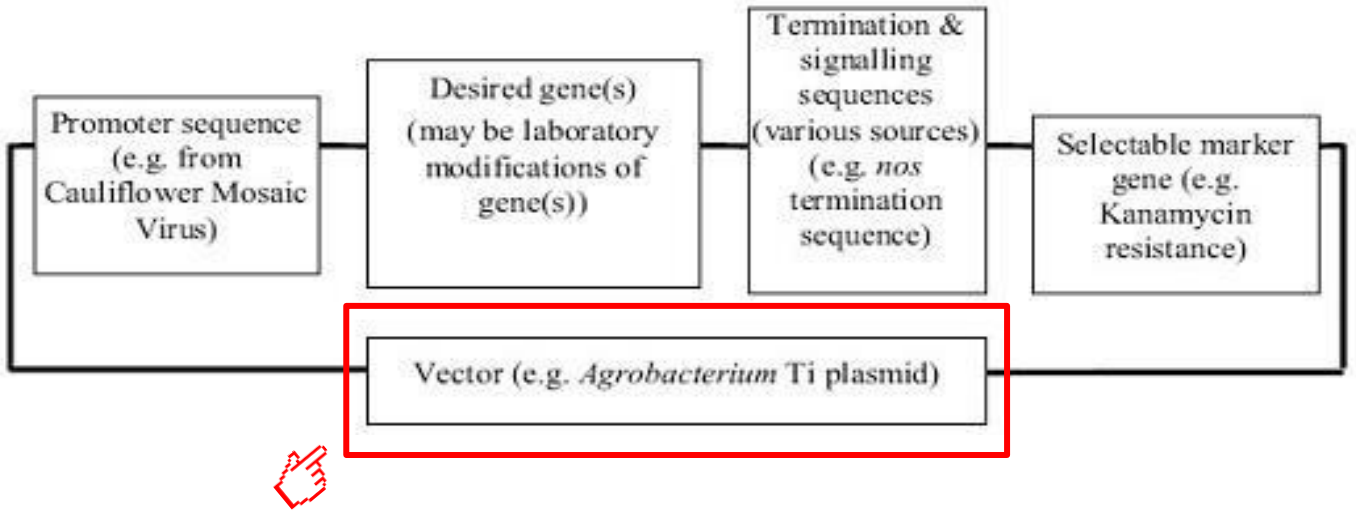
TRANSFORMATION CASSETTE



*A "**marker gene**" is often incorporated into the transformation cassette to help identify and/or select cells or individuals in which the transformation cassette(s) was successfully introduced. In some cases, it is removed from the LMOs at a later stage*

GENETIC ENGINEERING – MODERN BIOTECHNOLOGY

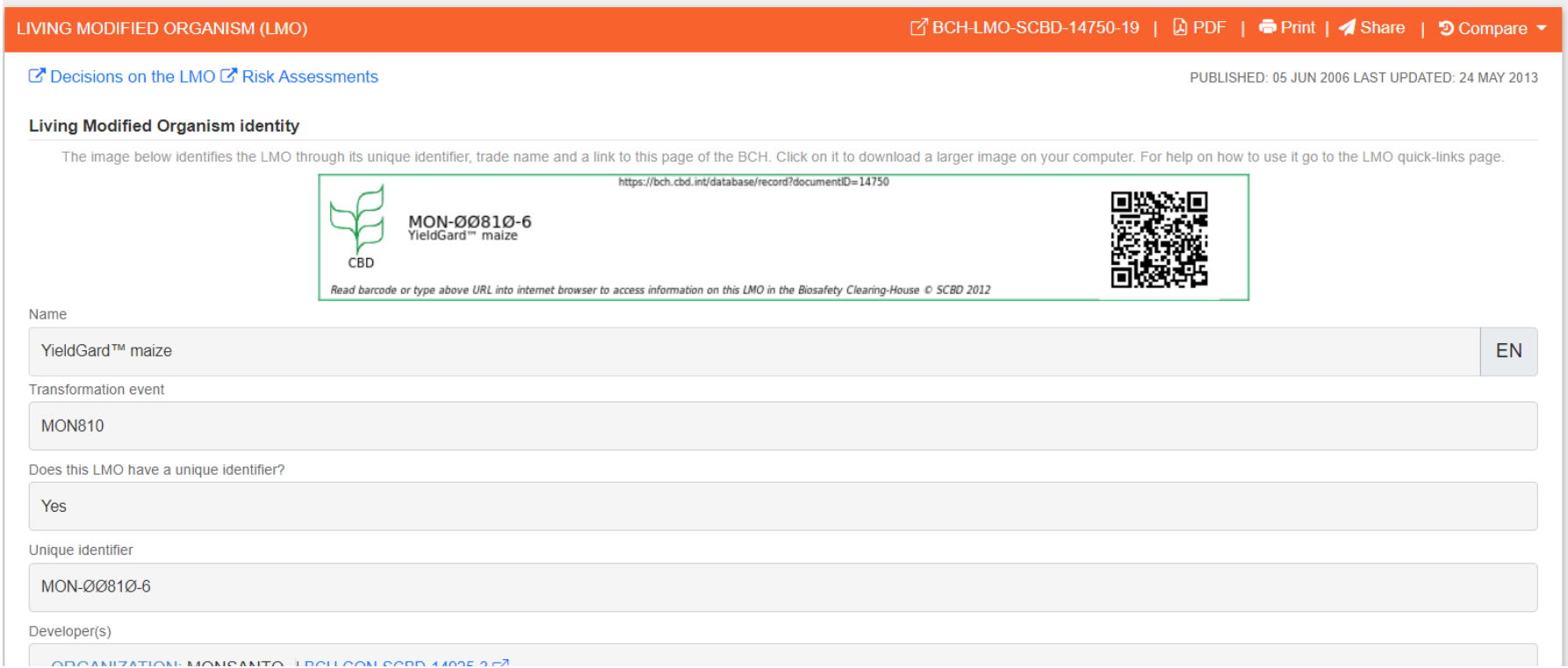
TRANSFORMATION CASSETTE



- The transformation cassette may be incorporated into a larger DNA molecule to be used as vector. The purpose of the vector is to assist the transfer of the transformation cassette into the recipient organism

MODIFICATION TECHNIQUES

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



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CBD

MON-ØØ81Ø-6
YieldGard™ maize

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Name

YieldGard™ maize EN

Transformation event

MON810

Does this LMO have a unique identifier?

Yes

Unique identifier

MON-ØØ81Ø-6

Developer(s)

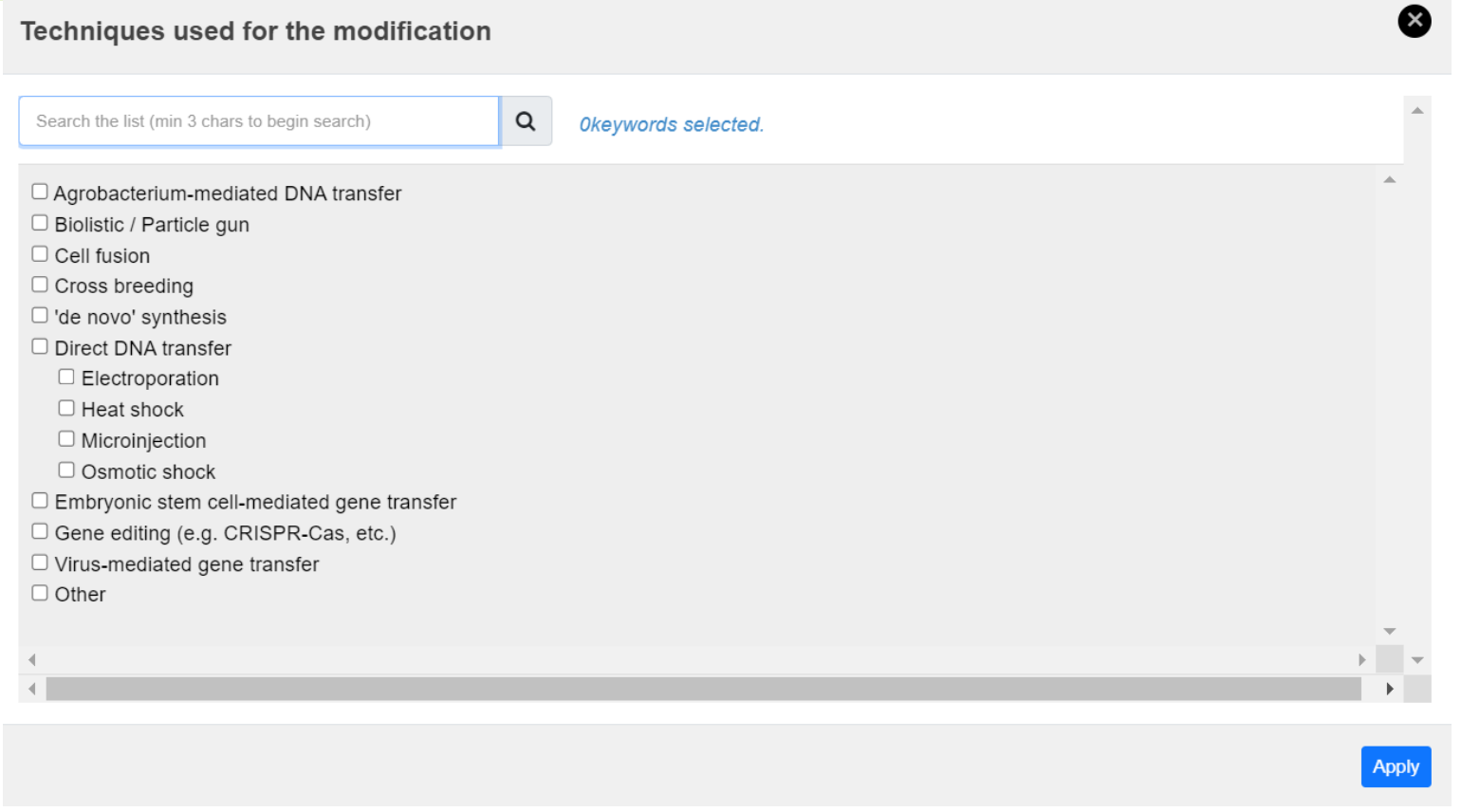
GENETIC ENGINEERING – MODERN BIOTECHNOLOGY

OVERVIEW ON THE PROCESS OF GENETIC ENGINEERING

- Finally, the transformation cassettes are integrated into the genome of the recipient organism through a process known as transformation. This can be carried out through different methods such as infection using Agrobacterium or particle bombardment or microinjection.

GENETIC ENGINEERING – MODERN BIOTECHNOLOGY

OVERVIEW ON THE PROCESS OF GENETIC ENGINEERING



GENETIC ENGINEERING – MODERN BIOTECHNOLOGY

COMMONLY USED METHODS IN GENETIC ENGINEERING

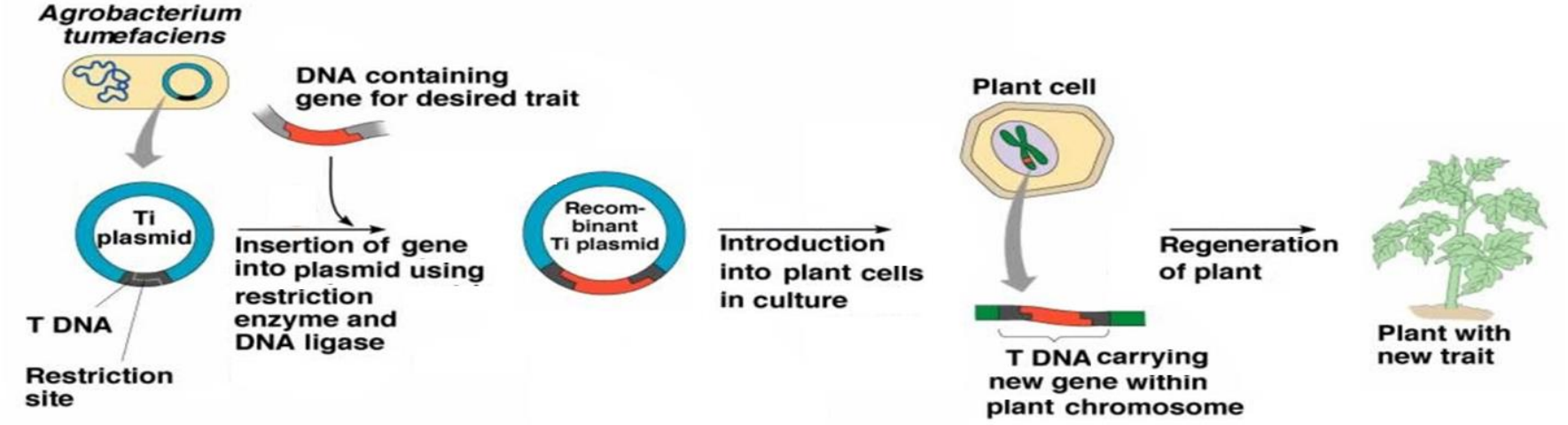
- **Agrobacterium tumefaciens** (Rhizobium radiobacter) is the causal agent of **crown gall disease** (the formation of tumors) in over 140 species of eudicots. It is a rod-shaped, Gram-negative soil bacterium.

GENETIC ENGINEERING – MODERN BIOTECHNOLOGY

TRANSFORMATION USING AGROBACTERIUM

- Tumors caused by Agrobacterium tumefaciens occur by transfer of DNA from the bacterium Ti plasmid (tumor-inducing plasmids)which integrates into the infected plant cell's genome producing tumors in plants.

- Researchers manipulate the Ti plasmids to remove the tumor-causing genes and insert the desired DNA fragment for transfer into the plant genome.

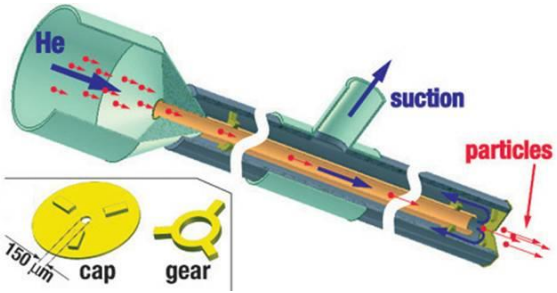


GENETIC ENGINEERING – MODERN BIOTECHNOLOGY

TRANSFORMATION USING GENE GUN

- for the physical introduction of DNA into plant cells containing cell walls. The gene gun is utilized to bombard the plant cell wall with many DNA coated metal particles by using compressed helium as the propellant.

- After the DNA-coated particles have been delivered to the cells, the DNA is used as a template for transcription (transient expression) and sometimes it integrates into a plant chromosome ('stable' transformation).



GENETIC ENGINEERING – MODERN BIOTECHNOLOGY

LMO PLANT GENERATION

- Transformed cells are then selected, e.g. with the help of a marker gene

- Then are treated with series of plant hormones, such as auxins and gibberellins, to divide and differentiate into an entire plant.

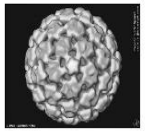
- The new plant that originated from a successfully transformed cell have new traits that are heritable (LMO).

Genetic sequence of interest isolated

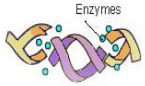
Streptomyces hygroscopicus

Bacillus thuringiensis

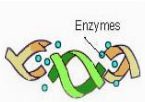
Escherichia coli



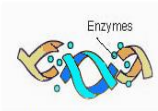
Cauliflower mosaic virus



Cry1Ab gene
Resistance to Insects - Lepidoptera (butterflies and moths)



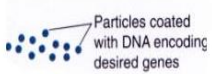
Phosphinothricin N-acetyltransferase gene
Resistance to herbicides - Glufosinate

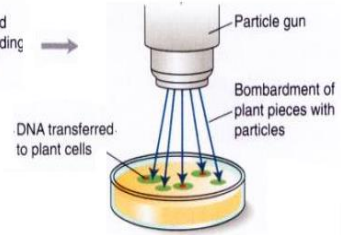


Beta-lactamase gene
Resistance to antibiotics - Ampicillin

CaMV 35S promoter
CaMV 35S terminator

bacterial cells lysed
DNA vector isolated and
gold or tungesten particle
coated with it

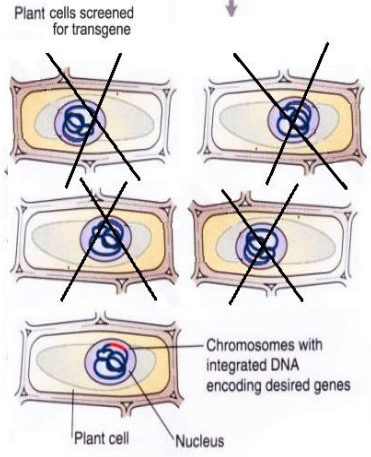


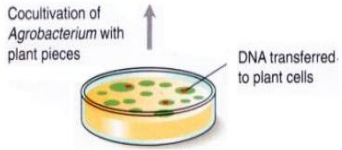


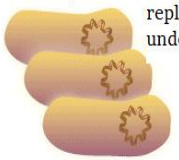
Plant with new trait

Shoot regeneration followed by root regeneration

Cell multiplication (callus)

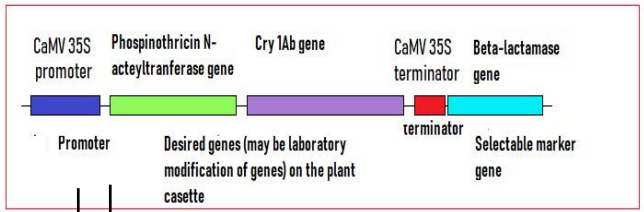






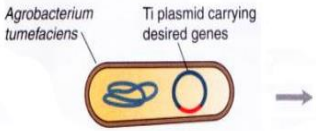
inserted into vector

Particle gun method



Agrobacterium method

inserted into Ti plasmid



Genetic Element Registry

Total records: 928

Export

Record ID	Unique identification	Identity & transformation event	Organism	Description
BCH-LMO-SCBD-114444-1	AAT-7Ø9AA-4	**Pod Borer-resistant cowpea** AAT709A	Vigna unguiculata Cowpea, Black eyed pea	Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths), Resistance to antibiotics - Kanamycin
BCH-LMO-SCBD-14752-6	ACS-BNØ11-5	**Navigator™ canola** Oxy-235	Brassica napus Turnip, Rapeseed, Canola Plant, Oilseed Rape, Rape, BRANA	Resistance to herbicides - Bromoxynil
BCH-LMO-SCBD-15101-6	ACS-BNØ1Ø-4	**Falcon™ rapeseed** GS40/90pHoe6/Ac	Brassica napus Turnip, Rapeseed, Canola Plant, Oilseed Rape, Rape, BRANA	Resistance to herbicides - Glufosinate
BCH-LMO-SCBD-14753-6	ACS-BNØØ1-4	**InVigor™ canola** RF1 (B93-101)	Brassica napus Turnip, Rapeseed, Canola Plant, Oilseed Rape, Rape, BRANA	Resistance to herbicides - Glufosinate, Resistance to antibiotics - Kanamycin, Changes in physiology and/or production - Fertility restoration
BCH-LMO-SCBD-14754-5	ACS-BNØØ2-5	**InVigor™ canola** RF2 (B94-2)	Brassica napus Turnip, Rapeseed, Canola Plant, Oilseed Rape, Rape, BRANA	Resistance to herbicides - Glufosinate, Resistance to antibiotics - Kanamycin, Changes in physiology and/or production - Fertility restoration
BCH-LMO-SCBD-14755-7	ACS-BNØØ3-6	**InVigor™ canola** RF3	Brassica napus Turnip, Rapeseed, Canola Plant, Oilseed Rape, Rape, BRANA	Resistance to herbicides - Glufosinate, Changes in physiology and/or production - Fertility restoration
BCH-LMO-SCBD-116285-1	ACS-BNØØ3-6 × MON-ØØØ73-7	**Herbicide tolerant, male fertility restoring canola** RF3 × RT73	Brassica napus Turnip, Rapeseed, Canola Plant, Oilseed	Resistance to herbicides - Glufosinate, Glyphosate, Changes in physiology and/or production - Reproduction, Fertility restoration

UNIQUE IDENTIFIERS

WHAT IS A UNIQUE IDENTIFIER?

- It is a digital alpha numeric code for each living modified plant that is approved for commercial use, including for use as food or feed.

- Unique Identifiers are generated by the developers of a new transgenic plant, and included in the dossiers that they forward to national authorities during the safety assessment process.

- Once approved, national authorities can then forward the unique identifier to the OECD Secretariat for inclusion in the OECD's product database, from which the information is automatically shared with the Biosafety Clearing-House.

UNIQUE IDENTIFIERS

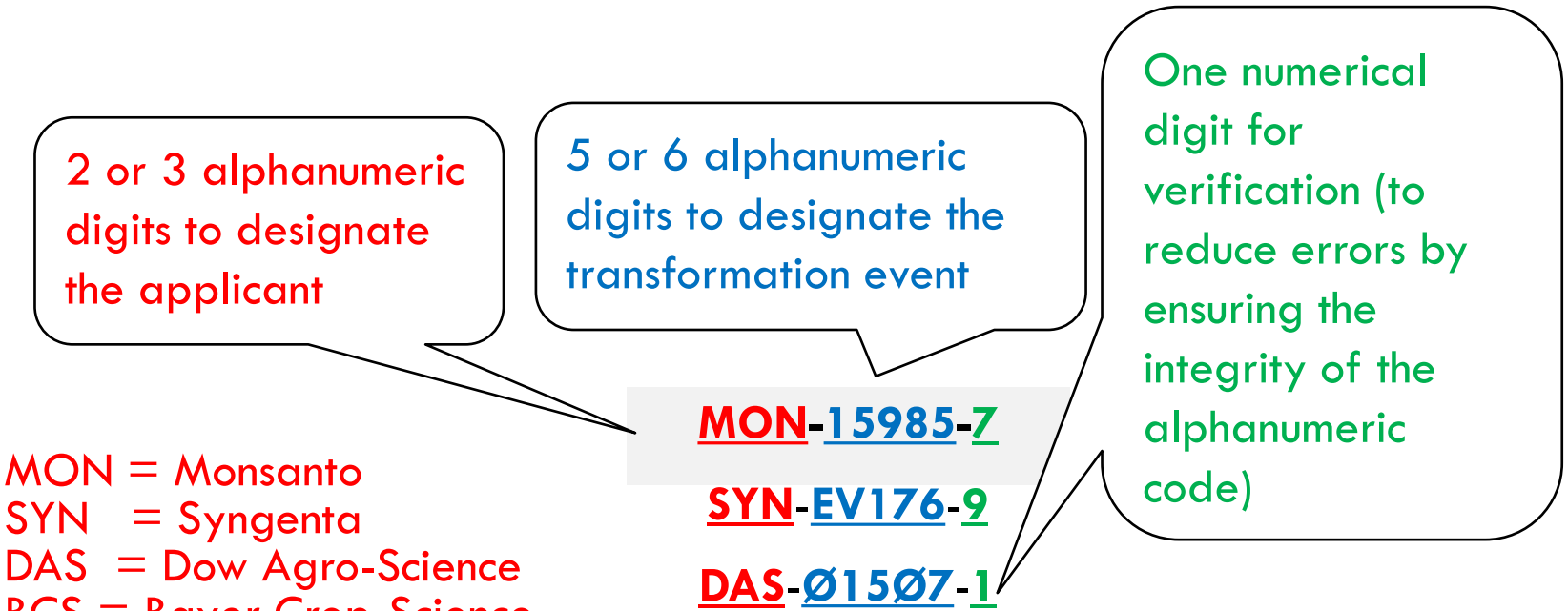
WHAT IS A UNIQUE IDENTIFIER?

- In accordance with the Cartagena Protocol, it is expected that the Unique identifier for LMOs intended for direct use as food, feed or for processing (decisions taken under Art. 11) to be available, since most of these organisms are expected to be approved for use in trade.

- The Third Meeting of the Parties to the Protocol also requested Governments to provide information on the unique identifier, where it exists, when decisions taken under the Advanced informed agreement are registered.

UNIQUE IDENTIFIERS

UNDERSTANDING THE CODE



GENETIC ENGINEERING – MODERN BIOTECHNOLOGY

WHAT IS A STACKED LMO?

- It is an LMO possessing new traits resulting from more than one transformation cassette. It can be produced by several approaches including conventional cross-breeding involving two LMOs that are either single transformation events or already stacked events, transformation of an LMO or simultaneous transformation with different transformation cassettes or vectors.

- Accordingly, the cassettes containing the transgenes and other genetic elements that were inserted in the original transformation events may be physically unlinked (i.e. located separately in the genome) and can segregate independently.

- Stacked LMOs may occur in the field in cross pollinating plants like maize (corn) if more than one LMO are planted in vicinity of each other.

UNIQUE IDENTIFIERS

UNDERSTANDING THE CODE

- For stacked LMOs, the unique identifiers show the multiple GM events that were combined.

BCS-BNØ12-7 X ACS-BNØØ3-6 X MON-883Ø2-9

BCS-GHØØØ2-5 X BCS-GHØØØ4-7

LMO with 3 stacked events

LMO with 2 stacked events

DETECTION AND IDENTIFICATION OF LMOS

Detection method(s)

External link(s)

ACS-BNØØ3-6 - EU Reference Laboratory for GM Food and Feed (EURL-GMFF) *[English]*

ACS-BNØØ3-6 - EU Reference Laboratory for GM Food and Feed (EURL-GMFF) *(JRC) [English]*

Perform your search by keyword, select a GMO unique identifier or click a link in the section below.

ac:ACS-BN003-6 Search or by GMO unique identifier:

View Entry Download View in GMO matrix View in GMO amplicons

Entry information	
Entry name	**QT-EVE-BN-003**; SV 0; linear; genomic DNA; STS; SYN; 139 BP.
Primary accession	**ACS-BN003-6**
Description	
Description	Quantitative PCR method for detection of oilseed rape event Rf3 (Savini et al., 2007).
Keywords	event_specific
From	Brassica napus (oilseed rape) - event Rf3 (ACS-BN003-6)
References	
1	Savini C., Bogni A., Mazzara M., Van Den Eede G.;**"Event-specific Method for the Quantification of Oilseed Rape Line Rf3 Using Real-time PCR - Validation Report and Protocol - Seeds Sampling and DNA Extraction";** Online Publication (2007). DOI 10.2788/28179 Reference Position 1-139

GMOs DETECTION

BRIEF OVERVIEW OF MOST COMMONLY USED METHODS

- LMOs are often developed by inserting one or more “genes of interest” which are DNA molecules encoding proteins that confer particular traits of interest, such as insect resistance or herbicide tolerance.

- Either the DNA or the protein can be targeted for the detection or identification of such LMOs.

- Both approaches, i.e. protein- or DNA-based methods, have advantages and disadvantages and the adoption of one over the other, or both, will depend largely on the available expertise, infrastructure to handle samples, laboratory equipment and regulatory requirements.

GMOs DETECTION

PROTEIN-BASED METHODS FOR LMO DETECTION

- Detect proteins that are manufactured in the cell according to the information coded by the transgenic (GMO) DNA by antibody recognition of an epitope specific to the transgenic protein.

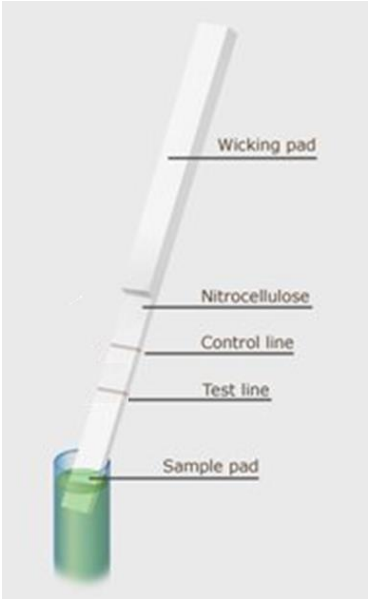
- Eg. Roundup Ready GM soy has been genetically engineered to be resistant to the glyphosate herbicide Roundup via insertion of a gene that codes for a glyphosate tolerant version of a plant enzyme, CP4 epsps.

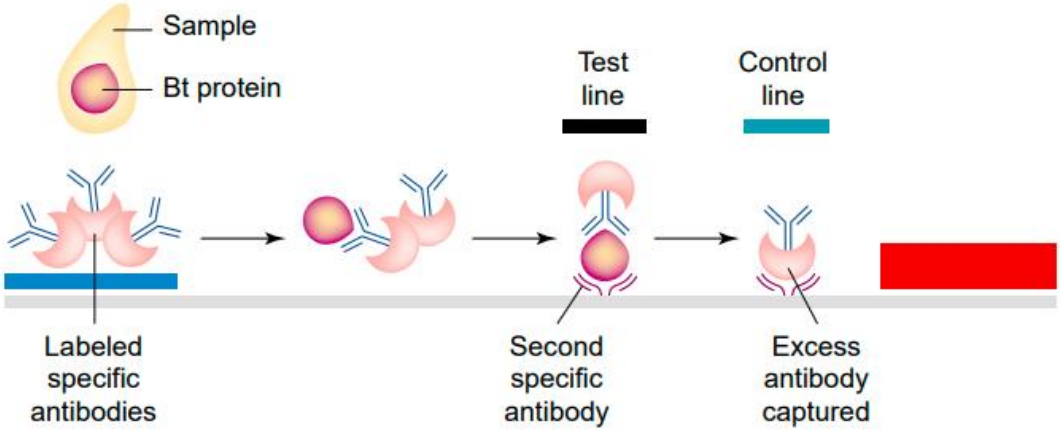
- Since the process of antibody production is extremely complex and costly, detection using these methods typically relies on the availability of commercial antibodies.

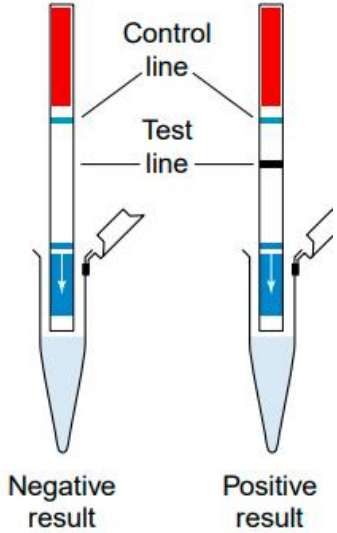
- The total crude proteins is extracted from a sample by adding water or buffer followed by sample homogenization then the testing is either in the form of a lateral flow strip test, a micro-well format as an enzyme-linked immunosorbent analysis (ELISA) or a gel electrophoresis protein immunoblot (also known as western blot)

GMOs DETECTION

LATERAL FLOW STRIP TESTING

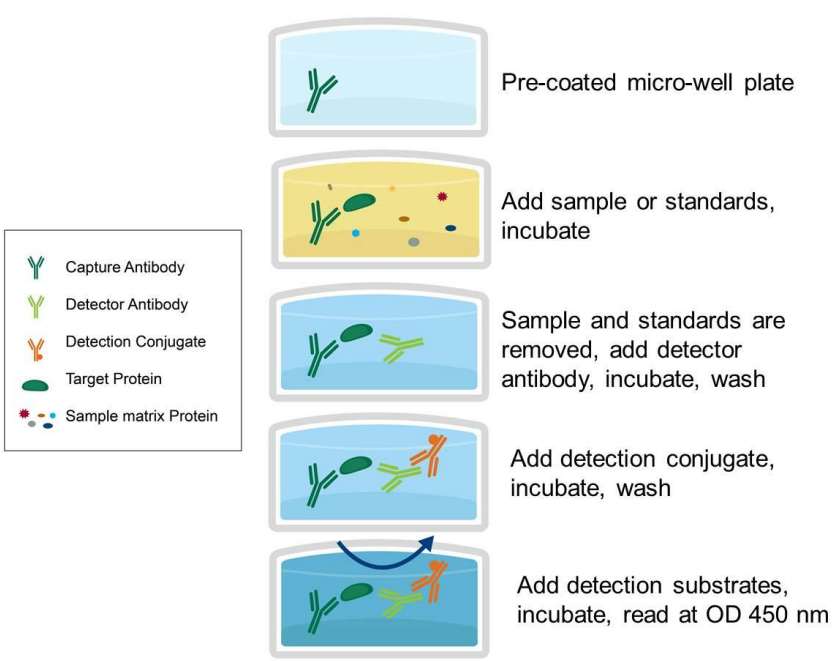


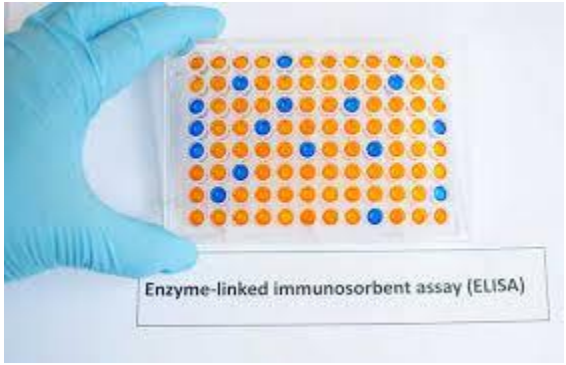




GMOs DETECTION

ELISA BASED APPROACH



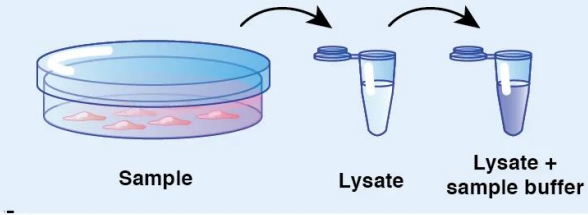


GMOs DETECTION

WESTERN BLOTTING

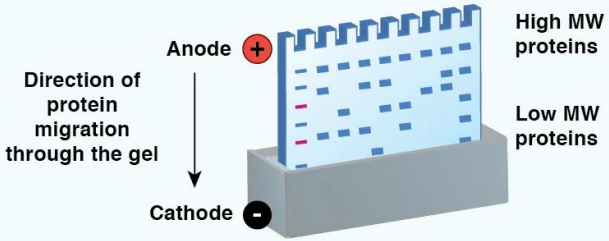
1 Sample preparation

Lyse the sample in an appropriate lysis buffer. Reduce and denature the sample with sample buffer containing SDS and β-mercaptoethanol. Heat the sample at 95°C 5 mins.



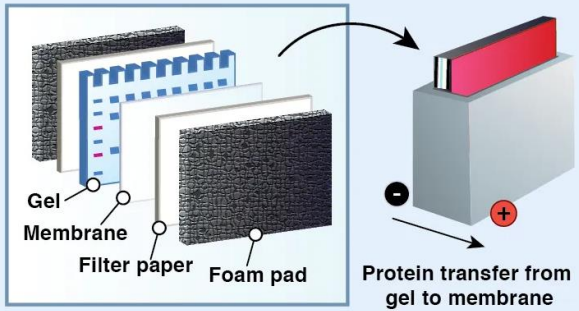
2 Gel electrophoresis

Load an optimized quantity of sample onto the gel. Perform gel electrophoresis at 100 - 200 V for 30 mins - 2 hrs. Proteins separate according to size, with smaller proteins migrating more quickly through the gel.



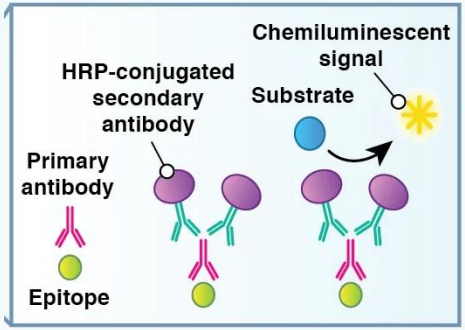
3 Membrane transfer

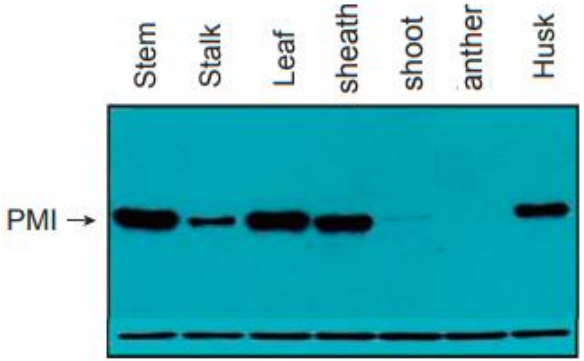
Prepare cold transfer buffer and the membrane. Assemble the transfer sandwich with the gel near the cathode (-) and the membrane near the anode (+). The negatively charged proteins will migrate out of the gel onto the membrane. Perform the transfer at 30 V O/N at 4°C or 100 V 1 hr.



4 Immunodetection

Use a total protein stain to check the transfer efficiency. Block the membrane in an appropriate blocking buffer (milk, BSA, etc.). Incubate the membrane with primary antibody 1 hr RT or 4°C O/N. Incubate with secondary antibody 1 hr RT. Perform the detection step (ex. using a chemiluminescent substrate kit). Perform data analysis.





The expression pattern of PMI protein in transgenic rice.

GMOs DETECTION

PROTEIN-BASED METHODS FOR LMO DETECTION

- Can not detect inserted genetic elements that do not produce a protein, such as regulatory sequences and new gene silencing technologies using double stranded RNA (dsRNA)

- Rely on the specific recognition of an antigen in the transgenic protein by an antibody and therefore, any changes in the tertiary structure of the protein renders the method ineffective. Such conformational changes are sometimes induced during sample processing where the samples are subjected to heat and/or chemical treatment.

- The detection capability is also affected by the expression level of the transgenic protein that can vary between different parts (tissues) of the LMO or different stages of its life cycle, and can be influenced by external factors such as climate and soil conditions.

GMOs DETECTION

DNA-BASED METHODS FOR LMO DETECTION

- Are based mainly on the use of the polymerase chain reaction (PCR). PCR is a method that employs synthetic DNA oligonucleotides, so called “primers”, to replicate or “amplify” targeted regions of an inserted DNA sequence that is present in the LMO. The amplified product can then be detected to determine whether or not DNA originating from an LMO is present in a sample.

- Following the extraction of DNA from a sample, target sequences only found in the LMO are amplified using primers that have been designed to specifically bind the target sequence during the PCR reaction.

- PCR based methods can be used on raw and processed products as long as DNA can be extracted from the sample.

GMOs DETECTION

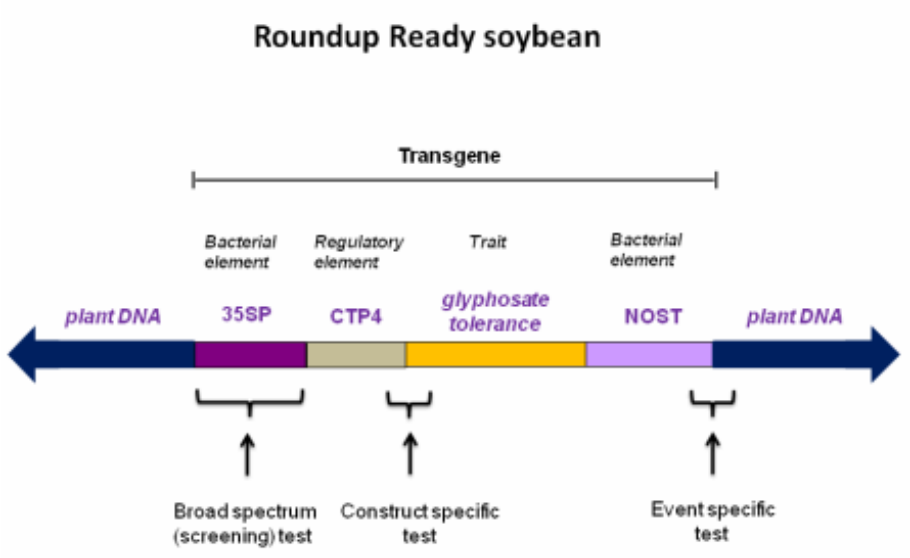
DNA-BASED METHODS FOR LMO DETECTION

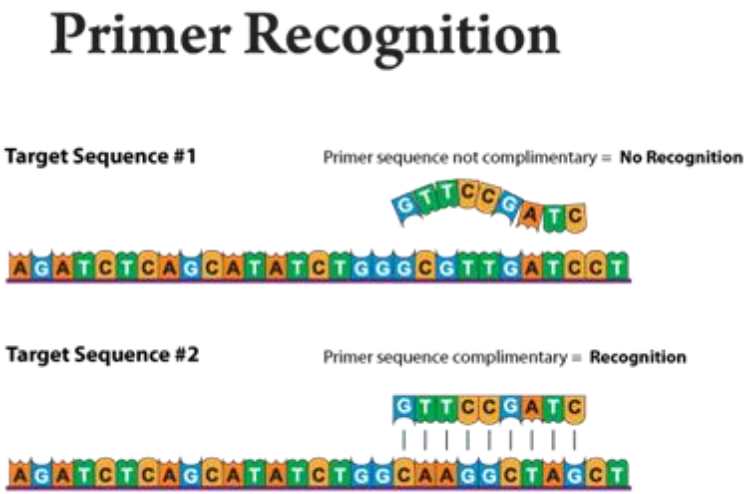
- Depending on the combination of primers used, the PCR detection can be GMO screening, transgene-specific, construct-specific and event-specific detection.

- **GMO screening** is used to determine whether a sample contains GMO through the detection of regulatory elements (promoter and terminator sequences) commonly associated with GMOs. For example, the 35S promoter and NOS terminator are found in more than 90 per cent of all commercial maize and soybean GMOs.
- **Transgene-specific** identification identifies a specific gene, for example Cry1Ab, Cry9c (insect resistance) or EPSPS (herbicide tolerance).
- **Construct-specific** methods target the region between two DNA elements found within a particular transgene construct, such as the promoter and gene.
- The most specific method to identify a GMO is **event-specific** detection where the PCR target sequence is a junction between the host DNA and the inserted gene construct

GMOs DETECTION

DNA-BASED METHODS FOR GMO DETECTION





GMOs DETECTION

DNA-BASED METHODS FOR GMO DETECTION

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-14972-12 PHOSPHINOTHRICIN N-ACETYLTRANSFERASE GENE | STREPTOMYCES HYGROSCOPICUS (STRHY)
Protein coding sequence | Resistance to herbicides (Glufosinate)

BCH-GENE-SCBD-14985-12 CRY1AB | BACILLUS THURINGIENSIS (BT, BACILLUS, BACTU)
Protein coding sequence | Resistance to diseases and pests (Insects, Lepidoptera (butterflies and moths))

BCH-GENE-SCBD-14975-5 BETA-LACTAMASE GENE | ESCHERICHIA COLI (ECOLX)
Protein coding sequence | Resistance to antibiotics (Ampicillin)

BCH-GENE-SCBD-100287-7 CAMV 35S PROMOTER | CAULIFLOWER MOSAIC VIRUS (CAMV)
Promoter

BCH-GENE-SCBD-100290-6 CAMV 35S TERMINATOR | CAULIFLOWER MOSAIC VIRUS (CAMV)
Terminator

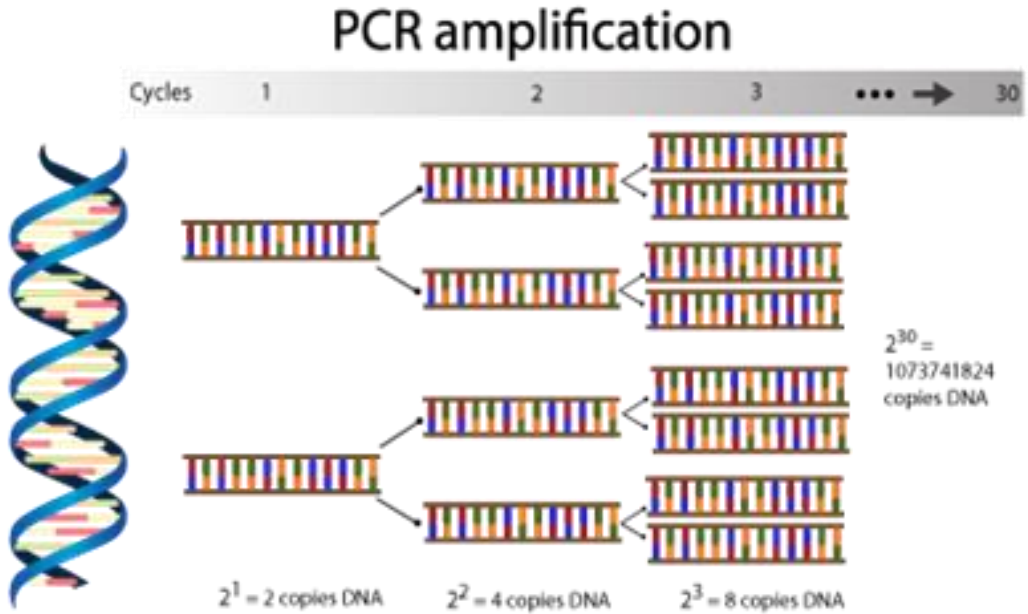
BCH-GENE-SCBD-101404-3 PHOSPHOENOLPYRUVATE CARBOXYLASE GENE PROMOTER | ZEA MAYS (MAIZE, CORN, MAIZE)
Promoter

BCH-GENE-SCBD-101405-2 CALCIUM-DEPENDENT PROTEIN KINASE PROMOTER | ZEA MAYS (MAIZE, CORN, MAIZE)
Promoter

BCH-GENE-SCBD-101406-4 PHOSPHOENOLPYRUVATE CARBOXYLASE, INTRON 9 | ZEA MAYS (MAIZE, CORN, MAIZE)
Intron

GMOs DETECTION

DNA-BASED METHODS FOR GMO DETECTION



GMOs DETECTION

DNA-BASED METHODS FOR GMO DETECTION

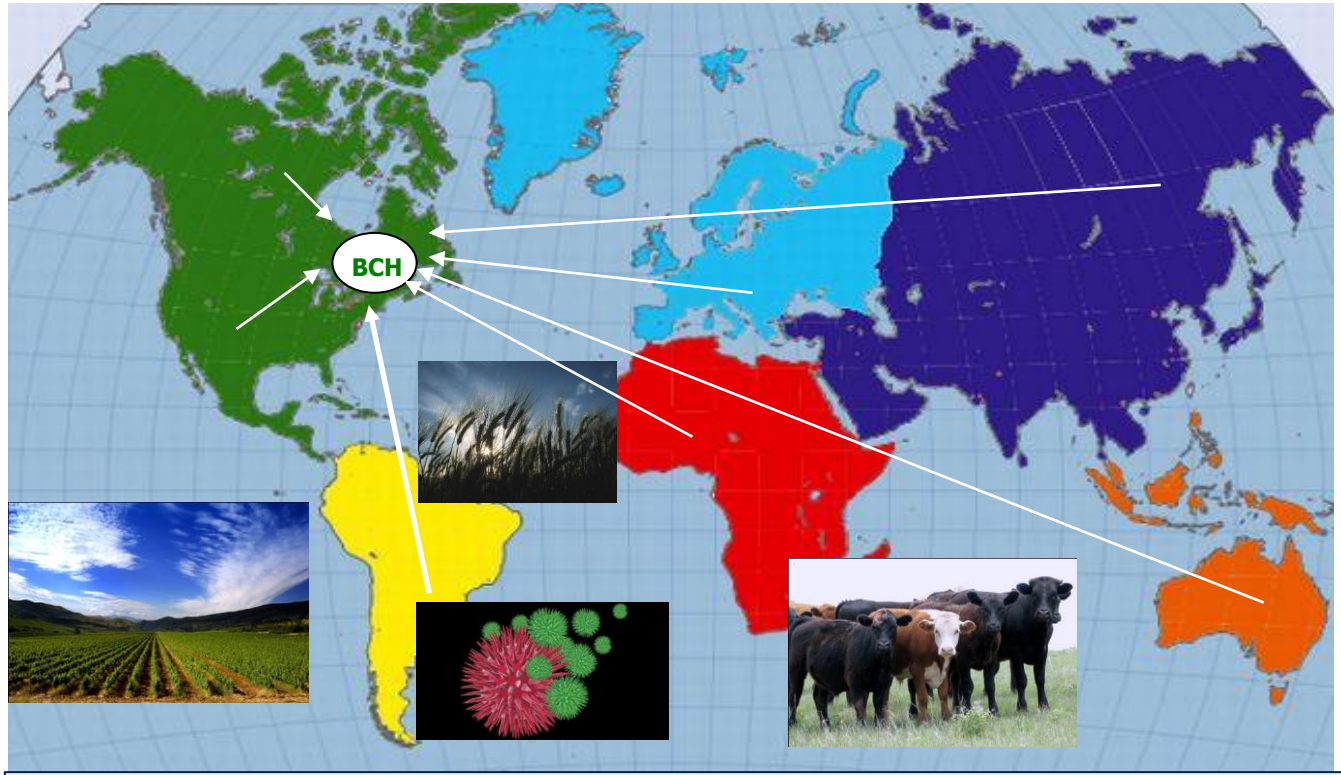
- DNA has a greater chemical stability as compared to proteins which allows it to withstand chemical and heat treatments.

- DNA is also present in all cells and therefore any part of the organism can be used for testing.

- PCR methods are more versatile than protein methods and PCR can be used to screen a sample for the presence of several potential LMOs simultaneously with relative ease.

- it is not possible to unequivocally distinguish a sample containing material from different single transformation events from another sample containing one or more stacked LM events.

RISK ASSESSMENT



- The BCH is a very useful tool to assist evaluating and conducting risk assessment and support decision making on living modified organisms (LMO) and Products thereof

It constitutes a repository of scientific, technical, environmental and legal information on, and experience with LMOs.

RISK ASSESSMENT

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 **(343)**
- Competent National Authorities **(408)**
- Supplementary Protocol Competent Authorities **(11)**
- Biosafety Laws, Regulations, Guidelines and Agreements **(1133)**
- Countries' Decisions or any other Communications **(2693)**
- [x] Risk Assessments generated by a regulatory process **(2574)**
- National Biosafety Websites or Databases **(150)**
- 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 **(361)**
- Country Profiles for Biosafety Clearing-House **(168)**

- Contacts **(2462)**

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 **(1566)**
- Biosafety Organizations **(375)**
- Laboratories for detection and identification of LMOs **(73)**
- Living Modified Organisms **(928)**
- Genetic elements **(828)**
- Organisms **(264)**
- [x] Risk Assessments generated by an independent or non-regulatory process **(32)**
- Submissions **(525)**
- Capacity Development Initiatives **(422)**
- BCH News **(558)**

RISK ASSESSMENT RECORD

https://bch.cbd.int/en/database/RA/BCH-RA-KR-262363-1

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA) | BCH-RA-KR-262363-1 | PDF | Print | Share

LAST UPDATED: 14 NOV 2022

General Information

Country

Republic of Korea

Title of the risk assessment

DP-202216-6 EN

Date of the risk assessment

21 Oct 2022

Competent National Authority(ies) responsible for the risk assessment

- COMPETENT NATIONAL AUTHORITY: | BCH-CNA-KR-100761-6

COMPETENT NATIONAL AUTHORITY:

Rural Development Administration(RDA)
300, Nongsaengmyeong-ro, Wansan-gu
Jeonju-si, Jeollabuk-do
54874, Republic of Korea
Phone: +82 63-238-0758
Fax: +82 63 238-1777
Email: sjkwon67@korea.kr Website: http://www.rda.go.kr

Contact details of the main responsible risk assessor

- PERSON: DR. SOO JIN KWON | BCH-CON-KR-115576-2

PERSON:

Dr. Soo Jin Kwon

THE CARTAGENA PROTOCOL AND RISK ASSESSMENT

- It recognizes that GMOs may have biodiversity, human health and socio-economic impacts, and that these impacts should be risk assessed or taken into account when making decisions on GMOs.
- The Protocol empowers governments to decide whether or not to accept imports of LMOs on the basis of risk assessments.
- Art.15 and Annex III of the CPB highlight the general principles, the methodology (steps of risk assessment) and points to consider.
- **LMOS and Products thereof**, Namely processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology,

GENERAL PRINCIPLES FOR RISK ASSESSMENT

- Scientific soundness (Reporting, verifiability and reproducibility);
- The Concept of a case by case base (LMO, Receiving Environment and the intended use);
- Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk;
- "Risks associated with living modified organisms or should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment. (comparator)

Individual Parties should use these general principles to guide the development and implementation of their own national risk assessment process.

ESTABLISHING THE ELEMENTS OF A CASE BY CASE RA

- Living modified organism
  - Characterization of the recipient organism or parental organisms
  - Description of the genetic modification
  - Identification of the LMO

- Likely potential receiving environment(s)
  - Physical characteristics
  - Biological characteristics

- Intended use
  - Consumers' habits, patterns, practices?!!

SETTING THE CONTEXT AND SCOPE

(i) Selecting relevant assessment endpoints or representative species on which to assess potential adverse effects;

(ii) Establishing baseline information; and

(iii) Establishing the appropriate comparator(s).

PROTECTION GOALS

" Ecosystems and Habitats: containing high diversity, large numbers of endemic or threatened species, or wilderness; required by migratory species; of social economic, cultural or scientific importance; or, which are representative, unique or associated with key evolutionary or other biological process;

Species and communities: threatened; wild relatives of domesticated or cultivated species; of medicinal, agricultural or other economic value; or social, scientific or cultural importance for research into the conservation and sustainable use of biological diversity such as indicator species…"

ENVIRONMENTAL RISK ASSESSMENT

- Synthesizing what is known about the LMO, its intended use and the likely potential receiving environment to establish the likelihood and consequences of potential adverse effects to biodiversity and human health resulting from the introduction of the LMO.

- Risk assessors need to identify the information needed and understand how it will be used.

- Using and interpreting existing information, as well as identifying information gaps and understanding how to deal with scientific uncertainty are crucial during the risk assessment.

CONDUCTING RISK ASSESSMENT

1. Hazard identification;
2. Evaluation of the likelihood;
3. Evaluation of the consequences;
4. Estimation of the overall risk;
5. Identification of risk management and monitoring strategies.

STEP 1

- Identification of any novel genotypic and phenotypic characteristics associated with the LMO that may have adverse effects
- Making risk hypothesis or scenario
- E.g. "The possibility that growing Bt corn may kill ladybird beetles due to ingestion of the Bt protein when preying on insects feeding on the GM corn, thereby reducing the abundance of coccinellids in the agroecosystem and increasing the incidence of pests."

STEP 1

When establishing risk scenarios, several considerations may be taken into account. These include, for example:

- Gene flow followed by undesired introgression of the transgene into species of interest;
- Toxicity to non-target organisms;
- Allergenicity;
- Tri-trophic interactions and indirect effects;
- Resistance development; and
- Will it perform as expected ?!!! (null hypothesis)

STEP 2

- Evaluation of the likelihood of adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the LMO.

- The likelihood of an adverse effect is dependent upon the probability of one or a series of circumstances actually occurring

- E.g. Introgression of the transgene: Outcrossing of the transgene with a non-modified organism and the likelihood of the establishment of the LMO progeny due to increased fitness resulting from the transgene for example

STEP 3

- Evaluation of consequences: They may be severe, minimal or anywhere in between. It may consider the effects on individuals (e.g. mortality, reduced or enhanced fitness, etc.) or on populations (e.g. increase or decrease in number, change in demographics, etc.) depending on the adverse effect being evaluated.

- Eg Consequences of effects to non-target organisms: When the inserted trait causes the plant to produce potentially toxic compounds, or if flower characteristics are changed, i.e. color, flowering period, pollen production, etc., then effects on pollinators have to be measured. A test of effects on honeybees (Apis mellifera) is always obligatory !!

STEP 4

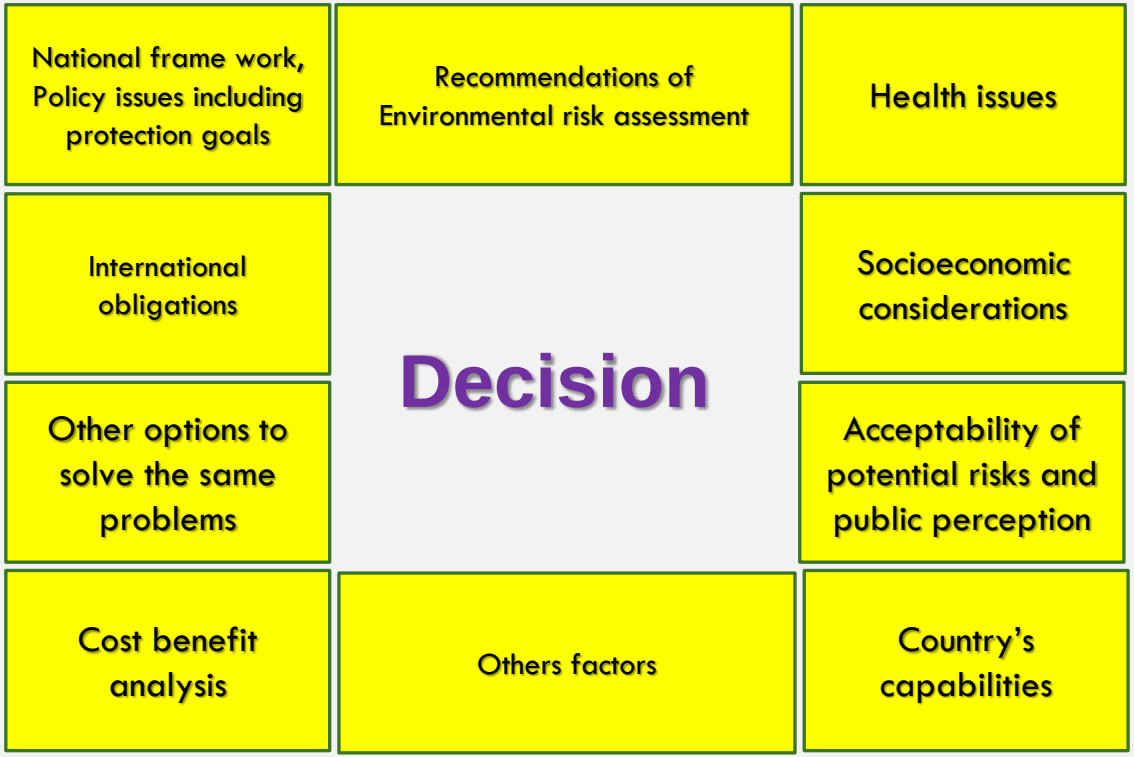
- Risk characterization
- Integration of likelihood and consequence of each of the individual risks identified through the preceding steps, and takes into account any relevant uncertainty that emerged, this far, during the process.
- The outcome of this step is the assessment of the overall risk of the LMO.

STEP 5.

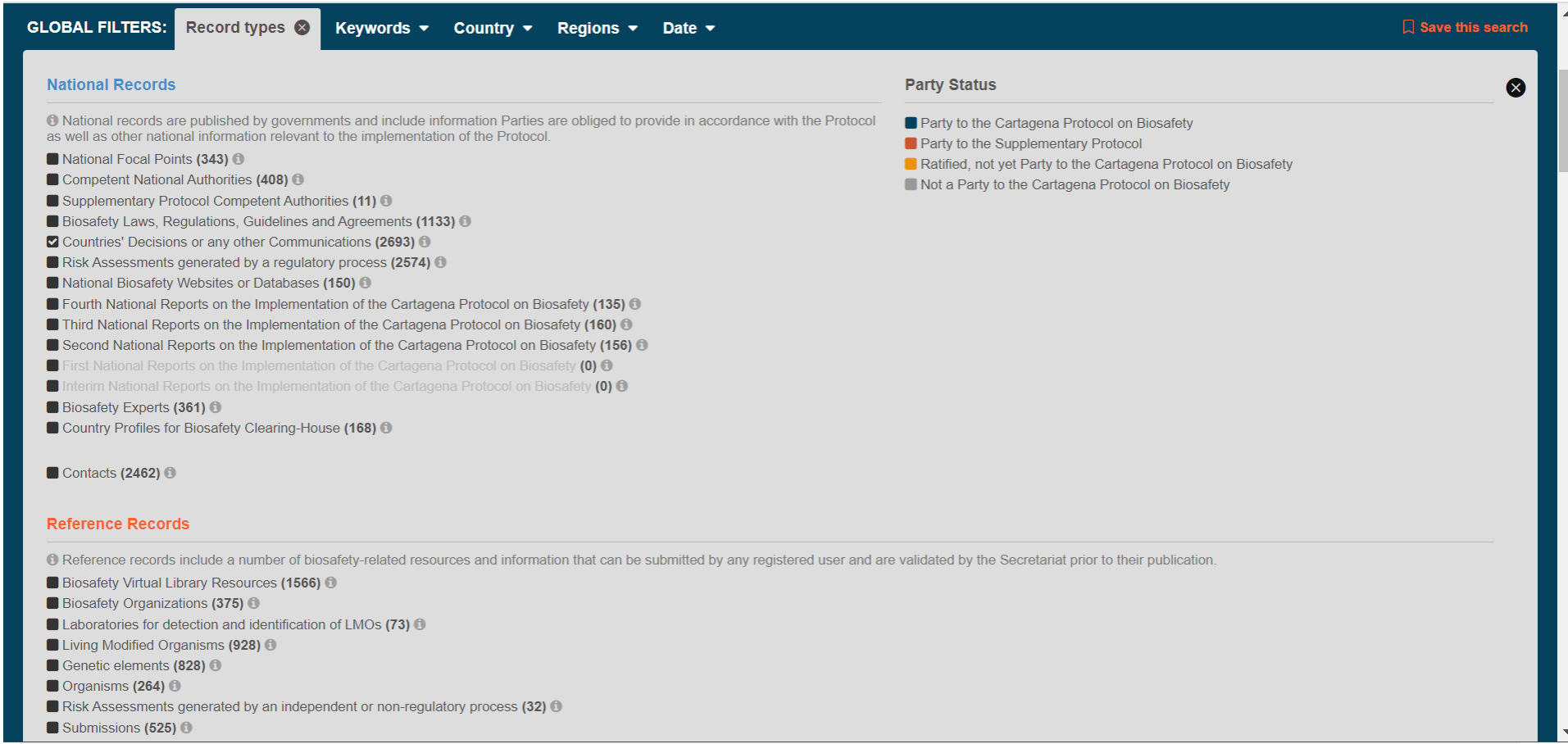
- Identification of Risk management or monitoring strategies
  - Risk Management: Measures to increase confidence when dealing with uncertainty or to the reduce likelihood or impact of the potential adverse effect to a level that is acceptable when the risk has been identified (Mitigation and preventive measures)
  - Monitoring: Aims at detecting changes (e.g. in the receiving environment(s) or in the LMO) after the release of the LMO. It can designed on the basis of the protection goals identified by national legislation and regulation, if available, and those parameters relevant to the indication of any increasing risk to the assessment endpoints. The strategies include "general surveillance" and "case-specific monitoring".

LMOS AND THEIR PRODUCTS

DECISION MAKING

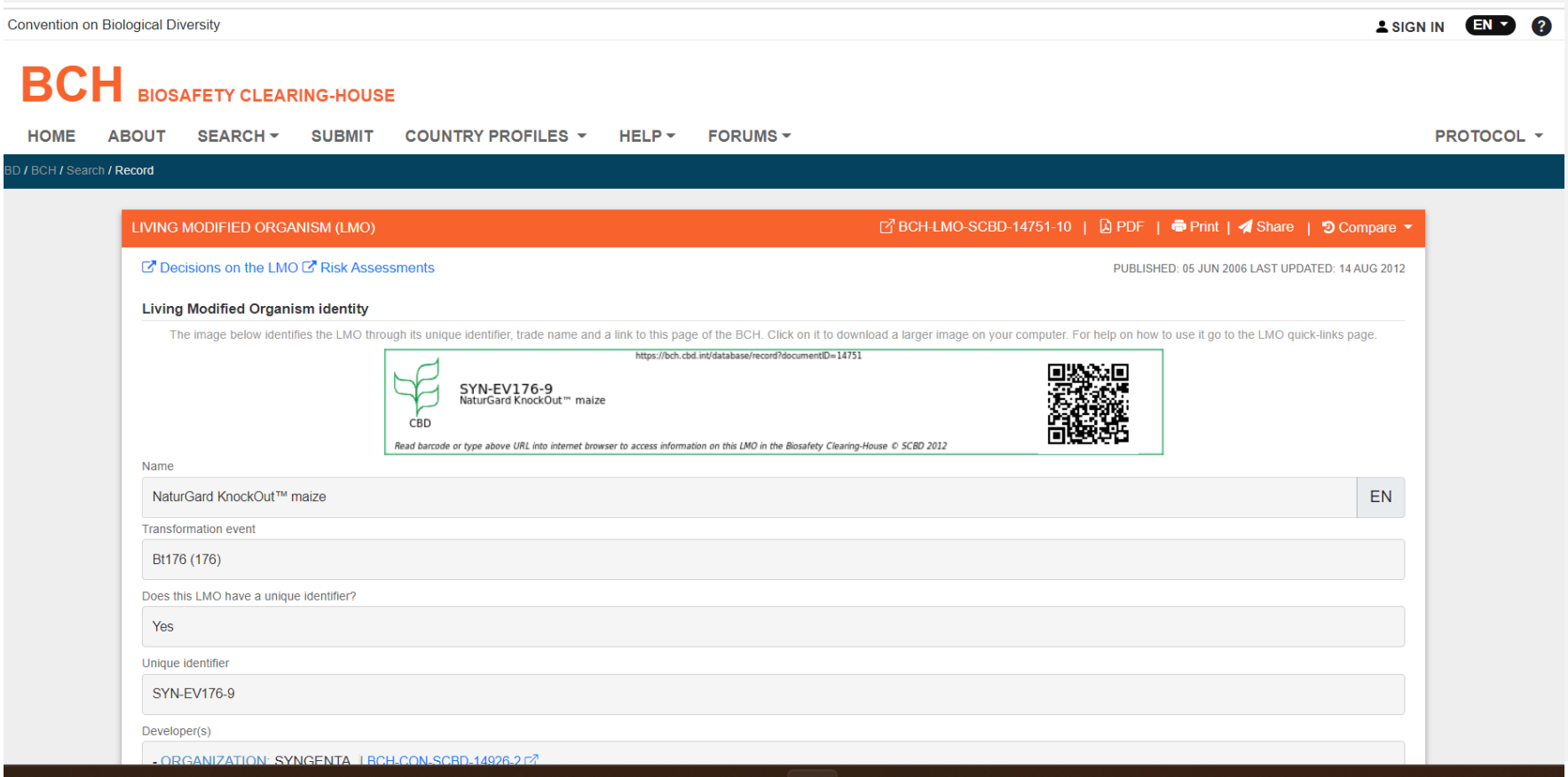


HOW TO ACCESS DECISIONS ON THE BCH



HOW TO ACCESS DECISIONS ON THE BCH

https://bch.cbd.int/en/database/record?documentID=14751



Thank you !

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