# Rejestry GMO - gdzie szukać informacji o GMO autoryzowanych i nieautoryzowanych w UE

Dr Anna Linkiewicz
Laboratorium Kontroli GMO, IHAR-PIB Radzików
Szkolenie 21.10.22

# Problemy analiz GMO

- Coraz więcej odmian transgenicznych,
- Złożoność konstruktów,
- Stacked events,
- Problem screeningu –standard lat 2000 czyli 35s/nos już nie wystarcza,
- Nieautoryzowane GMO,
- Nowe GMO powstałe z zastosowaniem Nowych technik genomowych (TALEN, CRISPR).

# Gdzie szukać informacji o GMO?

- ✓REJESTRY

# Rejestry i bazy danych GMO

- Rejestr Komisji Europejskiej (rozp. 1829/2003) ok 100 pozycji- https://ec.europa.eu/food/plant/gmo/eu_register_en
- Baza danych BCH ponad 700 pozycji (LMO) - http://bch.cbd.int/database
- Baza danych ISAAA ponad 400 pozycji - http://www.isaaa.org/gmapprovaldatabase/default.asp
- Baza danych EUGINIUS ponad 700 pozycji - http://www.euginius.eu
- Baza danych EURL-GMFF ok 200 pozycji - https://gmo-crl.jrc.ec.europa.eu/gmomethods/

Portal RASFF - https://ec.europa.eu/food/safety/rasff_en

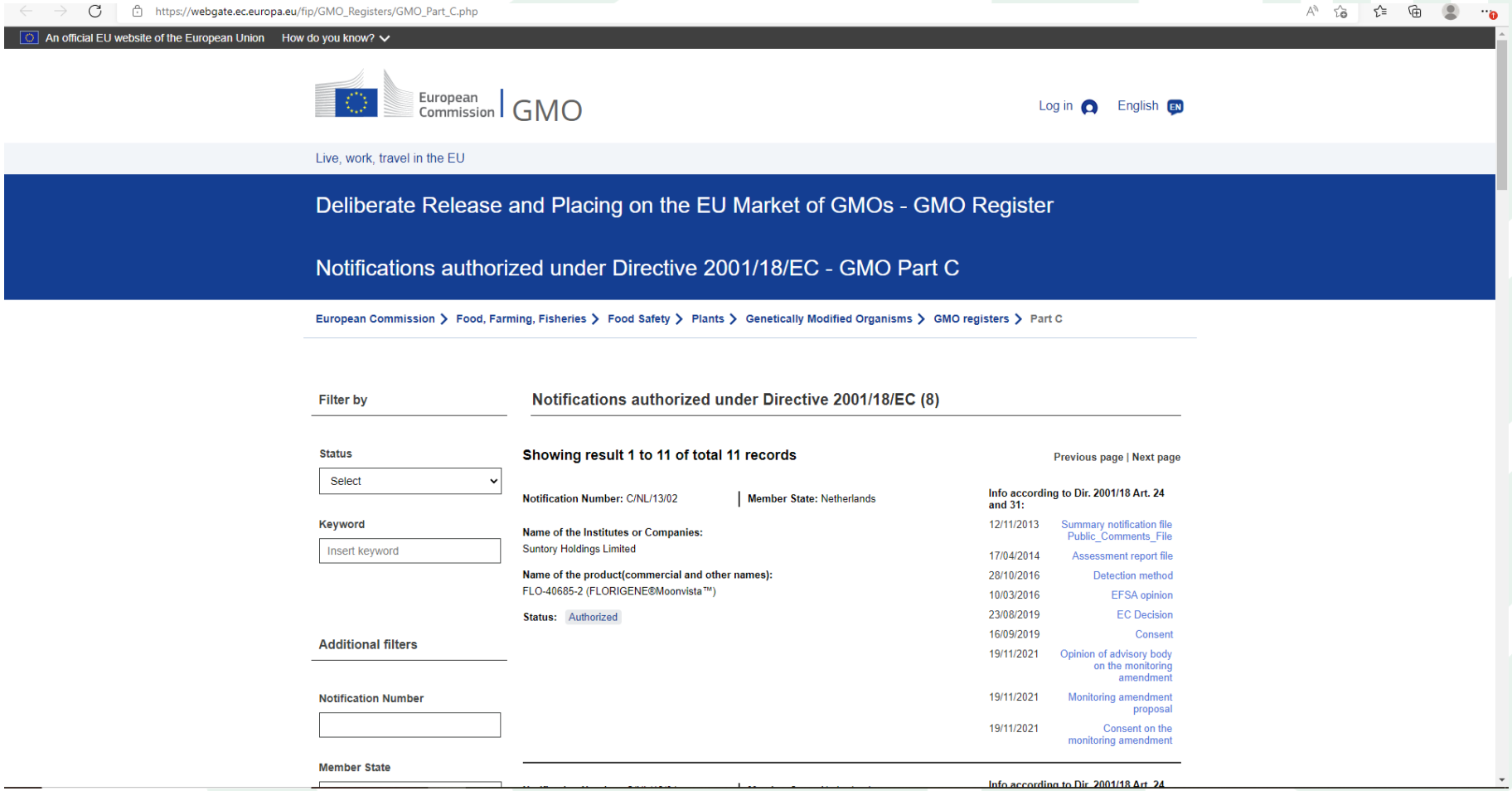
EFSA Panel GMO - http://www.efsa.europa.eu/en/panels/gmo?wtrl=01

# Rejestry Ministra Klimatu i Środowiska

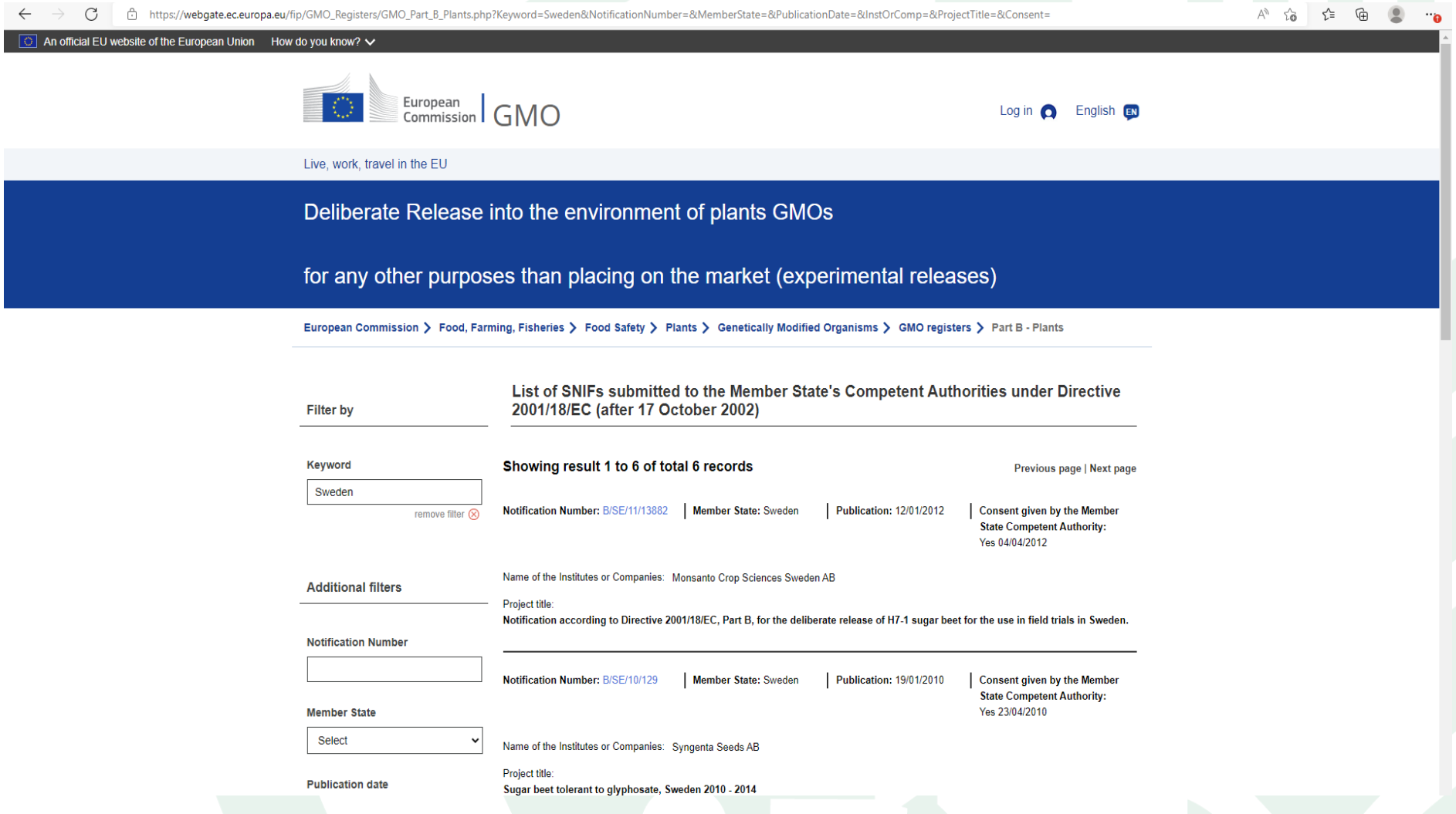
- Zgodnie z art. 34, 40, 50, 56 ustawy z dnia 22 czerwca 2001 r. o organizmach genetycznie zmodyfikowanych (Dz. U. 76, poz. 811, Minister Środowiska ma obowiązek prowadzić publiczne rejestry GMO: zamkniętego użycia GMO, zamierzonego uwolnienia GMO do środowiska, produktów GMO oraz wywozu za granicę i tranzytu przez terytorium Rzeczypospolitej Polskiej produktów GMO.
- **Rejestr Zamkniętego Użycia GMO**, zawiera wnioski o wydanie zgody na zamknięte użycie GMO wraz z dokumentacją, powiadomienia o ponownym zamkniętym użyciu GMO, zgody na zamknięte użycie GMO wraz z uzasadnieniami oraz informacje o cofnięciu i zmianie tej zgody, opinie Komisji, informacje o awariach.
- **Rejestr Zamierzonego Uwalniania GMO** do Środowiska, zawiera wnioski o wydanie zgody na zamierzone uwolnienie GMO do środowiska wraz z dokumentacją, zgody na zamierzone uwolnienie GMO do środowiska wraz z uzasadnieniami oraz informacje o cofnięciu i zmianie tej zgody, opinie Komisji, sprawozdania z przeprowadzonych działań.
- **Rejestr Produktów GMO:** wnioski o wydanie zezwolenia na wprowadzenie do obrotu produktu GMO wraz z dokumentacją, zezwolenia na wprowadzenie do obrotu produktu GMO wraz z uzasadnieniami oraz informacje o cofnięciu lub zmianach tych zezwoleń, decyzje w sprawie zakazu lub ograniczenia obrotu handlowego produktem GMO wraz z uzasadnieniem, opinie Komisji, informacje o zagrożeniach dla zdrowia ludzi lub dla środowiska i podjętych działaniach interwencyjnych jeśli okażą się konieczne dla zapewnienia bezpieczeństwa ludzi i środowiska. Od 2004 roku zgody na wprowadzenie produktu GMO do obrotu wydaje Komisja Europejska, dlatego nie prowadzone są krajowe rejestry wprowadzenia do obrotu GMO.

- **Rejestr Wywozu za Granicę i Tranzytu przez terytorium Rzeczypospolitej Polskiej produktów GMO** wnioski o wydanie zezwoleń na wywóz za granicę produktów GMO z dokumentacją, wnioski o wydanie zezwoleń na tranzyt przez terytorium Rzeczypospolitej Polskiej produktów GMO z dokumentacją, zezwolenia na wywóz za granicę wraz z uzasadnieniami, zezwolenia na tranzyt przez terytorium Rzeczypospolitej Polskiej produktów GMO wraz z uzasadnieniami, opinie Komisji.
- Rejestry są bezpłatne i publicznie dostępne na stronie www Ministerstwa Klimatu i Środowiska. Rejestry dotyczące GMO i GMM zostały przygotowane i są prowadzone przez Zespół ds. GMO w Departamencie Ochrony Przyrody MS.

# Rejestr autoryzacji GMO zgodnie z Dyrektywą 2001/18 WE



# Rejestr autoryzacji GMO zgodnie z Dyrektywą 2001/18 WE – uwolnienia eksperymentalne



# Rozporządzenie (WE) NR 1829/2003 Parlamentu Europejskiego i Rady z dnia 22 września 2003 r. w sprawie genetycznie zmodyfikowanej żywności i paszy

- Należy ustanowić rejestr genetycznie zmodyfikowanej żywności i paszy zatwierdzony na postawie niniejszego rozporządzenia i obejmujący dane szczegółowe produktu, badania wykazujące jego bezpieczeństwo w tym, jeżeli dostępne, odniesienia do niezależnych i sprawdzonych badań, a także metod pobierania próbek, identyfikacji i wykrywania. Dane inne niż poufne powinny być publicznie dostępne.

- Artykuł 28

  Rejestr wspólnotowy

1. Komisja ustanawia i prowadzi wspólnotowy rejestr genetycznie zmodyfikowanej żywności i paszy, zwany dalej „rejestrem”.
2. Rejestr udostępnia się publicznie.

# Rejestr zgodny z rozporządzeniem 1829/2003
# https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm

ı/dyna/gm_register/index_en.cfm

Search the register for products containing GMOs e.g. if you type 'cotton', you will get a list of all products containing cotton in their description..

This search covers the Community register of GM food and feed (Regulation EC 1829/2003) and the products subject to EC decisions on withdrawal from the market.

Keyword(s) : MON810

Registered / Withdrawn : All

Category : Please select a category

Reset search | Search

Search conducted on → **Status** : *All* - **Keyword**: *MON810*

# Community register of GM food and feed

## Genetically modified maize

| Transformation event<br>Unique ID<br>Company | Genes Introduced / Characteristics | Authorized use | Authorization Expiration Date | Details |
|---|---|---|---|---|
| **Maize (MON810)**<br>**MON-ØØ81Ø-6**<br>[ **Monsanto** ] | Genetically modified maize that contains:<br>**cry1A (b)** gene inserted to confer resistance to lepidopteran pests | Foods and food ingredients produced from MON810 (including food additives) | 03/07/2027 | |
| | | Pollen produced from MON810 maize | 5/11/2023 | |
| | | Feed containing or consisting of MON810 maize | 03/07/2027 | |
| | | Feed produced from MON810 maize (feed materials feed additives) | 03/07/2027 | |
| | | Seeds for cultivation | Renewal of authorisation ongoing | |
| **Maize (NK603 x MON810)**<br>**MON-ØØ6Ø3-6 x MON-ØØ81Ø-6**<br>[ **Monsanto** ] | Genetically modified maize that contains:<br>**cp4 epsps** gene inserted to confer tolerance to glyphosate herbicides and<br>the **cry1Ab** gene inserted to confer protection against certain lepidopteran insect pests (Ostrinia nubilalis, Sesamia spp.) | Foods and food ingredients containing, consisting of, or produced from MON-ØØ6Ø3-6xMON-ØØ81Ø-6 maize (including food additives) | 18/12/2028 | |
| | | Feed containing, consisting of, or produced from MON-ØØ6Ø3-6xMON-ØØ81Ø-6 maize (feed materials and feed additives) | | |

# Genetically Modified Organisms

## MON-ØØ81Ø-6

**EU register of genetically modified food and feed.**

| | |
|---|---|
| **Event** | MON810 |
| **Authorisation holder Name** | Bayer Agriculture BVBA |
| **Authorisation holder Address** | Bayer Agriculture BVBA<br>Scheldelaan 460<br>2040 Antwerp - BELGIUM |
| **Products** | (1) Foods and food ingredients produced from MON-ØØ81Ø-6 maize, including pollen;<br>(2) Feed containing, consisting of or produced from MON-ØØ81Ø-6 maize;<br>(3) MON-ØØ81Ø-6 maize in products containing it or consisting of it for any other use than food or feed or cultivation.<br>(4) MON-ØØ81Ø-6 maize seeds for cultivation |
| **Designation** | The genetically modified MON-ØØ81Ø-6 maize as described in the applications expresses the Cry1Ab protein, derived from Bacillus thuringiensis subsp. kurstaki, which confers protection against predation by certain lepidopteran insect pests, including the European corn borer (Ostrinia nubilalis) and pink borers (Sesamia spp.). |
| **Labelling** | Article 13(1) and 25(1) of Regulation (EC) No 1829/2003<br>Article 4(6) of Regulation (EC) No 1830/2003 |

https://webgate.ec.europa.eu/dyna/gm_register/gm_register_auth.cfm?pr_id=11

| | |
|---|---|
| **Method for detection** | Event specific Real-time PCR method for the quantification of genetically modified MON-ØØ81Ø-6 maize Validated on ground maize seeds (certified reference materials [CRM IRMM-413]), containing mixtures of genetically modified MON 810 and conventional maize, by the Federal Institute for Risk Assessment (BfR) in collaboration with the American Association of Cereal Chemists (AACC), Joint Research Centre (JRC) of the European Commission (EC) (Institute for Reference Material and Measurement (IRMM), Institute for Health and Consumer Protection (IHCP)), and GeneScan, Berlin, published at http://gmo-crl.jrc.ec.europa.eu/summaries/Mon810_validation_report.pdf |
| **Reference material** | Reference Material: ERM-BF413k accessible via the Joint Research Centre (JRC) of the European Commission, the Institute for Reference Materials and Measurements (IRMM) at http://www.irmm.jrc.be/html/reference_materials_catalogue/index.htm |
| **Unique identifier** | MON-ØØ81Ø-6 |
| **Annex II to the Cartagena Protocol** | Biosafety Clearing House<br>http://bch.cbd.int/database/record.shtml?documentid=101792<br>Maize MON810 pollen: http://bch.cbd.int/database/record.shtml?documentid=112243<br>Maize MON810 for food and feed: http://bch.cbd.int/database/record.shtml?documentid=112245 |
| **Conditions or restrictions on the placing on the market** | Cultivation prohibited in the following territories: (cf the list in Annex to the Decision)" |
| **Monitoring plan** | Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC |
| **Dates of authorisation** | 03/08/1998: seeds for cultivation<br>06/11/2013: pollen produced from MON810 maize<br>04/07/2017: foods and food ingredients produced from MON810; feed containing or consisting of MON810 maize; renewal of feed produced from MON810 maize (feed materials feed additives); |

https://webgate.ec.europa.eu/dyna/gm_register/gm_register_auth.cfm?pr_id=11

| | |
|---|---|
| **Legal base** | **Food produced from and feed containing, consisting of or produced from MON810 maize:**<br><br>Commission Implementing Decision 2013/649/EU of 6 November 2013 (pollen only)<br>Amended by Commission Implementing Decision (EU) 2019/1579 of 18 September 2019<br>Commission Implementing Decision 2017/1207/EU of 4 July 2017<br>Amended by Commission Implementing Decision (EU) 2019/1579 of 18 September 2019<br><br>**Seeds for cultivation**<br>Commission Decision 98/294/EC of 22 April 1998 concerning the placing on the market of genetically modified maize (Zea mays L. line MON 810), pursuant to Council Directive 90/220/EEC* and consent granted by the French authorities on 3 August 1998 (Journal Officiel de la République Française, 5 August 1998).<br>Commission Implementing Decision (EU) 2016/321 of 3 March 2016 adjusting the geographical scope of the authorisation for cultivation of genetically modified maize (Zea mays L.) MON 810 (MON-ØØ81Ø-6).<br><br>*products notified as existing products pursuant to Article 20 of Regulation (EC) No 1829/2003 |
| **Authorisation expiration dates** | 05/11/2023: Pollen produced from MON810 maize<br>03/07/2027: foods and food ingredients produced from MON810 (except pollen); feed containing, consisting or produced from MON810 maize<br>No expiration date as long as the renewal application is pending: MON 810 seeds for cultivation. |
| **Further information on risk assessment** | EFSA opinions:<br>http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2012-00988<br>http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2009-00656<br>http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2009-00657<br>http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2009-00658 |

https://webgate.ec.europa.eu/dyna/gm_register/gm_register_auth.cfm?pr_id=11

# Metoda detekcji

CRL-VL-25/04VR

EUROPEAN COMMISSION
DIRECTORATE GENERAL JRC
JOINT RESEARCH CENTRE
INSTITUTE FOR HEALTH AND CONSUMER PROTECTION
COMMUNITY REFERENCE LABORATORY FOR GM FOOD AND FEED

**CRL assessment on the validation of an event specific method for the relative quantitation of maize line MON 810 DNA using real-time PCR as carried out by Federal Institute for Risk Assessment (BfR)**

**Biotechnology & GMOs Unit**
**Institute for Health and Consumer Protection**
**DG Joint Research Centre**

**10 March 2006**

**Executive Summary**

An event-specific method for the quantitation of maize MON 810 by means of real-time PCR has been validated in a collaborative trial by the Federal Institute for Risk Assessment (BfR) in collaboration with the American Association of Cereal Chemists (AACC), Joint Research Centre (JRC) of the European Commission (EC), Institute for Reference Material and Measurement (IRMM), the Institute for Health and Consumer Protection (IHCP) and GeneScan, Berlin.

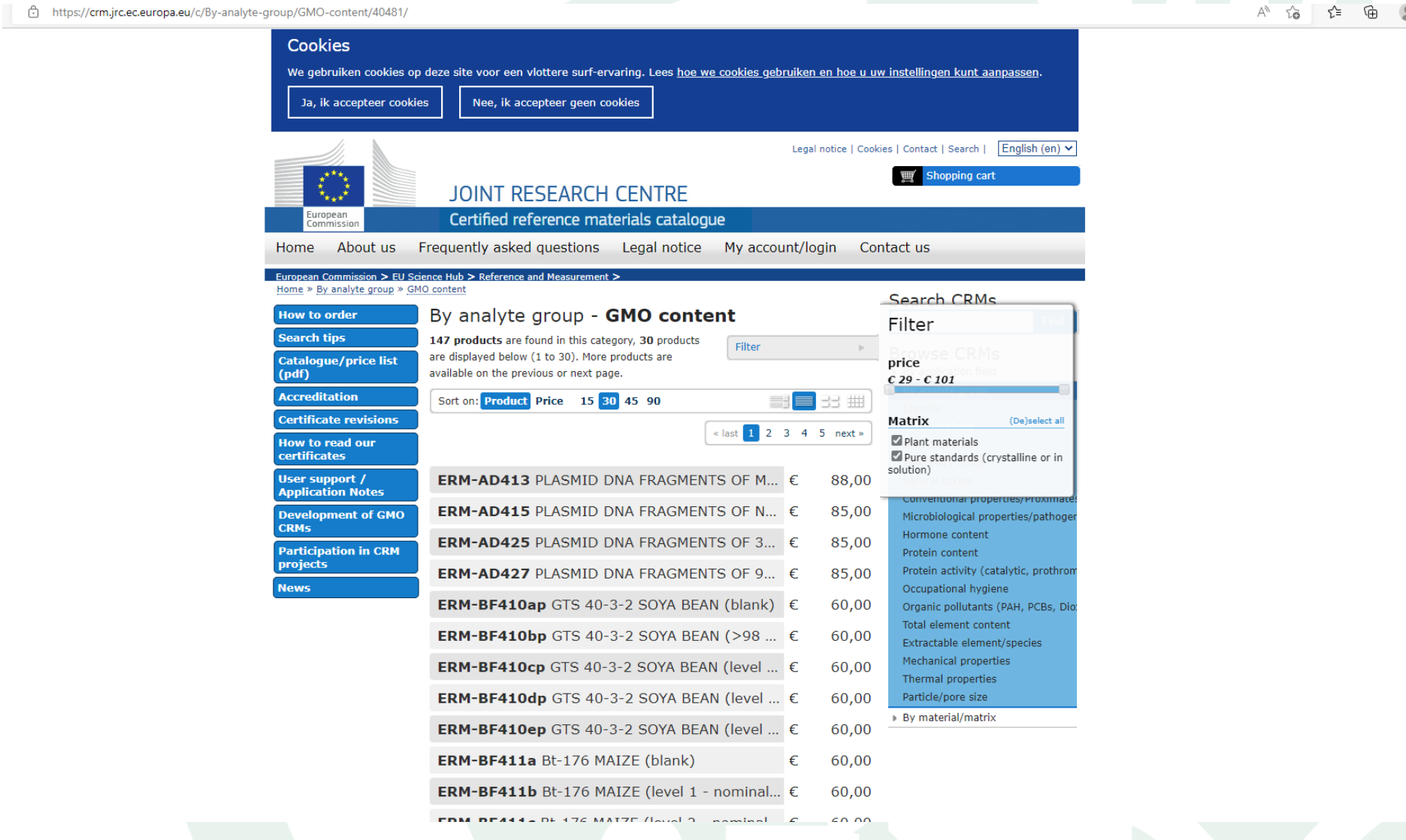
The trial involved fifteen laboratories and was conducted according to internationally accepted guidelines.

The method is annexed to the standard ISO 21570:2005, "Foodstuffs -- Methods of analysis for the detection of genetically modified organisms and derived products -- Quantitative nucleic acid based methods".



# CRM

# Rejestr CRM


https://crm.jrc.ec.europa.eu/c/By-analyte-group/GMO-content/40481/
Cookies
We gebruiken cookies op deze site voor een vlottere surf-ervaring. Lees hoe we cookies gebruiken en hoe u uw instellingen kunt aanpassen.
Ja, ik accepteer cookies
Nee, ik accepteer geen cookies
Legal notice | Cookies | Contact | Search | English (en)
Shopping cart
JOINT RESEARCH CENTRE
Certified reference materials catalogue
Home About us Frequently asked questions Legal notice My account/login Contact us
European Commission > EU Science Hub > Reference and Measurement >
Home » By analyte group » GMO content
How to order
Search tips
Catalogue/price list (pdf)
Accreditation
Certificate revisions
How to read our certificates
User support / Application Notes
Development of GMO CRMs
Participation in CRM projects
News
By analyte group - GMO content
147 products are found in this category, 30 products are displayed below (1 to 30). More products are available on the previous or next page.
Filter
Sort on: Product Price 15 30 45 90
« last 1 2 3 4 5 next »
ERM-AD413 PLASMID DNA FRAGMENTS OF M... € 88,00
ERM-AD415 PLASMID DNA FRAGMENTS OF N... € 85,00
ERM-AD425 PLASMID DNA FRAGMENTS OF 3... € 85,00
ERM-AD427 PLASMID DNA FRAGMENTS OF 9... € 85,00
ERM-BF410ap GTS 40-3-2 SOYA BEAN (blank) € 60,00
ERM-BF410bp GTS 40-3-2 SOYA BEAN (>98 ... € 60,00
ERM-BF410cp GTS 40-3-2 SOYA BEAN (level ... € 60,00
ERM-BF410dp GTS 40-3-2 SOYA BEAN (level ... € 60,00
ERM-BF410ep GTS 40-3-2 SOYA BEAN (level ... € 60,00
ERM-BF411a Bt-176 MAIZE (blank) € 60,00
ERM-BF411b Bt-176 MAIZE (level 1 - nominal... € 60,00
Search CRMs
Filter
price
€ 29 - € 101
Matrix
(De)select all
Plant materials
Pure standards (crystalline or in solution)
Microbiological properties/pathoger
Hormone content
Protein content
Protein activity (catalytic, prothrom
Occupational hygiene
Organic pollutants (PAH, PCBs, Dio
Total element content
Extractable element/species
Mechanical properties
Thermal properties
Particle/pore size
By material/matrix

# CRM – MON810

Shopping cart

European Commission

JOINT RESEARCH CENTRE

Certified reference materials catalogue

Home | Frequently asked questions | Legal notice | My account/login | Contact us

European Commission > JRC Science Hub > Knowledge>Reference and Measurement > Reference Materials

Home

How to order
Search tips
Catalogue/price list (pdf)
Accreditation
How to read our certificates
User support / Application Notes
News

## Search CRMs

Your search for "**mon810**" did result in **9 product(s)**

Filter

Sort on: Product Price 15 30 45 90

| | | |
|---|---|---|
| **ERM-AD413** PLASMID DNA FRAGMENTS OF M... | € | 86,00 |
| **ERM-BF413ak** MON 810 MAIZE (blank) | € | 60,00 |
| **ERM-BF413ck** MON 810 MAIZE (level 1 - nom... | € | 60,00 |
| **ERM-BF413ek** MON 810 MAIZE (level 2 - nom... | € | 98,00 |
| **ERM-BF413gk** MON 810 MAIZE (level 3 - no... | € | 60,00 |
| **ERM-BF415e** NK603 MAIZE (level 4 - nominal... | € | 98,00 |
| **ERM-BF417b** MON 863 x MON 810 MAIZE (le... | € | 69,00 |
| **ERM-BF417c** MON 863 x MON 810 MAIZE (lev... | € | 69,00 |
| **ERM-BF417d** MON 863 x MON 810 MAIZE (le... | € | 69,00 |

Search CRMs

mon810 Find

How to order
Search tips
Catalogue/price list (pdf)
Accreditation
How to read our certificates
User support / Application Notes
News

**ERM-BF413ek MON 810 MAIZE (level 2 - nominal 2 % GMO), additional certification of DNA copy number ratio**

Article in stock

Put in shopping cart

GMO content

**EUR 98,00**


Downloads for this reference material

Certificate ERM-BF413ek_cert.pdf
Certification report ERM-BF413k_report.pdf
Origin certificate ERM-BF413k_origin.pdf

Product information

| | |
|---|---|
| CRM code | **ERM-BF413ek** |
| Description on the invoice | **MON 810 MAIZE (level 2 - nominal 2% GMO)** |
| Sales unit | **vial** |
| Net mass | **1** |
| Gross mass | **26** |
| Mass unit | **Gram (g)** |
| Storage temperature | **+4 °C** |
| Remark | Subject to Intellectual Property Rights limitations - See instructions for use on the certificate |

Latest update: 4/11/2019 | Cookies | Legal notice | Contact | Top

# CRM – MON810

JOINT RESEARCH CENTRE
Directorate F – Health, Consumers and Reference Materials

## CERTIFICATE OF ANALYSIS

### ERM®- BF413ek

| MAIZE SEED POWDER | | |
|---|---|---|
| | Certified value | Uncertainty [5] |
| MON 810 maize mass fraction [1] | 19.8 g/kg [2] | 1.5 g/kg |
| MON 810 maize DNA copy number ratio [3] | 0.77 % [4] | 0.08 % |

1) Mass fraction of MON 810 maize (unique identifier code MON-ØØ81Ø-6) based on the masses of genetically modified MON 810 maize powder and non-modified maize powder and their respective water content.
2) The certified value is traceable to the International System of Units (SI).
3) Copy number ratio of MON 810 maize (unique identifier code MON-ØØ81Ø-6) as defined by the real-time Polymerase Chain Reaction detection method ISO 21570:2005, Annex D2, calibrated with the plasmid DNA Certified Reference Material ERM®-AD413.
4) The certified value is the unweighted mean of 17 accepted data sets, independently obtained from 11 laboratories. The value is traceable to the International System of Units (SI).
5) The certified uncertainty is the expanded uncertainty estimated in accordance with the Guide to the Expression of Uncertainty in Measurement (GUM) with a coverage factor $k = 2$, corresponding to a level of confidence of about 95 %.

This certificate is valid for one year after purchase.

Sales date:

The minimum amount of sample to be used is 100 mg.

Accepted as an ERM®, Geel, August 2009
Latest Revision: November 2018

Signed: D. Flo

Dr Doris Florian
Head of Unit Reference Materials
European Commission, Joint Research Centre
Directorate F – Health, Consumers and Reference Materials
Retieseweg 111
B-2440 Geel, Belgium

Registration No. 268-TEST
ISO Guide 34 for the production of reference materials

All following pages are an integral part of the certificate.
Page 1 of 2

## CERTIFICATION REPORT

### Certification of Reference Materials of Maize Seed Powder containing Genetically Modified MON 810 Maize

### Certified Reference Materials ERM®-BF413k (ERM®-BF413ak, ERM®-BF413ck, ERM®-BF413ek, ERM®-BF413gk)

JRC
EUROPEAN COMMISSION

EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Reference Materials and Measurements (Geel)
**Standards for Innovation and sustainable Development**

Geel, 2 May 2013

**ERM-BF413K SERIES**

**DECLARATION OF CONFORMITY AND ORIGIN:**

**To whom it may concern**

This is to certify that the certified reference materials ERM-BF413ak, ck, ek and gk:

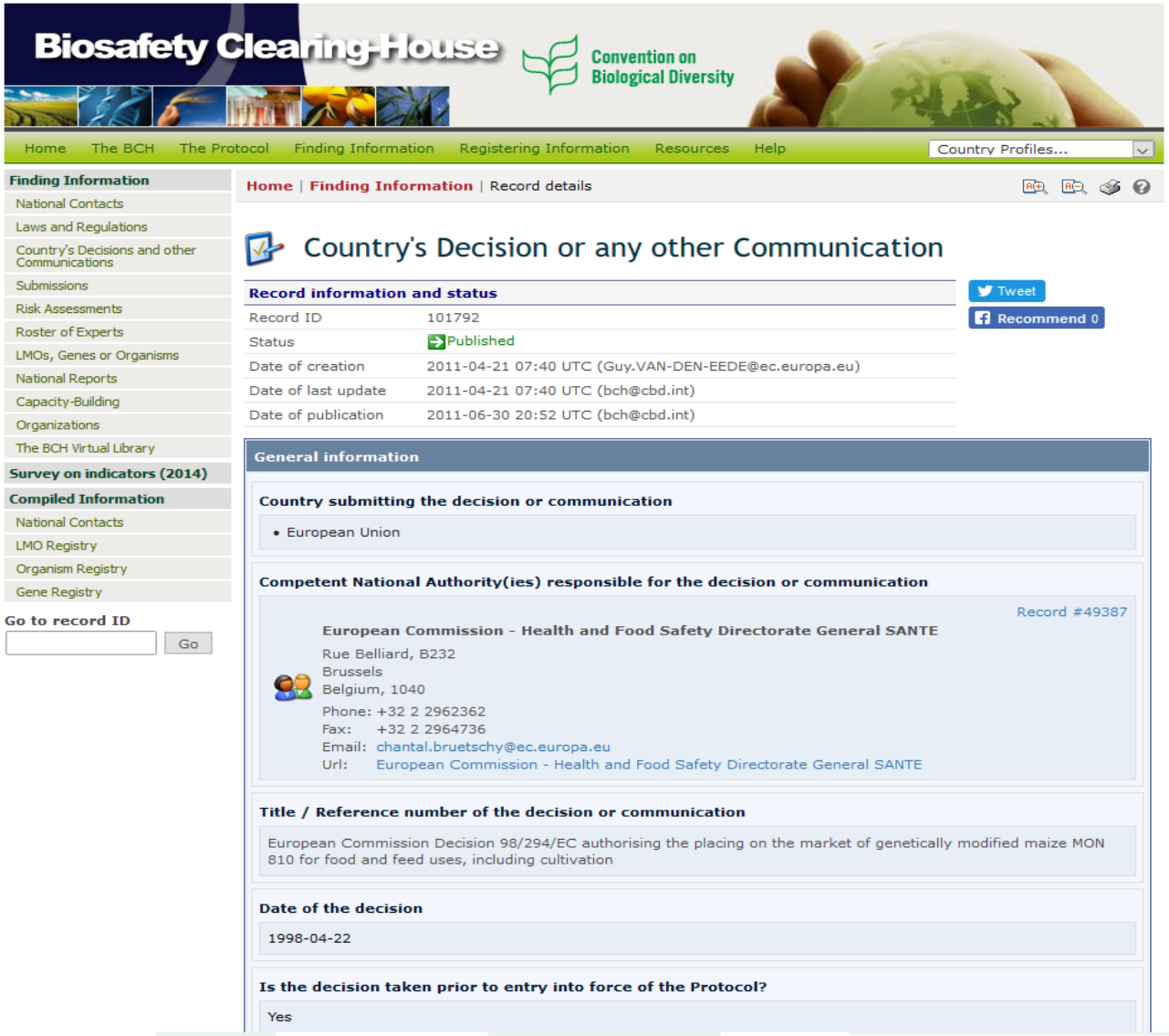
- Are maize seed powders prepared from maize seeds supplied by Monsanto Company, St Louis, Missouri (see attached document).
- Are of the two varieties DKC57-84 (MON 810 GLP-0403-14800-S) and EXP258B (conventional corn GLP040214688S) (see attached document).
- Are vacuum-dried, highly processed powders processed at the premises of IRMM. Processing was carried out under conditions avoiding any cross contamination.

Based on the available information and knowledge any infectious danger resulting from an exposure to the material can be excluded.

Prof. Dr. Hendrik Emons
Head of Unit

Retieseweg 111, B-2440 Geel - Belgium. Telephone: (32-14) 571 211. http://irmm.jrc.ec.europa.eu
Telephone: direct line (32-14) +32-(0)-14-571 722. Fax: (32-14) +32-(0)-14-571 548.

E-mail: hendrik.emons@ec.europa.eu




http://bch.cbd.int/database/record.shtml?documentid=101792

**Is this an amendment to a previous decision / communication?**

No

**Decision or communication details**

**Subject(s) of the decision**

- Decision on LMOs for direct use as food or feed, or for processing (Article 11, LMOs-FFPs)
  - Decision on domestic use of an LMO, including its placing on the market
- Decision on LMOs for intentional introduction into the environment (according Article 10 or domestic regulatory framework)

**Uses of the LMO(s)**

- LMOs for direct use as food
- LMOs for direct use as feed
- LMOs for processing

**Has the decision been taken in the absence of a domestic regulatory framework and in accordance with Article 11.6?**

No

**Was the decision triggered by a request for a transboundary movement of LMOs into the country?**

No

**Does the decision apply to transboundary movements of LMO(s) into the country?**

Yes

http://bch.cbd.int/database/record.shtml?documentid=101792

**Importer's or Applicant's contact details**

Record #43679

**Monsanto Europe S.A.**
Avenue de Tervuren 270-272
Brussels
Belgium, B-1150

**Result of the decision**

- Approval of the import/use of the LMO(s) without conditions

**Does the decision involve field trials?**

No

**Does the decision involve commercial release?**

Yes

**LMO identification**

**MON-ØØ81Ø-6 - YieldGard™ maize** Record #14750
Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths)
Show detection method(s)

**Risk assessment**

**European Food Safety Authority (EFSA) opinion on the safety of genetically modified insect resistant maize MON810 for food and feed uses, including seeds for cultivation** Record #101791
MON-ØØ81Ø-6 - YieldGard™ maize
Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths)

http://bch.cbd.int/database/record.shtml?documentid=101792

## Decision document

**Decision document**

eu authorisation cultivation feed maize mon810 decision 98-294-ec.pdf

EU GM Food Feed Register

## Additional Information

**Additional Information**

Detection Method validated by the European Union Reference Laboratory for GM Food and Feed (EURL GMFF)

**Other relevant website address or attached documents**

eu detection method maize mon810.pdf

European Union Reference Laboratory for GM Food and Feed (EURL GMFF)

http://bch.cbd.int/database/record.shtml?documentid=101792

# Modified Organism

## MON-ØØ81Ø-6 - YieldGard™ maize

LMO Information | Decisions on the LMO | Risk Assessments

Tweet

Recommend 2

**Record information and status**

| | |
|---|---|
| Record ID | 14750 |
| Status | Published |
| Date of creation | 2006-06-05 14:39 UTC (kirsty.mclean.consultant@cbd.int) |
| Date of last update | 2013-05-24 18:43 UTC (dina.abdelhakim@cbd.int) |
| Date of publication | 2013-05-24 18:43 UTC (dina.abdelhakim@cbd.int) |

**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.*

CBD

MON-ØØ81Ø-6
YieldGard™ maize

http://bch.cbd.int/database/record.shtml?documentid=14750

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

**LMO name**

YieldGard™ maize

**Transformation event**

MON810

http://bch.cbd.int/database/record.shtml?documentid=14750

**Unique identifier**

MON-ØØ81Ø-6

**Developer(s)**

Record #14925

**Monsanto**

800 North Lindbergh Blvd.
St. Louis, MO
United States of America, 63167

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

**Description**

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

**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.

**Zea mays - Maize, Corn, MAIZE** Record #246

**Related LMOs**

**PH-MON8Ø9-2 - Insect-resistant maize MON809** Record #14779

Resistance to antibiotics - Kanamycin Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths) Resistance to herbicides - Glyphosate

**Insect Resistant Maize MON801** Record #15410

Resistance to antibiotics - Kanamycin Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths) Resistance to herbicides - Glyphosate

http://bch.cbd.int/database/record.shtml?documentid=14750

## Characteristics of the transformation process

**Vector**

PV-ZMBK07 and PV-ZMGT10

**Techniques used for the modification**

- Biolistic / Particle gun

**Genetic elements construct**

| CaMV Enhanced 35S promoter | Hsp70 intron | Cry1Ab |
|---|---|---|
| #100366 | #100359 | #14985 |
| 0.61 Kb | 0.80 Kb | 3.46 Kb |

Further details

**Notes regarding the genetic elements introduced or modified in this LMO**

The transgenic maize line MON810 was genetically engineered to resist ECB by producing its own insecticide. This line was developed by introducing a synthetic version of the *cry1Ab* gene, isolated from the soil bacterium *Bacillus thuringiensis* (Bt) which was modified to enhance the expression of the Cry1Ab protein in plants, however the resulting amino acid sequence is identical to the native protein.

Molecular studies demonstrated that a single truncated copy of the *cryIAb* coding sequence was integrated into the corn genome along with the enhanced cauliflower mosaic virus 35S promoter (P-e35S), and the hsp 70 intron (I-Hsp70). The *nos* terminator was not integrated into MON810 due to a truncation of the 3' end of the gene cassette. Western analysis confirmed that a truncated Cry1Ab protein of approximately 91 kD (native Cry1Ab had a molecular weight of approximately 131 kD) was inserted into the genome.

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

Southern analysis confirms that the *nptII* gene (originally present in PVZMBK07 and PV-ZMGT10) is not present in MON 810.

http://bch.cbd.int/database/record.shtml?documentid=14750

**LMO characteristics**

**Modified traits**

- Resistance to diseases and pests
  - Insects
    - Lepidoptera (butterflies and moths)
      - European corn borer (Ostrinia nubilalis)

**Common use(s)**

- Food
- Feed
- Biofuel

**Detection method(s)**

**External link(s)**

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

MON-ØØ81Ø-6 - CropLife International Detection Methods Database

**Additional Information**

**Other relevant website address or attached documents**

MON810 - OECD Biotrack Product Database

MON810 - CERA GM Database

Safety Assessment of YieldGard Insect-Protected Corn Event MON 810

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

MON810 - Monsanto.pdf

http://bch.cbd.int/database/record.shtml?documentid=14750

**Records referencing this document (145)**

| ID | Description | |
|---|---|---|
| 145 record(s) found | | |
| | Country's Decision or any other Communication | 43 records |
| | Information Resource | 4 records |
| | Modified Organism | 27 records |
| | Organization | 37 records |
| | Risk Assessment | 34 records |

## Modified Organism

### MON-ØØ81Ø-6 - YieldGard™ maize

LMO Information | Decisions on the LMO | **Risk Assessments**

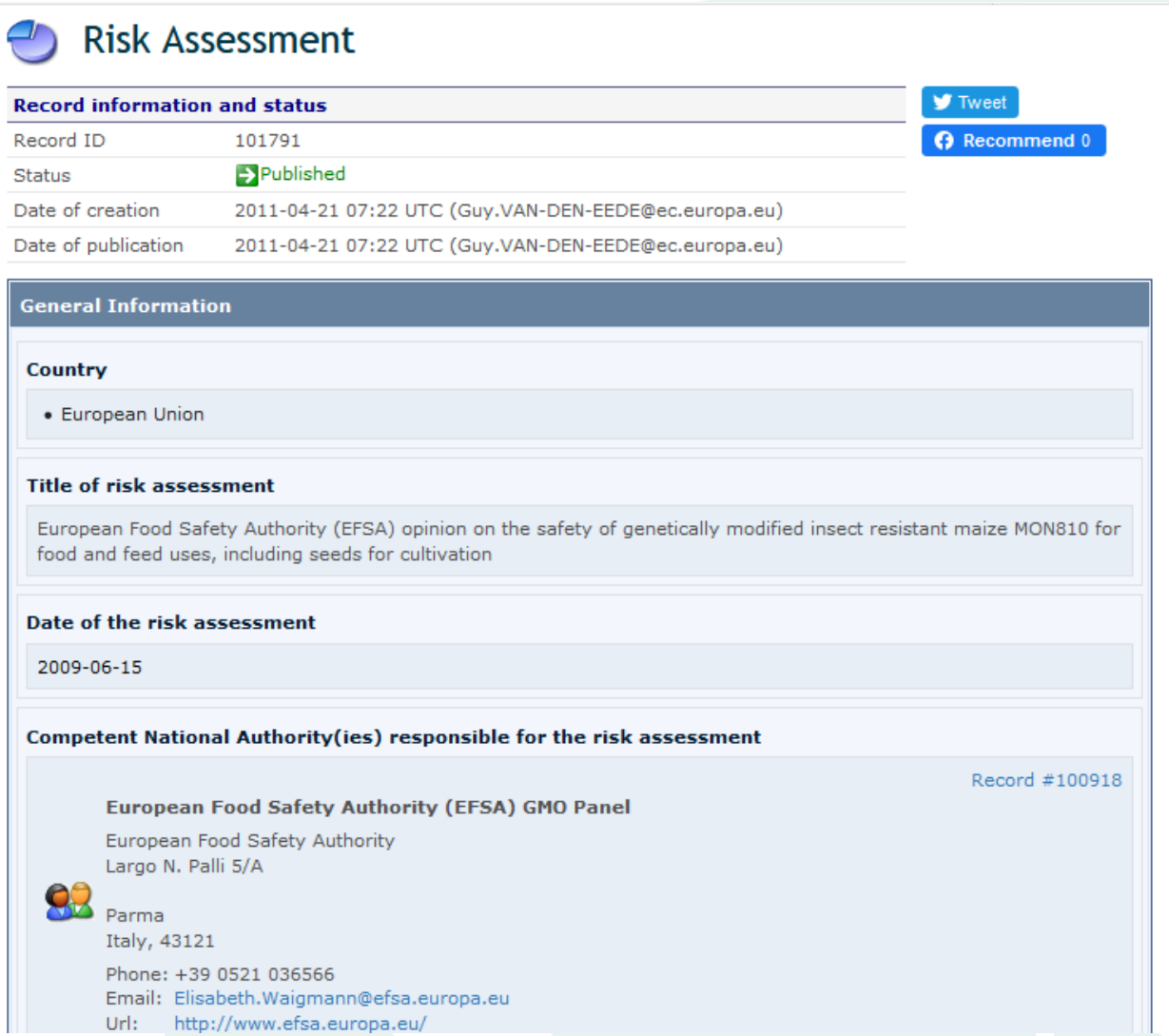
Tweet

Recommend 0

< Previous | 1 | 2 | Next >

| ID | Description | |
|---|---|---|
| 34 record(s) found | | |
| 101152 | **Austria** Risk assessment for GM maize line MON810 which may not be cultivated in Austria | MON-ØØ81Ø-6 Corn, MAIZE |
| 45581 | **Brazil** Risk Assessment for Insect Resistant Maize | MON-ØØ81Ø-6 Corn, MAIZE |
| 45439 | **Canada** Decision Document 97-19: Determination of the Safety of Monsanto Canada Inc.'s YieldgardTM Insect Resistant Corn (Zea mays L.) Line MON810 | MON-ØØ81Ø-6 Corn, MAIZE |

http://bch.cbd.int/database/record.shtml?documentid=14750



# Risk Assessment

Tweet

Recommend 0

| Record information and status | |
|---|---|
| Record ID | 101791 |
| Status | Published |
| Date of creation | 2011-04-21 07:22 UTC (Guy.VAN-DEN-EEDE@ec.europa.eu) |
| Date of publication | 2011-04-21 07:22 UTC (Guy.VAN-DEN-EEDE@ec.europa.eu) |

## General Information

**Country**

- European Union

**Title of risk assessment**

European Food Safety Authority (EFSA) opinion on the safety of genetically modified insect resistant maize MON810 for food and feed uses, including seeds for cultivation

**Date of the risk assessment**

2009-06-15

**Competent National Authority(ies) responsible for the risk assessment**

Record #100918

**European Food Safety Authority (EFSA) GMO Panel**

European Food Safety Authority
Largo N. Palli 5/A

Parma
Italy, 43121

Phone: +39 0521 036566
Email: Elisabeth.Waigmann@efsa.europa.eu
Url: http://www.efsa.europa.eu/

http://bch.cbd.int/database/record.shtml?documentid=101791

# Baza danych ISAAA


INTERNATIONAL SERVICE FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS

**GM Plants**

- Alfalfa
- Apple
- Argentine Canola
- Bean
- Carnation
- Chicory
- Cotton
- Cowpea
- Creeping Bentgrass
- Eggplant
- Eucalyptus
- Flax
- Maize
- Melon
- Papaya
- Petunia

## GM Approval Database

ISAAA presents an easy-to-use database of biotech/GM crop approvals for public use. It features the biotech/GM crop events that have been approved for commercialization/planting and importation (food and feed). Entries in the database represent the majority of the GM crop events approved worldwide, based on publicly available English (and translatable) decision documents of each approving country, Biosafety Clearing House of the Convention on Biological Diversity, and peer-reviewed scholarly articles. In using the database, please note that the approval of GM crops vary from country to country but all regulations are based on the same objective that each GM crop is safe for human or animal health and the environment. The database also includes discontinued events for recording purposes.

The GM Approval Database is one of the top sources of information on GM crop approvals. See how it has been used cited in reports, articles, and documents in the GMAD Citations Section.

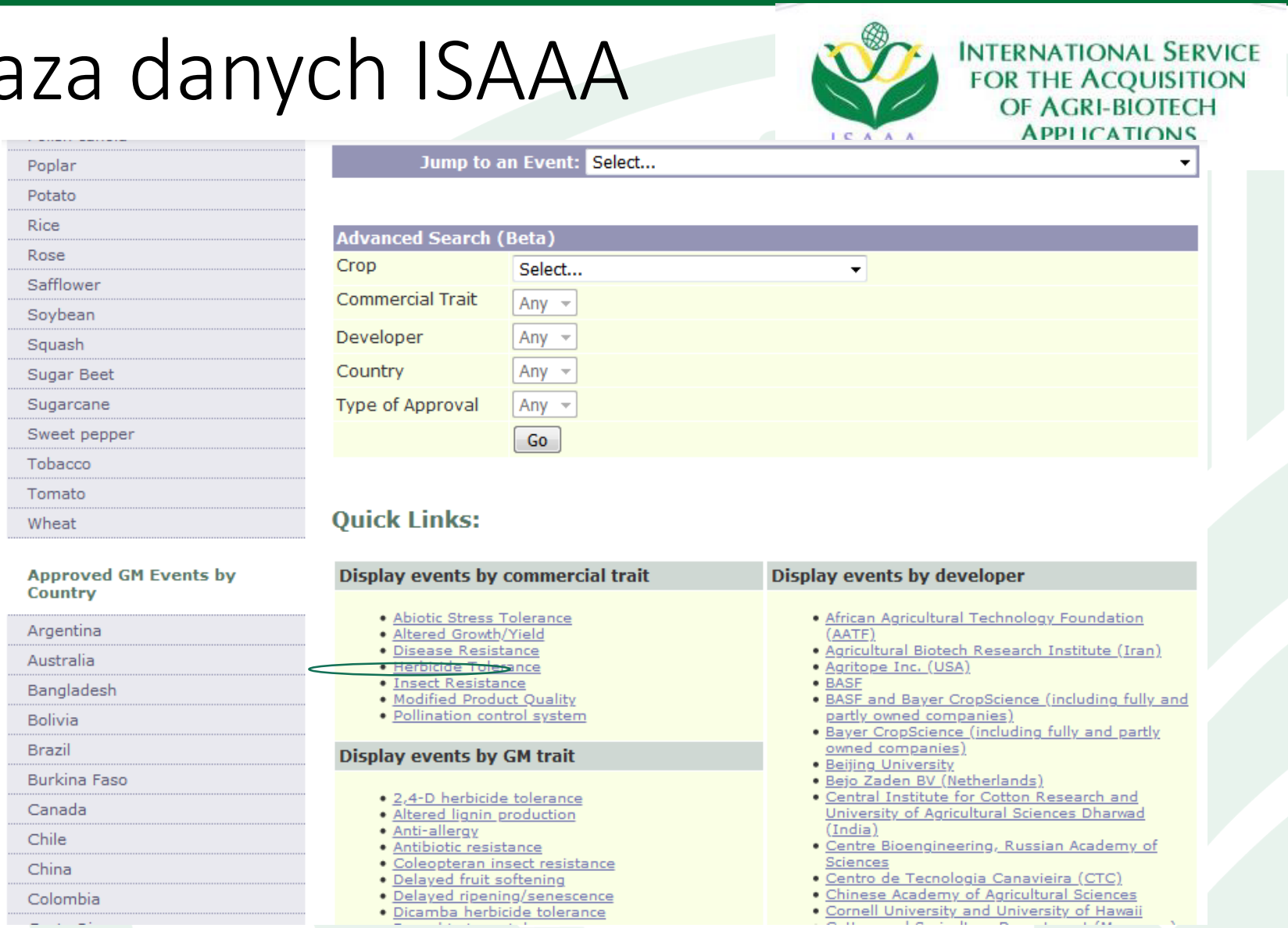
We invite corrections, additions/deletions, and suggestions for the improvement of the database.Contact us at gmapproval@isaaa.org or fill out our feedback form.

**Latest Update:**

| | |
|---|---|
| *October 22, 2019* | Brazil approved maize event MON87427 x MON89034 x MIR162 x NK603 for food, feed, and cultivation. |

http://www.isaaa.org/gmapprovaldatabase/default.asp

# Baza danych ISAAA

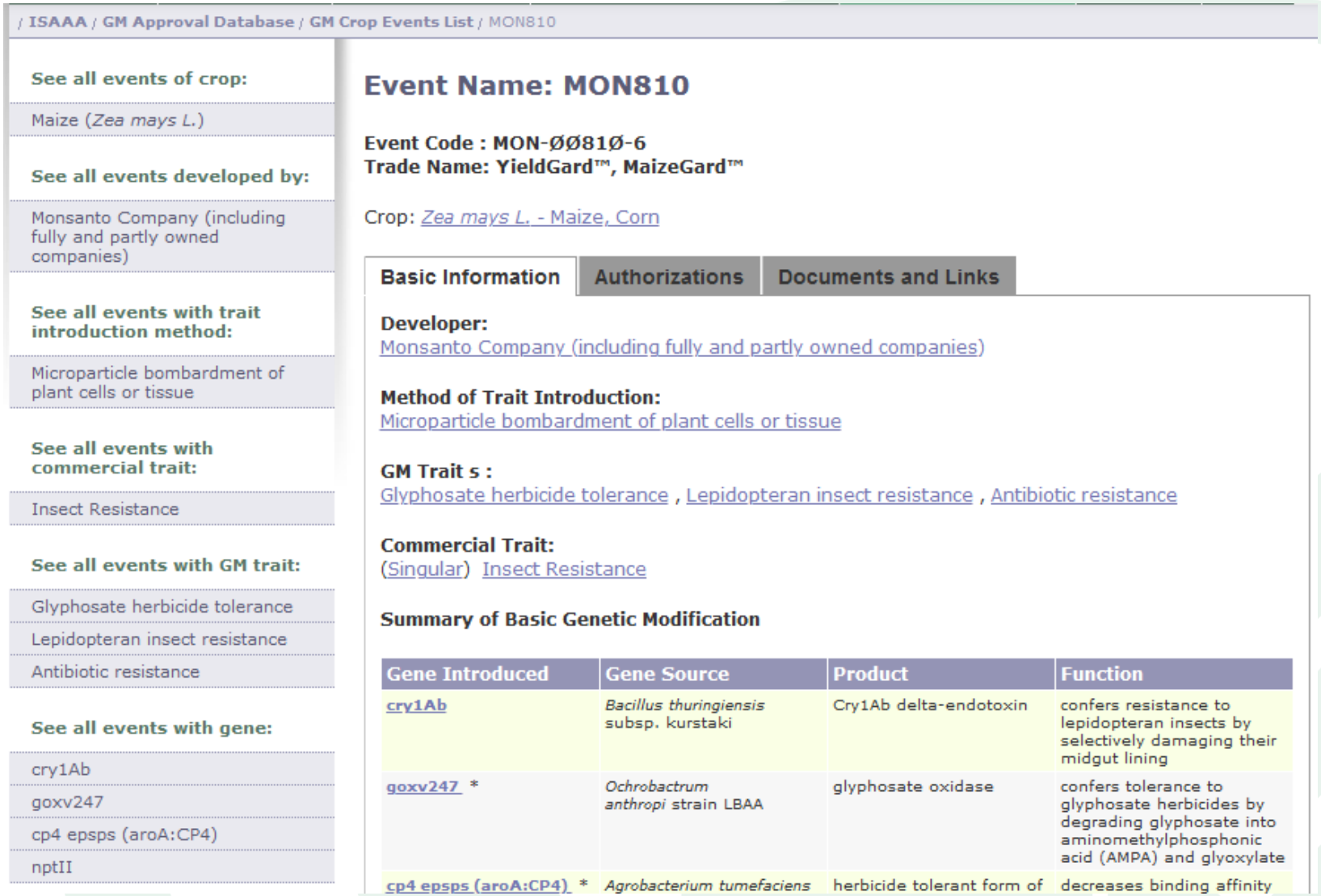



http://www.isaaa.org/gmapprovaldatabase/default.asp

| Crops | Events | Genes | GM Traits | Commercial Traits | Developers | Countries |
|---|---|---|---|---|---|---|

| **Maize** - ***Zea mays L.*** : 208 Events | |
|---|---|
| Name: 3272 x Bt11<br>Code: **SYN-E3272-5 x SYN-BTØ11-1** | not available |
| Name: 3272 x Bt11 x 59122 x MIR604 x TC1507 x GA21<br>Code: **SYN-E3272-5 x SYN-BTØ11-1 x DAS-59122-7 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x MON-ØØØ21-9** | not available |
| Name: 3272 x Bt11 x GA21<br>Code: **SYN-E3272-5 x SYN-BTØ11-1 x MON-ØØØ21-9** | not available |
| Name: 3272 x Bt11 x MIR604<br>Code: **SYN-E3272-5 x SYN-BTØ11-1 x SYN-IR6Ø4-5** | not available |
| Name: 3272 x Bt11 x MIR604 x GA21<br>Code: **SYN-E3272-5 x SYN-BTØ11-1 x SYN-IR6Ø4-5 x MON-ØØØ21-9** | not available |
| Name: 3272 x Bt11 x MIR604 x TC1507 x 5307 x GA21<br>Code: **SYN-E3272-5 x SYN-BTØ11-1 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9** | not available |
| Name: 3272 x MIR604<br>Code: **SYN-E3272-5 x SYN-IR6Ø4-5** | not available |
| Name: 3272 x MIR604 x GA21<br>Code: **SYN-E3272-5 x SYN-IR6Ø4-5 x MON-ØØØ21-9** | not available |
| Name: 33121<br>Code: **DP-Ø33121-3** | not available |
| Name: 4114<br>Code: **DP-ØØ4114-3** | not available |
| Name: 5307<br>Code: **SYN-Ø53Ø7-1** | **Agrisure® Duracade™** |
| Name: 5307 x GA21<br>Code: **SYN-Ø53Ø7-1 x MON-ØØØ21-9** | not available |
| Name: 5307 x MIR604 x Bt11 x TC1507 x GA21<br>Code: **SYN-Ø53Ø7-1 x SYN-IR6Ø4-5 x SYN-BTØ11-1 x DAS-Ø15Ø7-1 x MON-ØØØ21-9** | **Agrisure® Duracade™ 5122** |

http://www.isaaa.org/gmapprovaldatabase/commercialtrait/default.asp?TraitTypeID=2&Trait=Insect%20Resistance



/ ISAAA / GM Approval Database / GM Crop Events List / MON810

**See all events of crop:**

Maize (*Zea mays L.*)

**See all events developed by:**

Monsanto Company (including fully and partly owned companies)

**See all events with trait introduction method:**

Microparticle bombardment of plant cells or tissue

**See all events with commercial trait:**

Insect Resistance

**See all events with GM trait:**

Glyphosate herbicide tolerance

Lepidopteran insect resistance

Antibiotic resistance

**See all events with gene:**

cry1Ab

goxv247

cp4 epsps (aroA:CP4)

nptII

## Event Name: MON810

**Event Code : MON-ØØ81Ø-6**
**Trade Name: YieldGard™, MaizeGard™**

Crop: *Zea mays L.* - Maize, Corn

**Basic Information** | **Authorizations** | **Documents and Links**

**Developer:**
Monsanto Company (including fully and partly owned companies)

**Method of Trait Introduction:**
Microparticle bombardment of plant cells or tissue

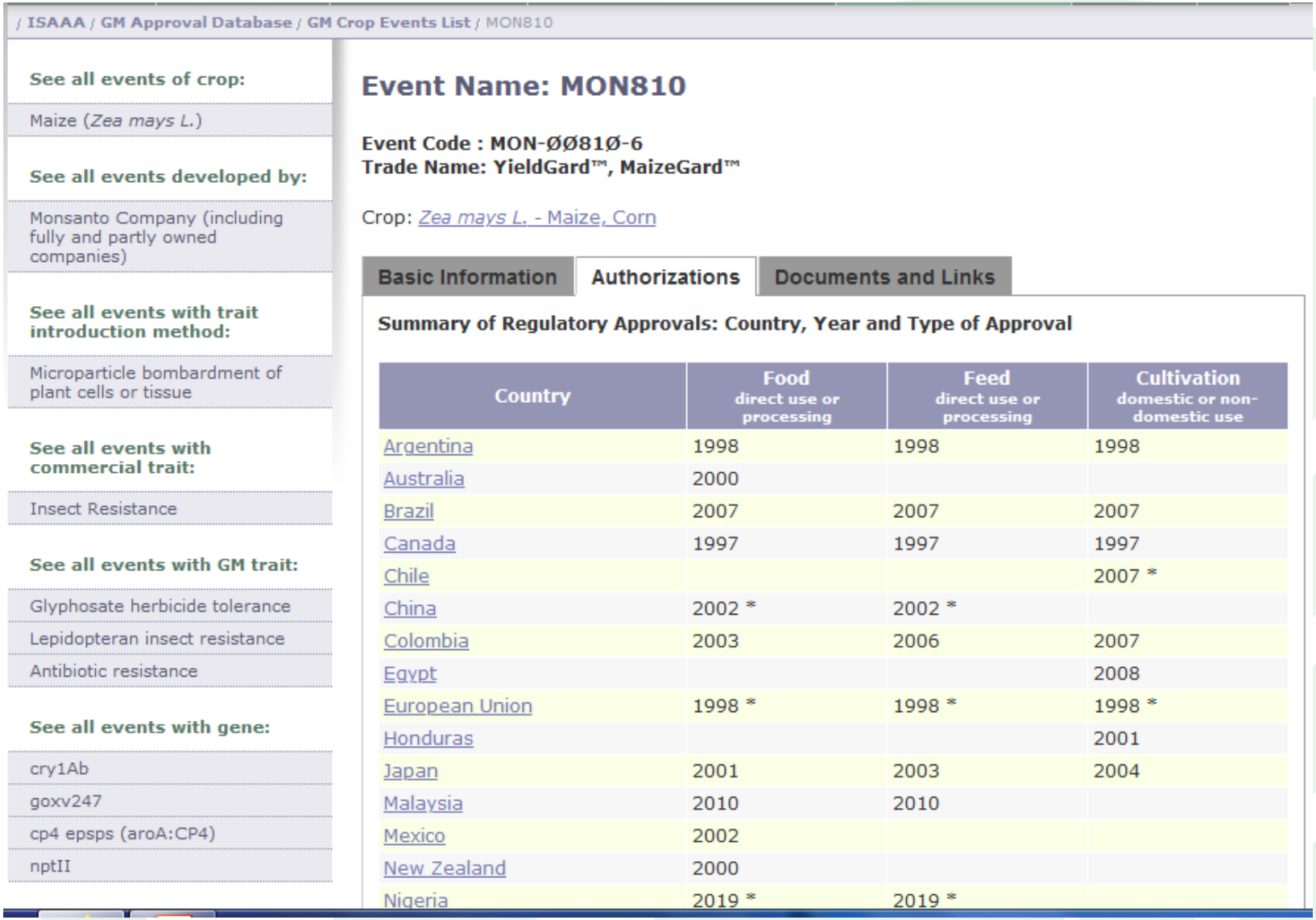
**GM Trait s :**
Glyphosate herbicide tolerance , Lepidopteran insect resistance , Antibiotic resistance

**Commercial Trait:**
(Singular) Insect Resistance

**Summary of Basic Genetic Modification**

| Gene Introduced | Gene Source | Product | Function |
|---|---|---|---|
| cry1Ab | *Bacillus thuringiensis* subsp. kurstaki | Cry1Ab delta-endotoxin | confers resistance to lepidopteran insects by selectively damaging their midgut lining |
| goxv247 * | *Ochrobactrum anthropi* strain LBAA | glyphosate oxidase | confers tolerance to glyphosate herbicides by degrading glyphosate into aminomethylphosphonic acid (AMPA) and glyoxylate |
| cp4 epsps (aroA:CP4) * | *Agrobacterium tumefaciens* | herbicide tolerant form of | decreases binding affinity |

http://www.isaaa.org/gmapprovaldatabase/event/default.asp?EventID=85



/ ISAAA / GM Approval Database / GM Crop Events List / MON810

**See all events of crop:**

Maize (*Zea mays L.*)

**See all events developed by:**

Monsanto Company (including fully and partly owned companies)

**See all events with trait introduction method:**

Microparticle bombardment of plant cells or tissue

**See all events with commercial trait:**

Insect Resistance

**See all events with GM trait:**

Glyphosate herbicide tolerance

Lepidopteran insect resistance

Antibiotic resistance

**See all events with gene:**

cry1Ab

goxv247

cp4 epsps (aroA:CP4)

nptII

## Event Name: MON810

**Event Code : MON-ØØ81Ø-6**
**Trade Name: YieldGard™, MaizeGard™**

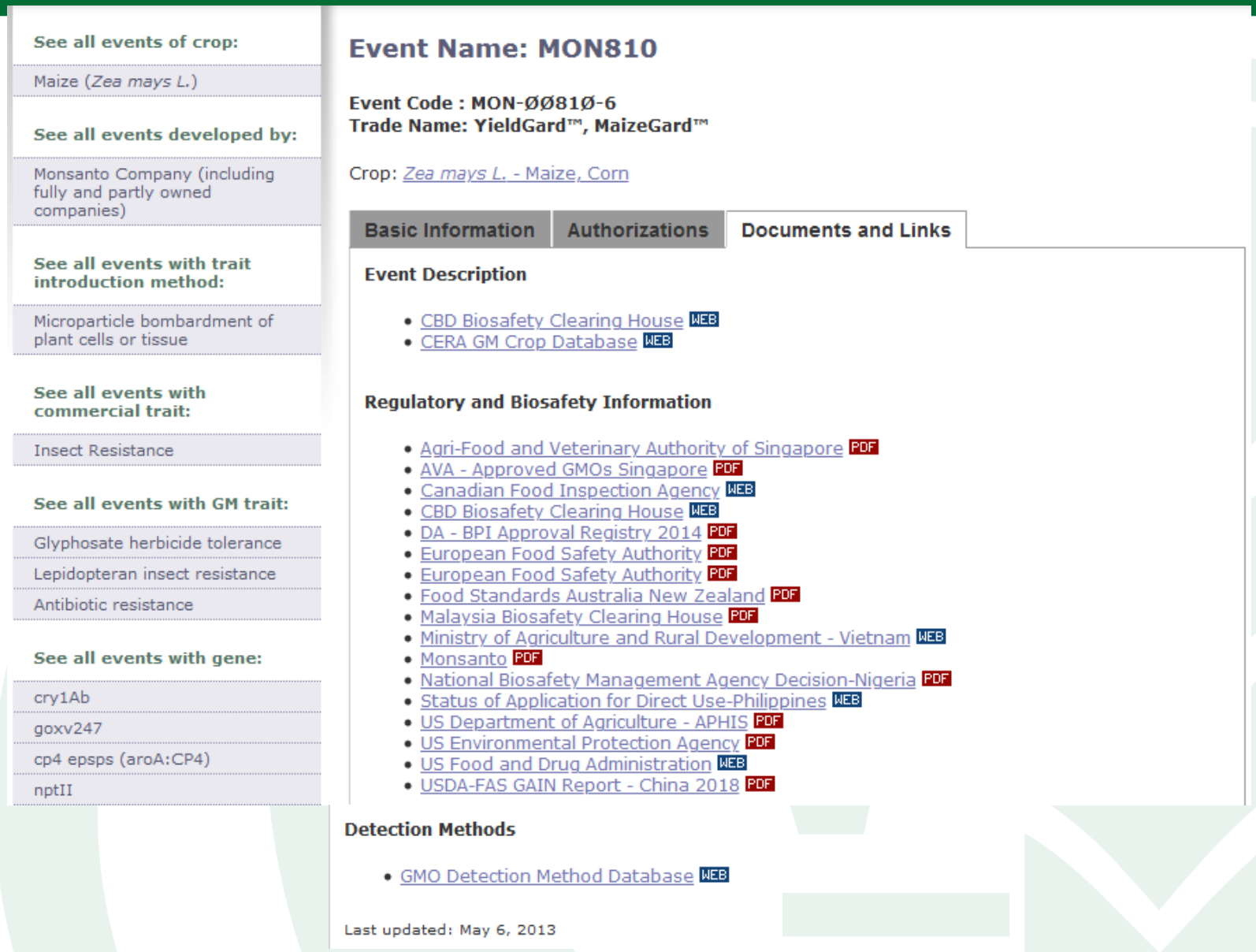
Crop: *Zea mays L.* - Maize, Corn

**Basic Information** | **Authorizations** | **Documents and Links**

**Summary of Regulatory Approvals: Country, Year and Type of Approval**

| Country | Food direct use or processing | Feed direct use or processing | Cultivation domestic or non-domestic use |
|---|---|---|---|
| Argentina | 1998 | 1998 | 1998 |
| Australia | 2000 | | |
| Brazil | 2007 | 2007 | 2007 |
| Canada | 1997 | 1997 | 1997 |
| Chile | | | 2007 * |
| China | 2002 * | 2002 * | |
| Colombia | 2003 | 2006 | 2007 |
| Egypt | | | 2008 |
| European Union | 1998 * | 1998 * | 1998 * |
| Honduras | | | 2001 |
| Japan | 2001 | 2003 | 2004 |
| Malaysia | 2010 | 2010 | |
| Mexico | 2002 | | |
| New Zealand | 2000 | | |
| Nigeria | 2019 * | 2019 * | |

http://www.isaaa.org/gmapprovaldatabase/event/default.asp?EventID=85



**See all events of crop:**

Maize (*Zea mays L.*)

**See all events developed by:**

Monsanto Company (including fully and partly owned companies)

**See all events with trait introduction method:**

Microparticle bombardment of plant cells or tissue

**See all events with commercial trait:**

Insect Resistance

**See all events with GM trait:**

Glyphosate herbicide tolerance

Lepidopteran insect resistance

Antibiotic resistance

**See all events with gene:**

cry1Ab

goxv247

cp4 epsps (aroA:CP4)

nptII

## Event Name: MON810

**Event Code : MON-ØØ81Ø-6**
**Trade Name: YieldGard™, MaizeGard™**

Crop: *Zea mays L.* - Maize, Corn

**Basic Information** | **Authorizations** | **Documents and Links**

**Event Description**

- CBD Biosafety Clearing House WEB
- CERA GM Crop Database WEB

**Regulatory and Biosafety Information**

- Agri-Food and Veterinary Authority of Singapore PDF
- AVA - Approved GMOs Singapore PDF
- Canadian Food Inspection Agency WEB
- CBD Biosafety Clearing House WEB
- DA - BPI Approval Registry 2014 PDF
- European Food Safety Authority PDF
- European Food Safety Authority PDF
- Food Standards Australia New Zealand PDF
- Malaysia Biosafety Clearing House PDF
- Ministry of Agriculture and Rural Development - Vietnam WEB
- Monsanto PDF
- National Biosafety Management Agency Decision-Nigeria PDF
- Status of Application for Direct Use-Philippines WEB
- US Department of Agriculture - APHIS PDF
- US Environmental Protection Agency PDF
- US Food and Drug Administration WEB
- USDA-FAS GAIN Report - China 2018 PDF

**Detection Methods**

- GMO Detection Method Database WEB

Last updated: May 6, 2013

http://www.isaaa.org/gmapprovaldatabase/event/default.asp?EventID=85


https://gmo-crl.jrc.ec.europa.eu/default.htm

Legal Notice | Cookies | English (EN)

European Commission

JOINT RESEARCH CENTRE

European Union Reference Laboratory for GM Food and Feed

European Commission > EU Science Hub > EU-RL GMFF

- EU-RL GMFF Home
- Legal basis
- Tasks and duties
- Guidance documents
- Status of dossiers
- Proficiency tests
- Methods database
- JRC GMO
- JRC GMO
- Capacity
- ENGL
- Emerge Unauth
- Contact

## Emergencies / Unauthorised

Page dedicated to GM wheat

Verification Report on the extraction and analysis of GM pollen DNA in honey

Page dedicated to Commission implementing decision 2013/287/EU (emegency measures regarding unauthorised GM rice in rice products originating from China)

Page dedicated to CDC Triffid flax (FP967)

Page dedicated to Bt63 rice

Page dedicated to E32 maize

Page dedicated to LLRICE601 rice

Page dedicated to BT10 maize

## Page dedicated to Commission implementing decision 2013/287/EU

**(emergency measures regarding unauthorised GM rice in rice products originating from China)**

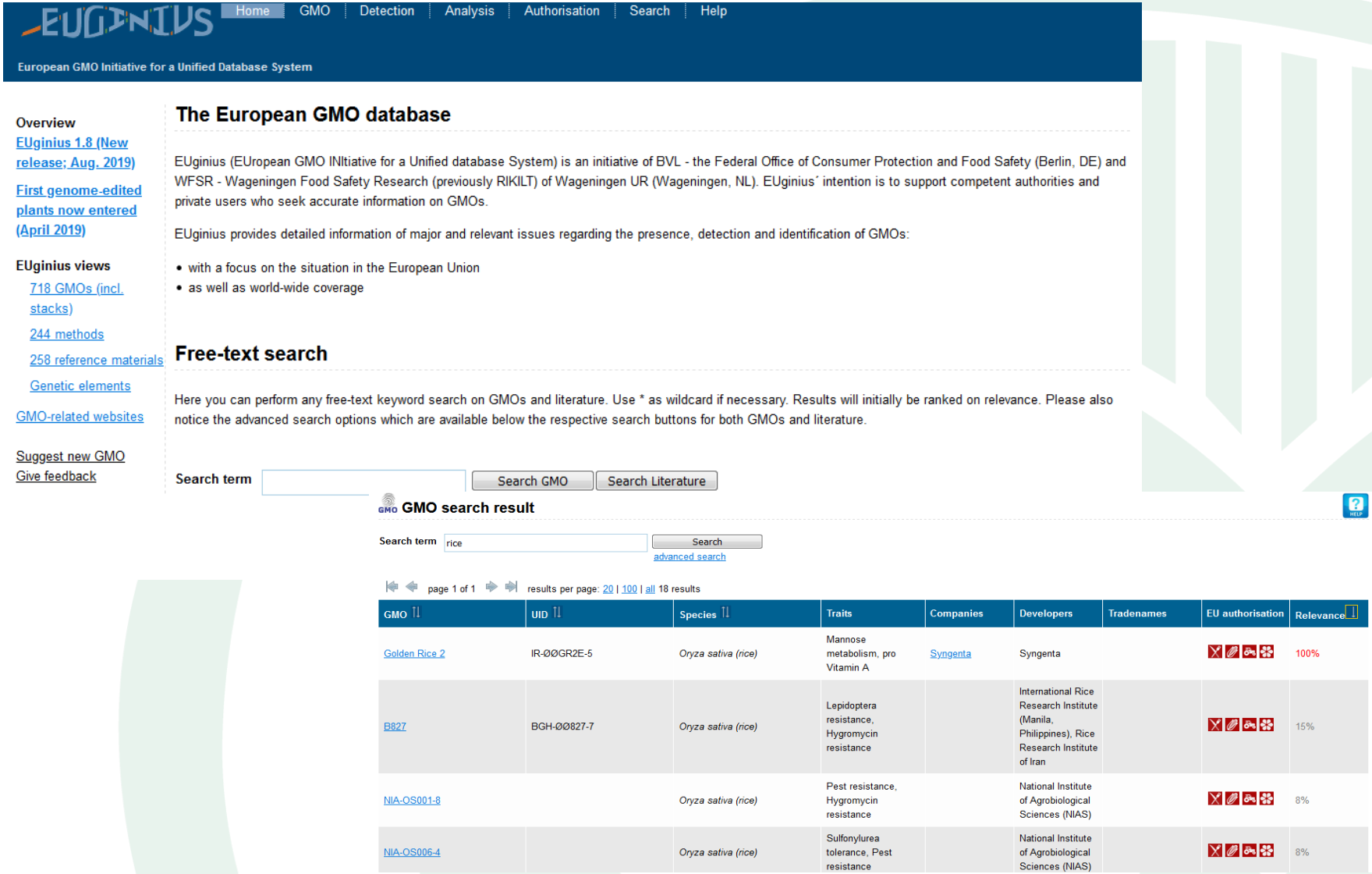
In support to the Commission Implementing Decision 2013/287/EU, amending Decision 2011/884/EU, the European Union Reference Laboratory for Genetically Modified Food and Feed (EU-RL GMFF) prepared a revision of the previously published guidance document. This document provides further guidance on the correct use of the methods indicated in the Decision, including measures aimed at improving the specificity of the detection approach.

*Documents*

Revised Guidance on the Detection of Genetically Modified Rice Originating from China Using Real-Time PCR for the detection of P-35S, T-nos and Cry1Ab/Ac 08/05/2014

https://gmo-crl.jrc.ec.europa.eu/emerg-unauth.html

https://gmo-crl.jrc.ec.europa.eu/emerg-unauth.html




http://www.euginius.eu

# EUginius


**European GMO initiative for a unified database system**

- Mission: provide information on GMO (thematically organized modules)
- Target audience: commercial and governmental labs for GMO control and detection as well as the interested public

# EUginius

https://www.euginius.eu/euginius/pages/home.jsf

EUGINIUS

Home | GMO | Detection | Analysis | Authorisation | Search | Help

European GMO Initiative for a Unified Database System

Overview
News on (commercialised) genome-edited organisms
""""" New help file """""
How to optimise my screening strategy?

EUginius views
870 GMOs (incl. stacks)
259 methods
440 reference materials
Genetic elements

GMO-related websites

Suggest new GMO
Give feedback

## The European GMO database

EUginius (EUropean GMO INItiative for a Unified Database System) is an initiative of BVL - the Federal Office of Consumer Protection and Food Safety (Berlin, DE) and WFSR - Wageningen Food Safety Research (formerly RIKILT) of Wageningen UR (Wageningen, NL). EUginius´ intention is to support competent authorities and private users who seek accurate information genetically modified organisms.

EUginius provides detailed information of major and relevant issues regarding the presence, detection and identification of GMOs:

- with a focus on the situation in the European Union
- as well as world-wide coverage

Since the European Union classifies organisms developed using 'new genomic techniques' (NGTs) into the GMOs, EUginius provides information about commercialised organisms as well as about published ones which present market-relevant traits. Please note that EUginius does not contain an exhaustive list of organisms delevoped with NGTs and presence of a market-relevant trait does not necessarily imply admission to the market.

## Free-text search

Here you can perform any free-text keyword search on GMOs and literature. Use * as wildcard if necessary. Search for "gene editing" to find all registered organisms developed using NGTs.

Please also notice the advanced search options which are available below the respective search buttons for both GMOs and literature.

Search term | Search GMO | Search Literature

advanced GMO search | advanced Literature search

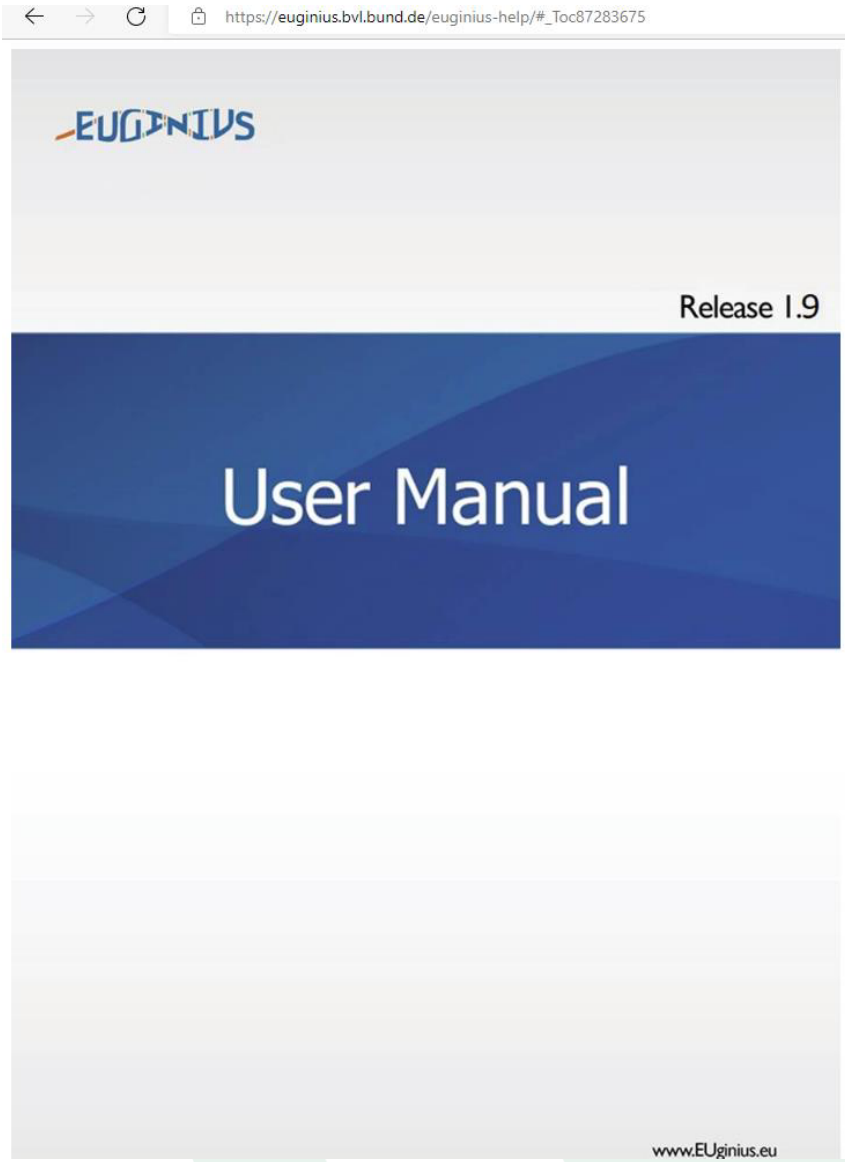
## About the partners

- The Federal Office of Consumer Protection and Food Safety (BVL) fulfils many tasks in the area of food safety.
- Wageningen Food Safety Research (WFSR) is an independent research institute in the area of the safety and wholesomeness of food.
- more about the partners...

Members of the EUginius group are also the organisations below:

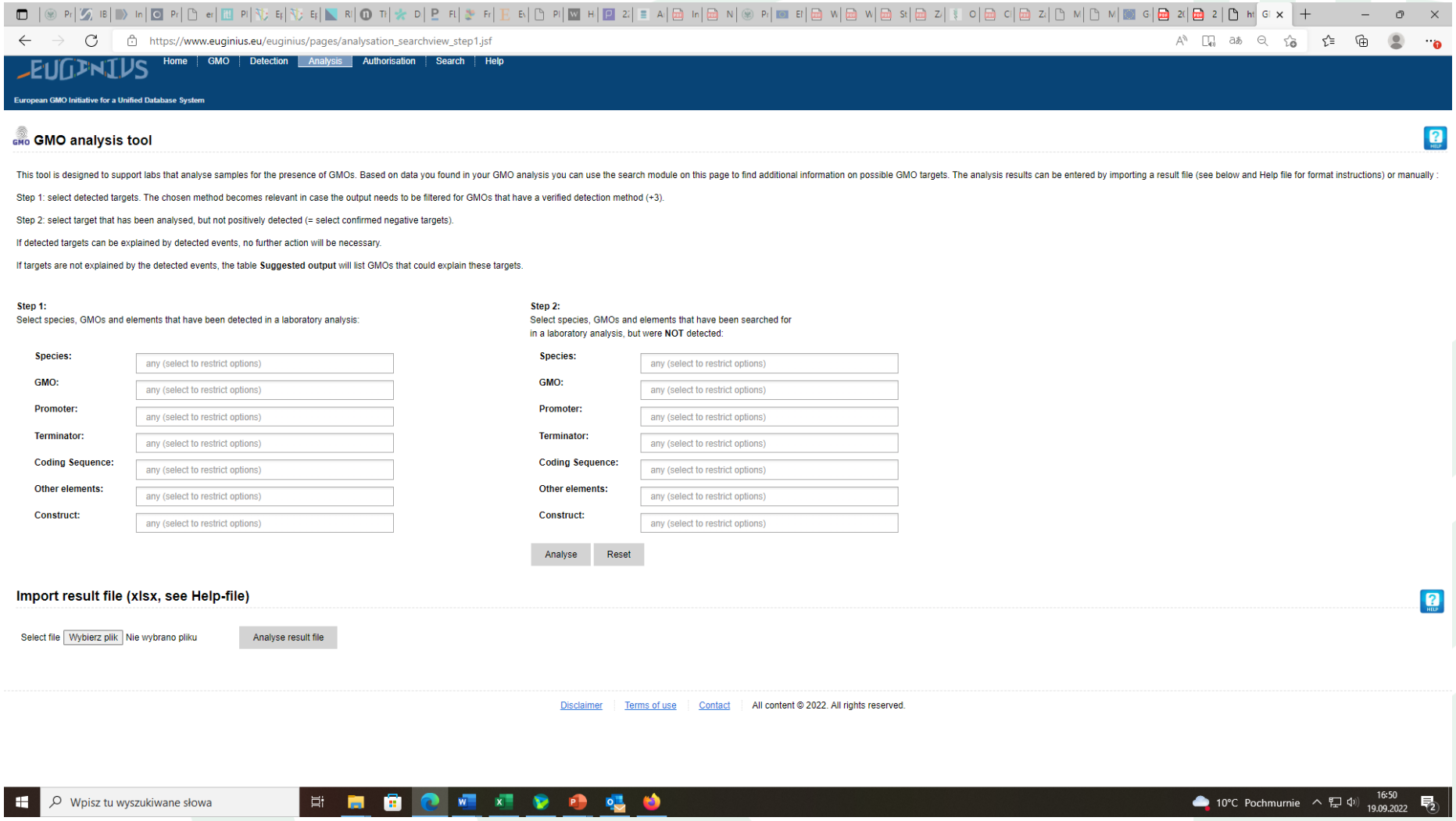
WAGENINGEN UNIVERSITY & RESEARCH

Federal Office of Consumer Protection and Food Safety


https://euginius.bvl.bund.de/euginius-help/#_Toc87283675
EUGINIUS
Release 1.9
User Manual
www.EUginius.eu

# EUginius

# EUginius


https://www.euginius.eu/euginius/pages/analysation_searchview_step1.jsf
EUGINIUS
Home
GMO
Detection
Analysis
Authorisation
Search
Help
European GMO Initiative for a Unified Database System
GMO analysis tool
This tool is designed to support labs that analyse samples for the presence of GMOs. Based on data you found in your GMO analysis you can use the search module on this page to find additional information on possible GMO targets. The analysis results can be entered by importing a result file (see below and Help file for format instructions) or manually :
Step 1: select detected targets. The chosen method becomes relevant in case the output needs to be filtered for GMOs that have a verified detection method (+3).
Step 2: select target that has been analysed, but not positively detected (= select confirmed negative targets).
If detected targets can be explained by detected events, no further action will be necessary.
If targets are not explained by the detected events, the table Suggested output will list GMOs that could explain these targets.
Step 1:
Select species, GMOs and elements that have been detected in a laboratory analysis:
Species:
GMO:
Promoter:
Terminator:
Coding Sequence:
Other elements:
Construct:
any (select to restrict options)
Step 2:
Select species, GMOs and elements that have been searched for in a laboratory analysis, but were NOT detected:
Species:
GMO:
Promoter:
Terminator:
Coding Sequence:
Other elements:
Construct:
any (select to restrict options)
Analyse
Reset
Import result file (xlsx, see Help-file)
Select file
Wybierz plik
Nie wybrano pliku
Analyse result file
Disclaimer
Terms of use
Contact
All content © 2022. All rights reserved.
Wpisz tu wyszukiwane słowa
10°C Pochmurnie
16:50
19.09.2022

Dziękuję za uwagę

Kontakt: a.linkiewicz@ihar.edu.pl