

Legislation connected with GMO

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Biotechnology of Drugs 2024

Legislation connected with GMO



**The EU has got itself into a fine mess,
and it is the EU who must clean it!**

Act No. 78/2004 Coll

**Directive 2001/18/EC of the European Parliament
and of the Council of 12 March 2001 on the
deliberate release into the environment of
genetically modified organisms and repealing
Council Directive 90/220/EC**

Council Directive 90/219/EEC of 23 April 1990

Council Directive 98/81/EC of 26 October 1998

Genetically modified organism

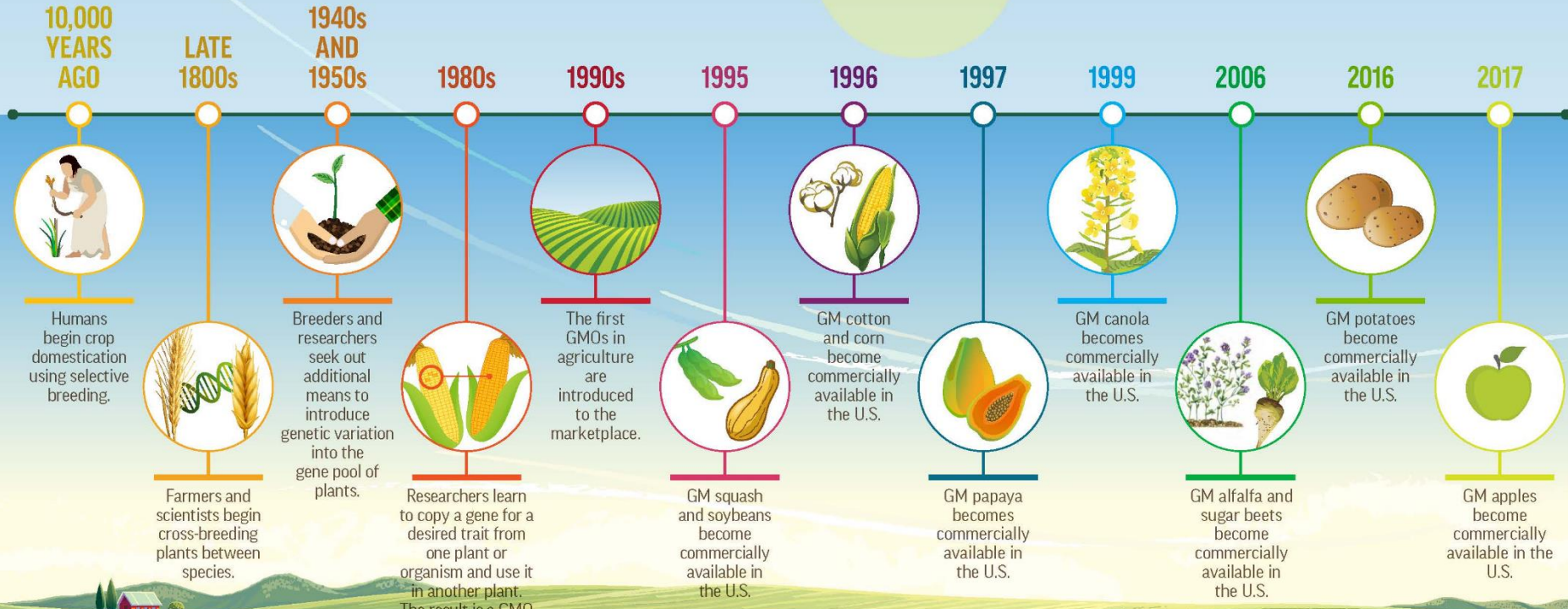
Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001

Genetically modified organism (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination; genetic modification occurs at least through the use of the techniques listed in Annex I A, part 1

Genetic product

Genetic product means a preparation consisting of, or containing, a **GMO** or a combination of **GMOs**, which is placed on the market;

The History of Genetic Modification in **CROPS**



Manipulation with GMO

- 1) **Contained use** of genetically modified organisms; where appropriate stringent containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment
- 2) **Deliberate release** means any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment
- 3) **Placing on the market** means making available to third parties, whether in return for payment or free of charge

Manipulation with GMO

- 1) The precautionary principle** = ensure that all appropriate measures are taken to avoid adverse effects on human and animal health, the environment and biological diversity
- 2) Conditions stipulated on the delivery list must be observed by user**
- 3) Any person, before undertaking a deliberate release into the environment of a GMO, or the placing on the market of GMOs, as or in products, where the intended use of the product involves its deliberate release into the environment, is to submit a notification to the national competent authority.**

Risk categories

1st category

- **No risk or insignificant for health or environment (most laboratories)**

2nd category

- **Low risk which is easily removed (laboratories producing recombinant proteins)**

3rd category

- **Risk which is removable only by sophisticated corrections**

4th category

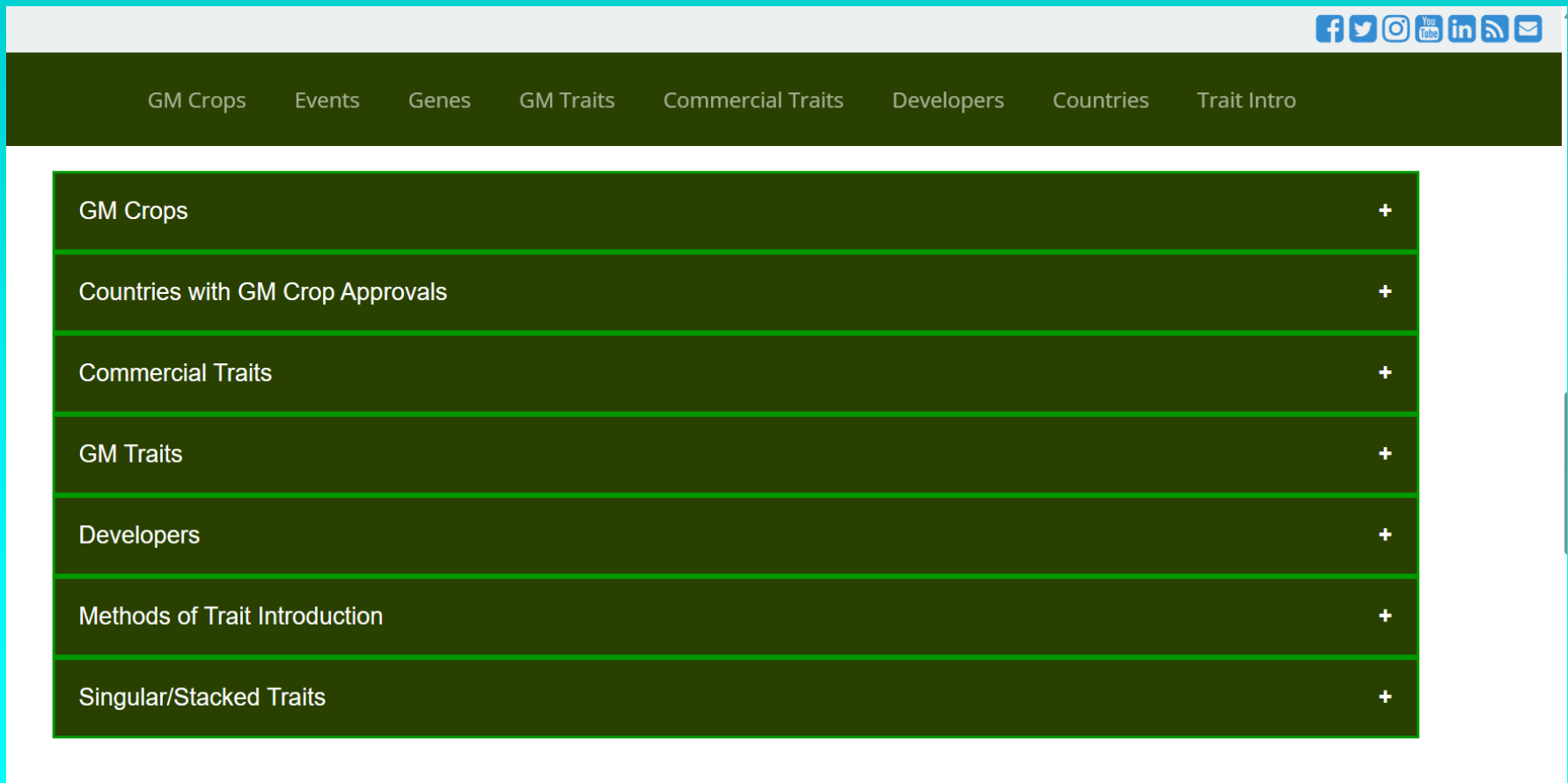
- **High risk**



GMO in the world

GM APPROVAL DATABASE

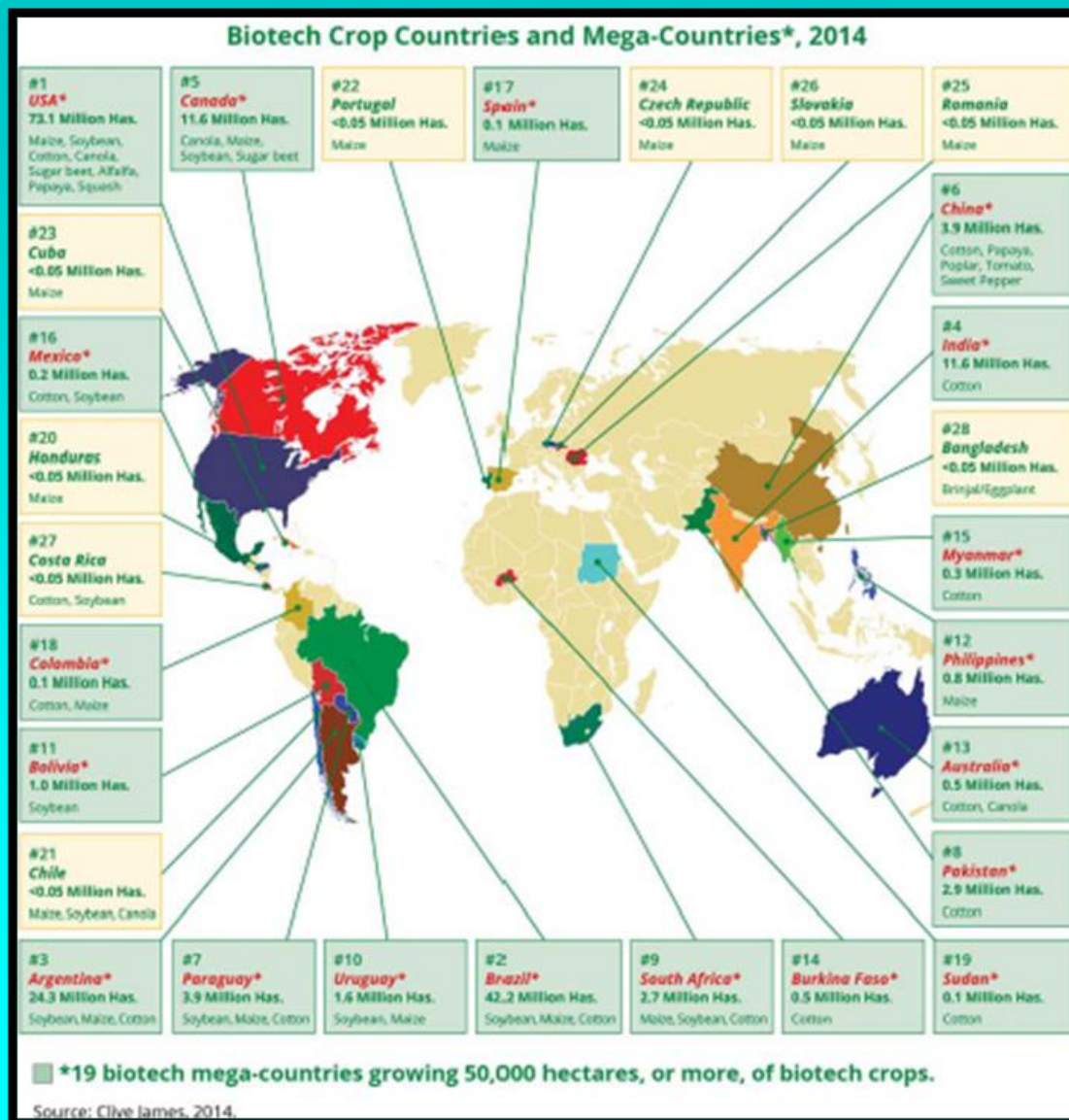
<https://www.isaaa.org/gmapprovaldatabase/default.asp>



The screenshot shows the website's interface. At the top right, there are social media icons for Facebook, Twitter, Instagram, YouTube, LinkedIn, RSS, and Email. Below these is a dark green navigation bar with white text links: GM Crops, Events, Genes, GM Traits, Commercial Traits, Developers, Countries, and Trait Intro. The main content area features a list of database sections, each in a dark green box with white text and a plus sign on the right side, indicating expandable content.

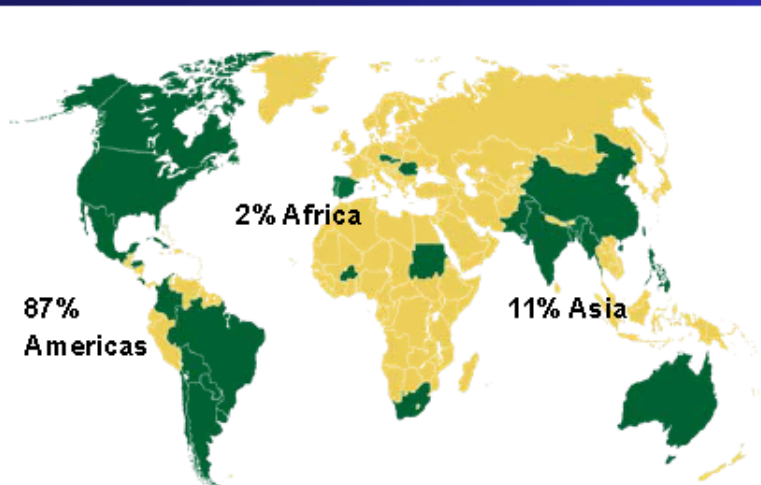
GM Crops	+
Countries with GM Crop Approvals	+
Commercial Traits	+
GM Traits	+
Developers	+
Methods of Trait Introduction	+
Singular/Stacked Traits	+

GM crops in the world in 2014

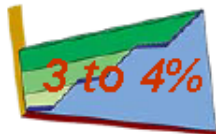


Main growers

Global Area (Million Hectares) of Biotech Crops, 2014: by Country



Increase over 2013



28 countries which have adopted biotech crops

In 2014, global area of biotech crops was 181.5 million hectares, representing an increase of 3 to 4% over 2013, equivalent to 6.3 million hectares.

Source: Clive James, 2014.

Biotech Mega Countries

50,000 hectares (125,000 acres), or more

Million Hectares

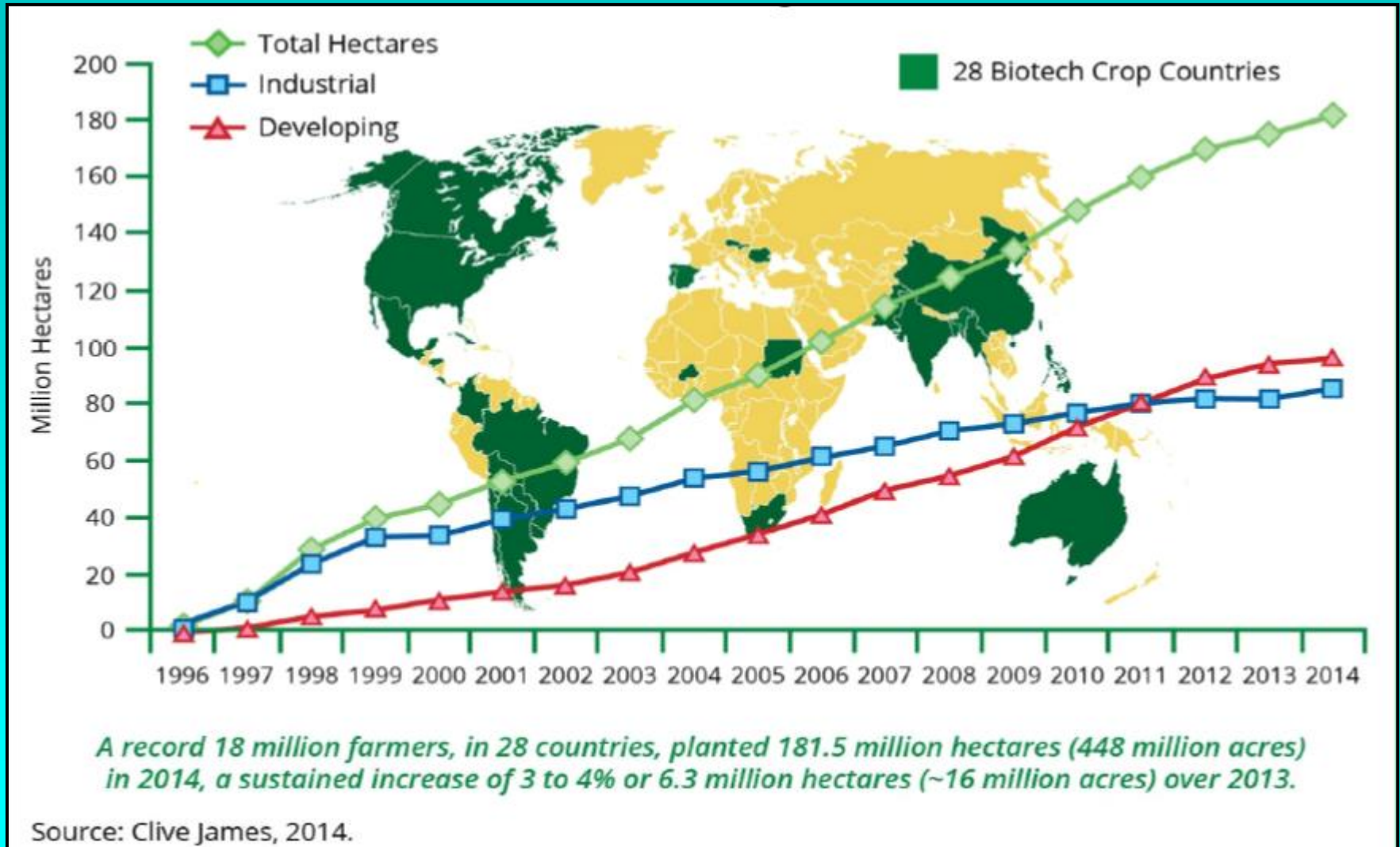
1.	USA	73.1
2.	Brazil*	42.2
3.	Argentina*	24.3
4.	India*	11.6
5.	Canada	11.6
6.	China*	3.9
7.	Paraguay*	3.9
8.	Pakistan*	2.9
9.	South Africa*	2.7
10.	Uruguay*	1.6
11.	Bolivia*	1.0
12.	Philippines*	0.8
13.	Australia	0.5
14.	Burkina Faso*	0.5
15.	Myanmar*	0.3
16.	Mexico*	0.2
17.	Spain	0.1
18.	Colombia*	0.1
19.	Sudan*	0.1

Less than 50,000 hectares

Honduras*	Romania
Chile*	Slovakia
Portugal	Costa Rica*
Cuba*	Bangladesh*
Czech Republic	

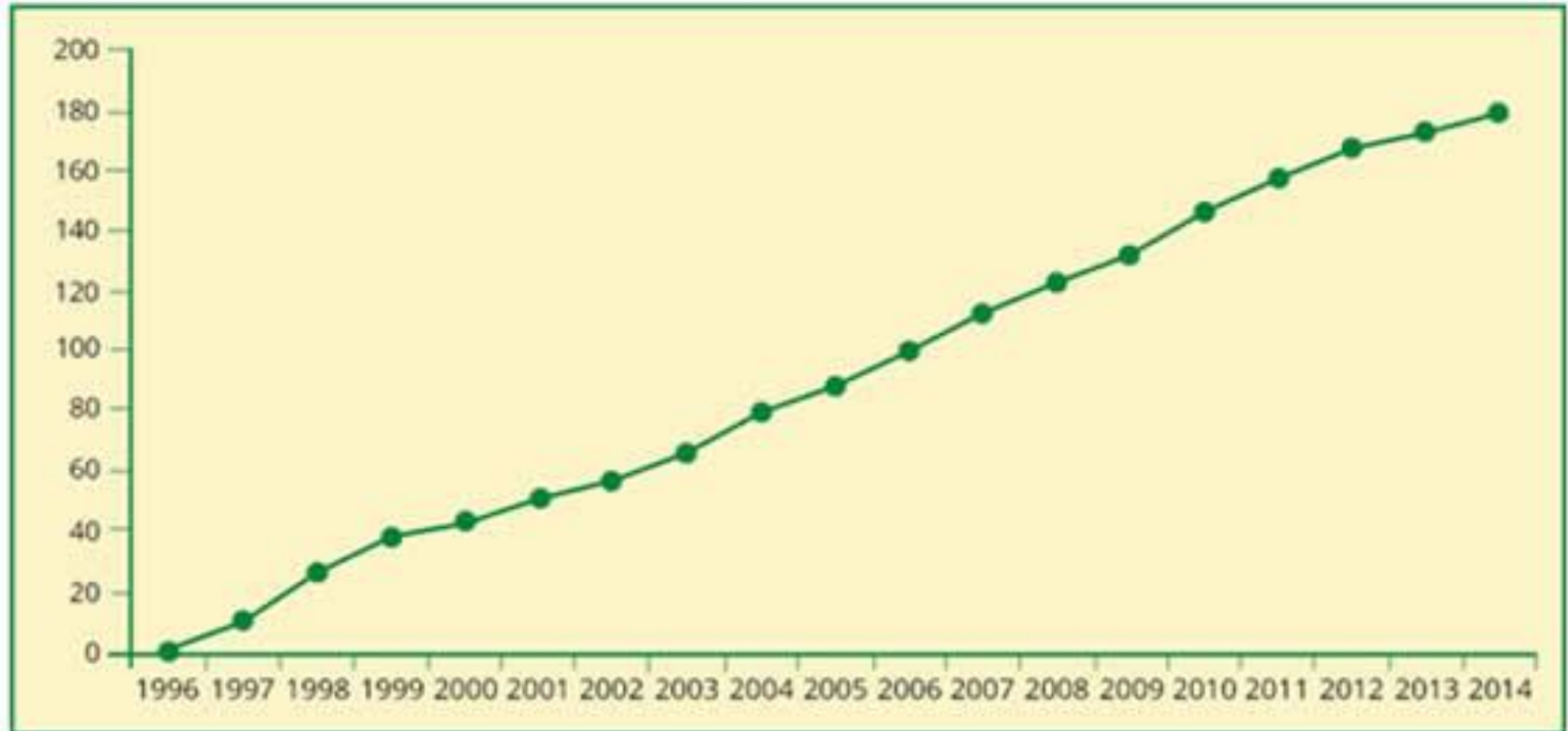
* Developing countries

The first 30 years of transgenic plants



Growing area of GM crops

Figure 1. Global Area of Biotech Crops, 1996 to 2014 (Million Hectares)



Source: Clive James, 2014.

Growing area of GM crops

Table 1. Global Area of Biotech Crops, 1996 to 2014

	Hectares (Million)	Acres (Million)
1996	1.7	4.3
1997	11.0	27.5
1998	27.8	69.5
1999	39.9	98.6
2000	44.2	109.2
2001	52.6	130.0
2002	58.7	145.0
2003	67.7	167.2
2004	81.0	200.0
2005	90.0	222.0
2006	102.0	250.0
2007	114.3	282.0
2008	125.0	308.8
2009	134.0	335.0
2010	148.0	365.0
2011	160.0	395.0
2012	170.3	420.8
2013	175.2	433.2
2014	181.5	448.0
TOTAL	1,784.9	4,413.5

Increase of 3-4%, 6.3 million hectares (15.6 million acres) between 2013 and 2014.

Source: Clive James, 2014.

Table 2. Global Area of Biotech Crops in 2013 and 2014: by Country (Million Hectares)**

Country	2013	2014
USA*	70.1	73.1
Brazil*	40.3	42.2
Argentina*	24.4	24.3
India*	11.0	11.6
Canada*	10.8	11.6
China*	4.2	3.9
Paraguay*	3.6	3.9
Pakistan*	2.8	2.9
South Africa*	2.9	2.7
Uruguay*	1.5	1.6
Bolivia*	1.0	1.0
Philippines*	0.8	0.8
Australia*	0.6	0.5
Burkina Faso*	0.5	0.5
Myanmar*	0.3	0.3
Mexico*	0.1	0.2
Spain*	0.1	0.1
Colombia*	0.1	0.1
Sudan*	0.1	0.1
Honduras	<0.1	<0.1
Chile	<0.1	<0.1
Portugal	<0.1	<0.1
Cuba	<0.1	<0.1
Czech Republic	<0.1	<0.1
Romania	<0.1	<0.1
Slovakia	<0.1	<0.1
Costa Rica	<0.1	<0.1
Bangladesh	--	<0.1
TOTAL	175.2	181.5

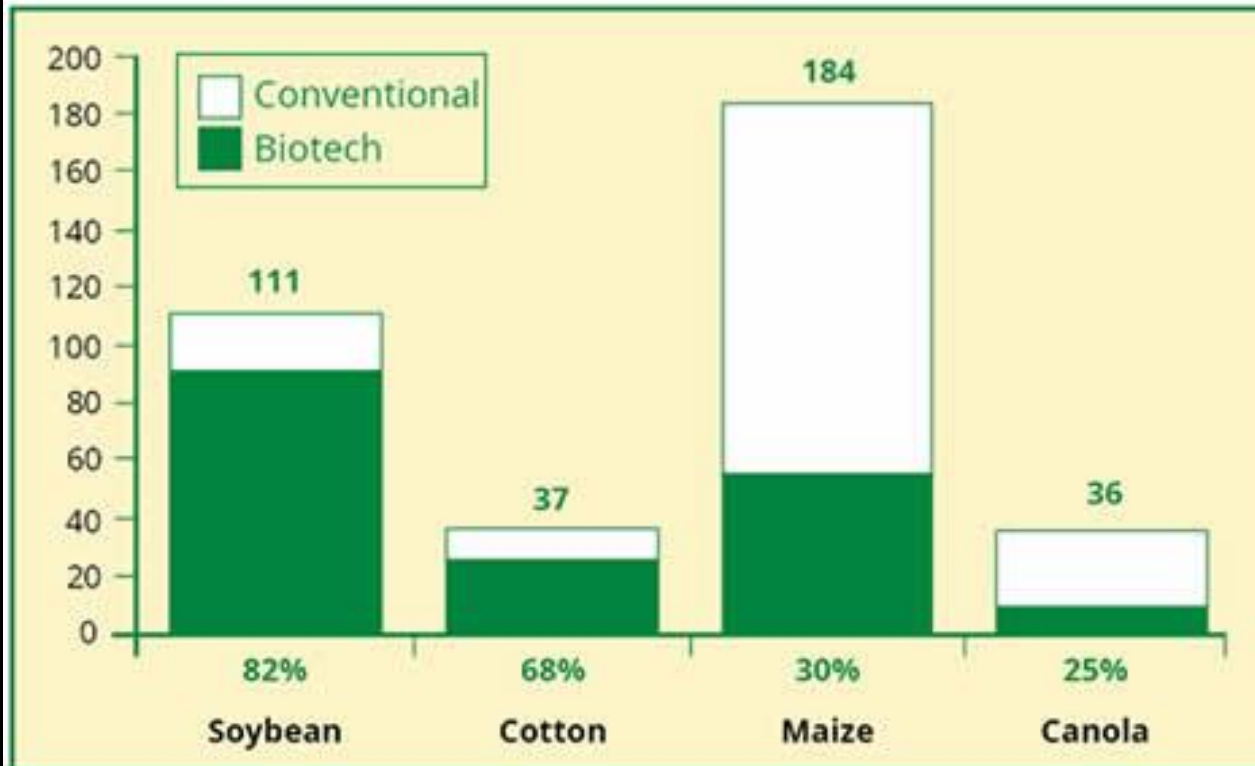
Source: Clive James, 2014.

* Biotech mega-countries which grew more than 50,000 hectares, or more.

** Rounded-off to the nearest hundred thousand.

Proportion of main crops

Figure 3. Biotech Crop Area as % of Global Area of Principal Crops, 2014 (Million Hectares)



Source: Clive James, 2014.

Total area of transgenic crops

Year	Area (mil. hectare)	Year-on-year increase
2008	125	9,4 %
2009	134	7,2 %
2010	148	10,4%
2011	160	8,1%
2012	170	6,3%
2013	175	2,9%
2014	182	4,0%

<http://www.isaaa.org/resources/publications/pocketk/16/>

GM crops areas in 2014

Country	Area (mil. ha)	Crops
USA	73,1	soybean, corn, cotton, canola, pumpkin, papaya, alfalfa
Brazílie	42,2	soybean, cotton
Argentina	24,3	soybean, corn, cotton
Kanada	11,6	rapeseed, maize, soya
Indie	11,6	cotton
Čína	3,9	cotton plant, tomato, poplar, petunia, papaya, paprika
EU (5)	0,1	corn

28 countries total, area 181,5 milions of hectare

GM crops areas in 2007-2009 (mil. ha)

Country	2007	2008	2009
USA	57.7	62.5	64.0
Brazil	15.0	15.8	21.4
Argentina	19.1	21.0	21.3
India	6.2	7.6	8.4
Canada	7.0	7.6	8.2
China	3.8	3.8	3.7
Paraguay	?	2.7	2.2
EU (8)	0.1	?	?

Harvested areas of the main GM and conventional crops (mil. ha)

Crop	GM 1996	GM 2004	CON2004	GM/CON
Soya	0.5	48.4	91.6	53%
Corn	0.3	19.3	145.1	13%
Cotton	0.8	9.0	34.9	26%
Canola	0.1	4.3	26.2	16%
TOTAL	1.7	81.0	297.8	27%

Source: FAO 2004

Harvester areas of GM crops (mil. ha)

Crop	Area in 2004	%
Round-up Ready soya	48.4	60
Bt corn	11.2	14
Bt cotton	4.5	6
Herbicide tolerant corn	4.3	5
Herbicide tolerant canola	4.3	5
Bt/Herbicide tolerant corn	3.8	4
Bt/Herbicide tolerant cotton	3.0	4
Herbicide tolerant cotton	1.5	2
TOTAL	81.0	100

Source: James 2004

Chinese like GM rice

Parameter	GM rice	Conventional rice
Number of treatments by pesticides	0.5x	3.7x
Expenses for pesticides (Juan/ha)	31	243
Amount of pesticides (kg/ha)	2.0	21.2
Labour for spraying (days/ha)	0.73	9.1
Yield (kg/ha)	6 364	6 151
Number of farmers	123	224

Huang et al. (2005): Science 308, 688-690

Disorders of farmers

Percentage of farmers, who become ill as a consequence of using pesticides (without permanent consequences)

Year	Producers of only GM rice	Producers of both types of rice		Producers of only conventional rice
		on fields with GM	on conventional fields	
2002	0	0	7.7	8.3
2003	0	0	10.9	3.0

Huang et al. (2005): Science 308, 688-690

What happens in China?

1) Corn with phytase

- **Enzyme digests phytates**
- **The enzyme is not present in pigs, non-digested phytates from slurry phosphates are produced by micro-organisms; the phosphates contaminate water sources**
- **GM corn is much better feed for pigs**

2) Approval of Bt rice

Breakthrough event in Asia

GMO in EU ?



The European GMO database

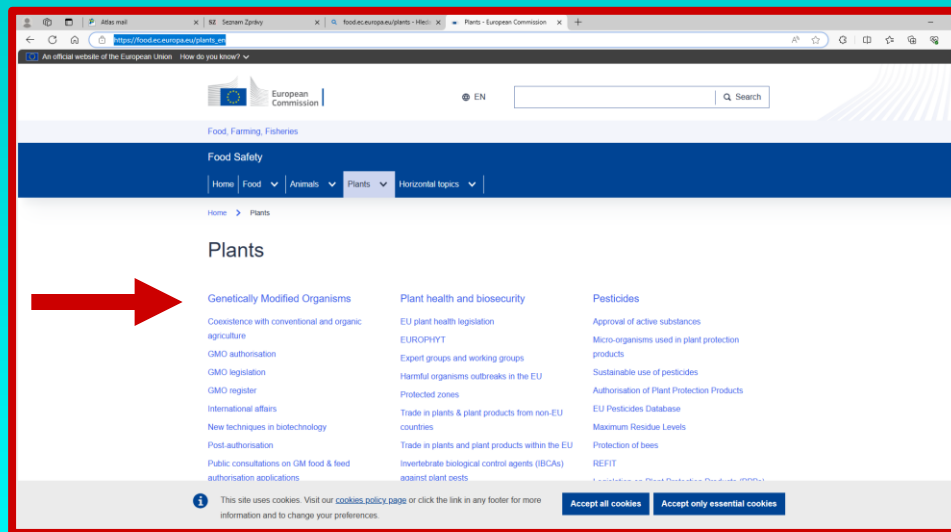
<https://euginius.eu/euginius/pages/home.jsf>

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 on genetically modified organisms.

GMO and food safety in EU

https://food.ec.europa.eu/plants_en

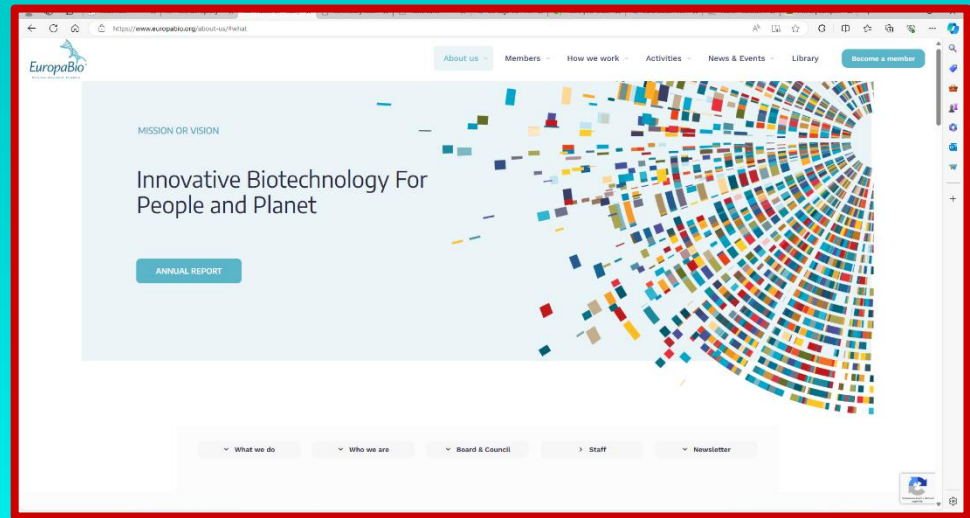


EU Register of authorised GMOs

<https://webgate.ec.europa.eu/dyna2/gm-register/>

Innovative biotechnology for people and planet

<https://europabio.org>



The European Association for Bioindustries, is Europe's largest and most influential biotech industry group. Initiated in 1996 to represent the interests of the biotechnology industry at European level, and constantly engaged in a dialogue with the European Parliament, the European Commission and the Council of Ministers EuropaBio aims to influence legislation on biotechnology, representing Healthcare and Industrial biotechnology sectors.

Biosafety Clearing-House

<https://bch.cbd.int/en/>

The screenshot shows the homepage of the Biosafety Clearing-House (BCH) website. At the top, there is a navigation bar with the text "Convention on Biological Diversity" on the left and "SIGN IN EN" on the right. Below this is the BCH logo and the text "BIOSAFETY CLEARING-HOUSE". A secondary navigation bar includes links for "HOME", "ABOUT", "SEARCH", "SUBMIT", "COUNTRY PROFILES", "HELP", "FORUMS", and "PROTOCOL".

The main content area features a large background image of a field of yellow flowers. A central text block states: "The Biosafety Clearing-House (BCH) is an online platform for exchanging information on Living Modified Organisms (LMOs) and a key tool for facilitating the implementation of the Cartagena Protocol on Biosafety." Below this text are three dark blue buttons: "EXPLORE THE MAP", "GET STARTED", and "RECENT RECORDS".

Underneath the buttons is a section titled "Announcements" with three featured items:

- WEBINAR: "Where to find Help materials in BCH and ABSCH?"** (dated 28 Mar 2024). The description includes "Date and Time: 11 April 2024 at 9a.m. EDT".
- The Implementation Plan and the Capacity-building Action Plan for the Cartagena Protocol on Biosafety** (dated 07 Dec 2023). The description includes "Read the Implementation Plan and the Capacity-building Action Plan, adopted at CP-MOP 10.".
- Poll on Public Awareness, Education and Participation regarding LMOs** (dated 02 Oct 2023). The description includes "Results of the poll".

A "SEE MORE" button is located at the bottom right of the announcements section. At the very bottom of the page, there is a section titled "Parties to the Cartagena Protocol" and a circular icon with a question mark.

The BCH Knowledge Base is an online tool designed to help users become familiar with the Clearing-House, learn how to submit records, search for information and complete other important tasks.

EUSAGE

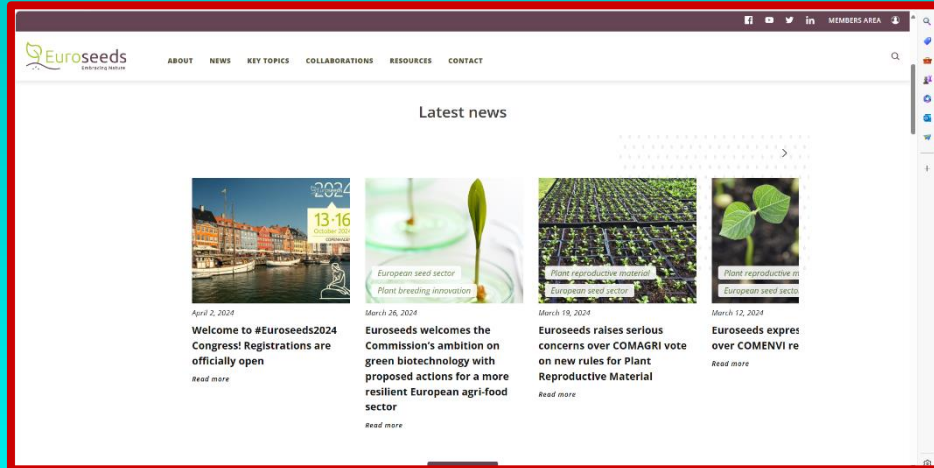
<https://www.eu-sage.eu/>



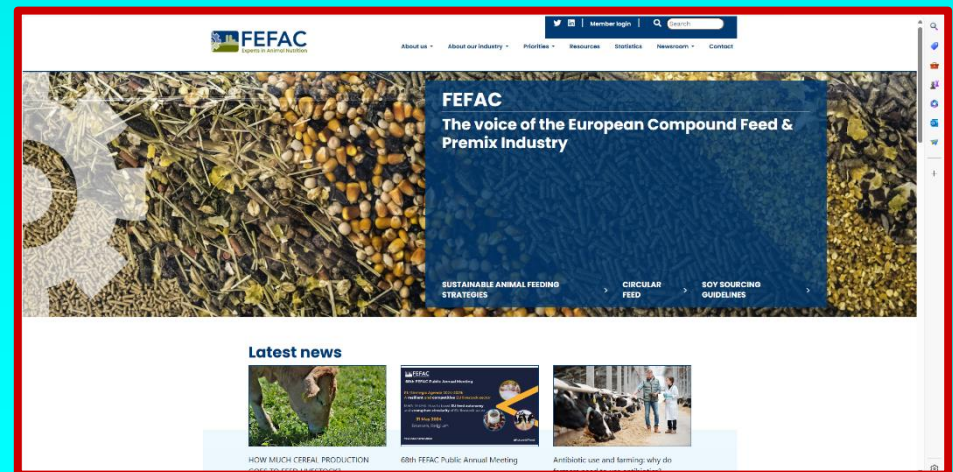
EU-SAGE is a network representing plant scientists at 134 European plant science institutes and societies that have joined forces to provide information about genome editing and promote the development of European and EU member state policies that enable the use of genome editing for sustainable agriculture and food production.

More other

<https://euroseeds.eu/>



<https://fefac.eu/>



New 2015 Directive

"Directive of the EP and of the Council amending Directive 2001/18/EC as regards the possibility for Member States to prohibit or restrict the cultivation of GMOs in their territory"

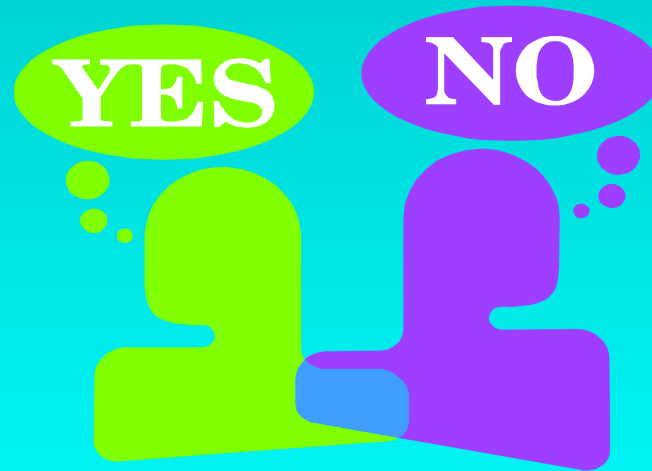
**Adopted by the European Parliament
on January 13th, 2015**

- **Member States may prohibit or restrict the cultivation of GMOs in part or all of their countries**
- **Not restrict the free circulation of EU-authorized GM seed, planting and propagating material, or affect the authorisation and risk assessment process carried out by EFSA**

Opinions of member countries

on GM food and feed, status in 2015

Czech Republic
Estonia
Finland
Netherlands
Spain
Portugal
Romania
Sweden
Belgium
Ireland
United Kingdom



Germany
Italy
Denmark

Cyprus
Luxembourg
Hungary
Poland
Austria
Greece
Slovenia
Latvia
Malta
Lithuania
Bulgaria
France
Slovakia
Croatia

Allowed for Import and Processing of GM commodities in EU

As of 31st January 2024

5 plant species

94 varieties

**Cottonwood
5 varieties**

**Maize
47 varieties**

**Rapeseed
8 varieties**

**Soya
26 varieties**

**Sugar beet
1 variety**

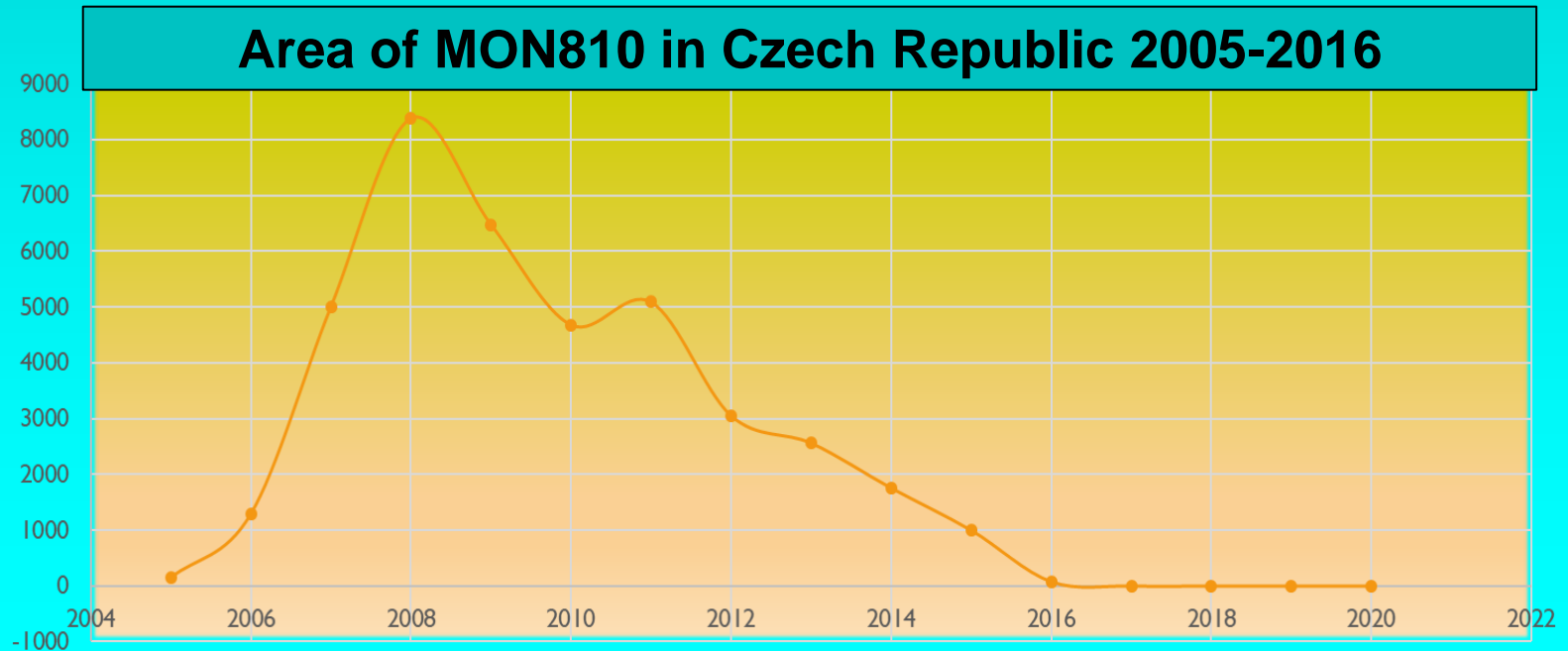
[http://ec.europa.eu/food/dyna/
gm_register/index_en.cfm](http://ec.europa.eu/food/dyna/gm_register/index_en.cfm)

Authorised cultivation of GM plants in the EU

As of 31st January 2024

1 plant species

GM corn MON810



Occurrence of GM food and feed on the EU market

Food of plant origin → **NO**

Feed of plant origin → **YES**



Food of animal origin in EU → **NO**

Food of animal origin outside of EU → **YES**

GM allowed in the world



As of 31st January 2024

32 plant species

577 varieties



<https://www.isaaa.org/gmapprovaldatabase/>

Import of GM feed into the EU

- **Conventional feed accounts for only 15% in the EU**
- **The EU is mainly dependent on protein-rich feeds - imports up to 75%**

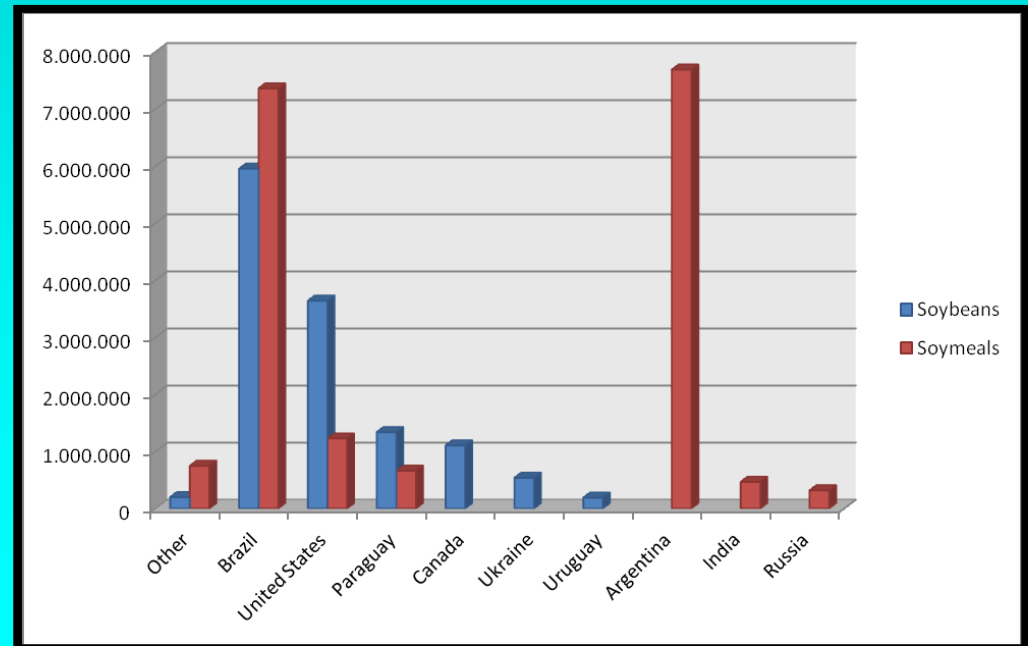


Import of GM soya into the EU

One of the most important commodities in the feed industry is soybeans

- 82% of soya produced worldwide is GM soya
- The EU produces less than 2% of its soy annually!!!
- 13 million tonnes of soya
- 18 million tonnes of soybean meal

Imports of soya beans and soya bean meal



Source: www.fefac.org

Requests regarding handling GM corn

Variety	Feature	Import and processing	Growing
NK 603	Glyphosate	YES	YES
59122	Western corn rootworm + Gluphosinate	YES	YES
GA21	Glyphosate	YES	YES
T25	Gluphosinate	YES	YES
1507	European high-flyer + Gluphosinate	YES	NO
MIR604	Western corn rootworm + Gluphosinate	YES	NO

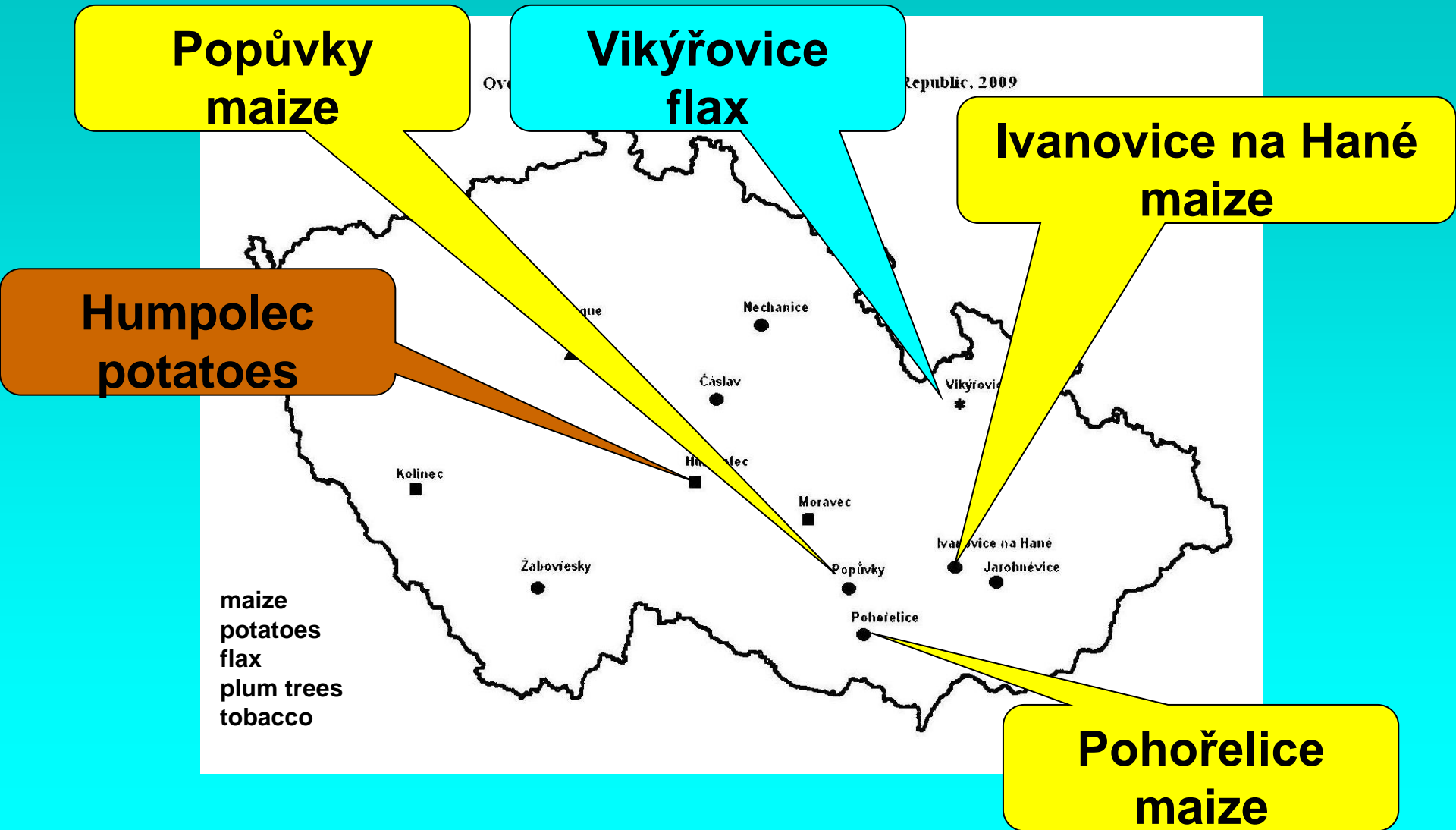
Requests for treatment with hybrids

Varieties	Feature	Import and processing	Growing
NK 603 x MON 810	European high-flyer + Glyphosate	YES	YES
1507 x 59122	European high-flyer + Gluphosinate	YES	YES
NK 603 x 1507	Western corn rootworm + glufosinát	YES	YES
MON89034 x MON88017	Western corn rootworm + Glyphosate	YES	YES
59122 x 1507 x NK 603	Western corn rootworm + Gluphosinate + Glyphosate	YES	YES
Bt11 x MIR162 x GA21	Western corn rootworm + Gluphosinate + Glyphosate	YES	YES

Other GM crops in EU – 03/2010

Crop	Feature	Mode	Using
Soya	Glyphosate	growing	-
Sugar beet	Glyphosate	growing	-
Potatoe	Starch composition	growing	industry
Rape	Glyphosate	transport	feed, industry
Rice	Gluphosinate	transport	feed, industry
Cotton	<i>Lepitoptera</i> + gluphosinate	transport	-
Gillyflower	Colour of flower + resistance to herbicide	transport	flowers

GM crops in CZ in 2009



Areas for individual crops (CZ)

Crop	Company	Area
potatoes	BASF, UEB	11.33 ha
maize	Monsanto, Pioneer, Syngenta	11.91 ha
plum trees	VÚRV	0.09 ha
flax	Agritec	0.03 ha
tobacco	UK Praha	0.002 ha

Labelling of GM food and feed

Products consisting of or containing GMOs, food produced from GMOs or feed produced from GMOs must be labelled (1829/2003):

„This product contains genetically modified organisms”

This does not apply to foods containing GMOs, the proportion of which in individual ingredients or in a single-ingredient food does not exceed 0.9%, provided that the presence of this material is adventitious or technically unavoidable.

Labelling of GM food and feed

Are medicines containing products of GM organisms correctly labelled in the Czech Republic and the EU?



Marking in other countries

- Producers in the EU, Japan, Malaysia and Australia are obliged to label products containing GMOs
- They do not need to be labelled in the USA and Canada because they do not pose a threat to human or animal health or cause environmental damage. They are considered to be normal foodstuffs.

Approach according to the characteristics of the final product not according to the technique by which it is obtained!

Livestock fed GM feed

Meat, milk, eggs and other products from animals fed GM feed do not need to be labelled because the products are indistinguishable from conventional food

After all, when an animal (or human) ingests GM feed (food), it breaks down the DNA into basic bases and uses these for its own use



GM crops available in CZ

The same situation as in the EU

- **Import of GM soya for oil production**



- **Import and growing of GM maize (different varieties) for food and feed**

What about in the world?

- **GM rapeseed** for the production of margarine and edible oils
- **GM corn** - corn flour, starch, popcorn, vegetable oils, sweeteners
- **GM soy** - bakery and meat products, tofu, tempeh, soybean oil, chocolate emulsifier
- In the USA, GM alfalfa, sugar beet, canola, papaya, pumpkin
- **GM tomatoes** and **GM peppers** in China
- In 2014, Cuba was the only country in the world where products from GM animals - Nile tilapia - are distributed



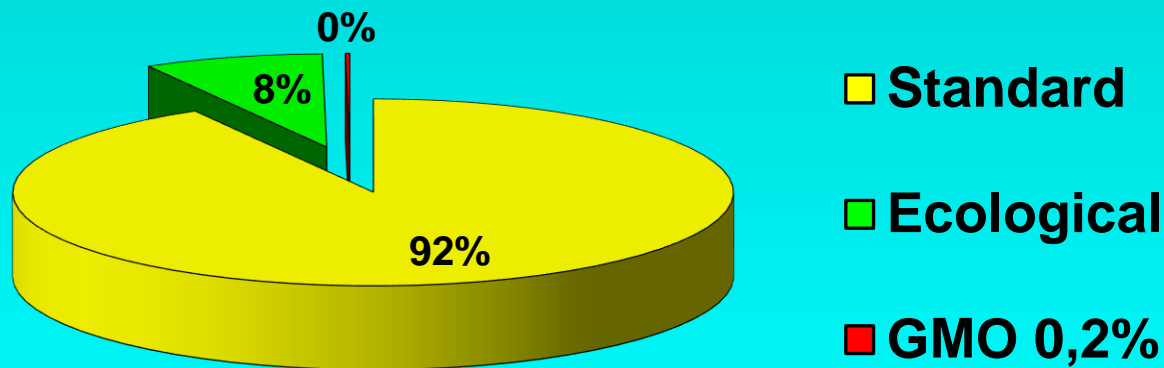
Brazil Releases Genetically Modified Mosquitoes to Combat Dengue Cases



- The British biotechnology company Oxitec developed genetically modified male mosquitoes, which carry a gene that kills female offspring before reaching their maturity
- Only female *Aedes aegypti* mosquitoes carry dengue fever and spread the virus to people
- Hence, releasing modified mosquitoes could help reduce the population of mosquitoes in the country
- Brazil placed the eggs of modified male mosquitoes in boxes with water to prompt hatching
- They complete the cycle inside these boxes in about ten days, and the adult insects come out to do their work.”
- This method could reduce the population by up to 90%.

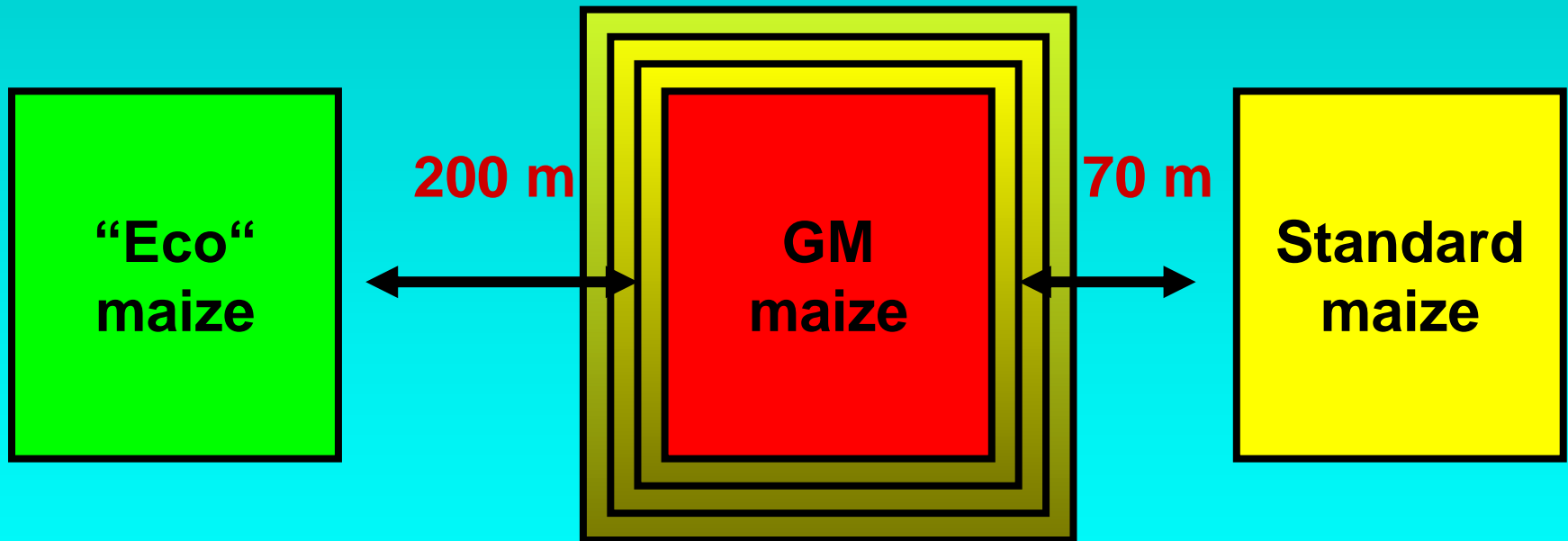
Rules of coexistence

**Farmed fields constitute an area totalling about
4 264 000 ha in the Czech Republic**



Distances between crops

Depends on “heritability” of individual crops



Sowing decreases the requested distance

Declaration of Farmers Biotech Network – 4 December 2009

Declaration appealing to European leaders to invest in green biotechnology agriculture.

The declaration states: "We demand the freedom of choice between traditional, organic and green biotechnology agriculture. We call upon the EU Commission and the European Parliament to allow us to become more competitive and more sustainable.

National governments must also provide significant political and public support to strengthen our ability to meet current and future expectations of farm productivity."

<http://www.isaaa.org/kc/cropbiotechupdate/article/default.asp?ID=5119>

The Pope and GMO ?



The Pontifical Academy of Sciences



In May 2009 on its meeting, the Academy surprisingly blessed GMO as a possible solution to the problems with starvation, safety and permanent sustainability of life in developing countries

Independent risk assessment of GMOs

European Food Safety Authority (EFSA)

Independent advisory body to the European Commission on technical matters related to GMOs

- **Provide objective, science-based advice**
- **Provide clear information based on the most up-to-date scientific knowledge and data**

EFSA GMO Panel

- **Risk assessment of GMOs**
- **Development of guidelines for the processing of applications for GMO authorisation**
- **Assessing applications for the authorisation of GM food and feed on the market**

Czech Commission for the Management of GMOs and Genetic Products

**advisory body to the Ministry of the
Environment**

Number of members: 17

**Selected professional professions + group
of external collaborators**

What does CC GMO deal with?

- Preparation of expert opinions on Notices of Disposal (dozens per year) and Applications for Environmental Release (units per year) as well as other technical matters
- Cooperation in the development of legislation, methodological guidelines and recommendations of the Ministry of the Environment
- Preparation of opinions on applications for placing GMOs on the EU market and other EU documents
- Advisory and consultative activities in communication with notifiers and applicants
- Active participation in cooperation with other Czech authorities - ČIŽP, MZd, MZe, SÚJB, SÚKL and international organisations - ENGL, EFSA, OECD, contacts with similar commissions in other countries

What does CC GMO deal with?

- **Direct cooperation with the GMO Department of the Ministry of Environment: ad hoc consultations, expert opinions on issues, participation in monitoring, etc.**
- **Ensures the highest level of expertise - organizes expert lectures, members and collaborators inform about participation in seminars and conferences, monitor the latest scientific knowledge in the field of genetic modifications - www pages**
- **Informs the public: organising public meetings, publishing minutes of meetings and opinions on current materials on the public website of the Ministry of Environment - GMO**

🏠 → Témata → Rizika pro životní prostředí → Geneticky modifikované organismy (GMO)

→ Česká komise pro nakládání s GMO

Česká komise pro nakládání s GMO

Dokumenty

■ Statut a jednací řád ČK GMO

Statut a jednací řád České komise pro nakládání s geneticky modifikovanými organismy a genetickými produkty.

GMO

Seznam členů České komise pro nakládání s geneticky modifikovanými organismy a genetickými produkty

GMO

Statut České komise pro nakládání s geneticky modifikovanými organismy a genetickými produkty.

https://www.mzp.cz/cz/ceska_komise_pro_nakladani_gmo

Seznam členů a spolupracovníků ČK GMO

Neveřejně dostupné kontakty pro členy a spolupracovníky České komise pro nakládání s

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