

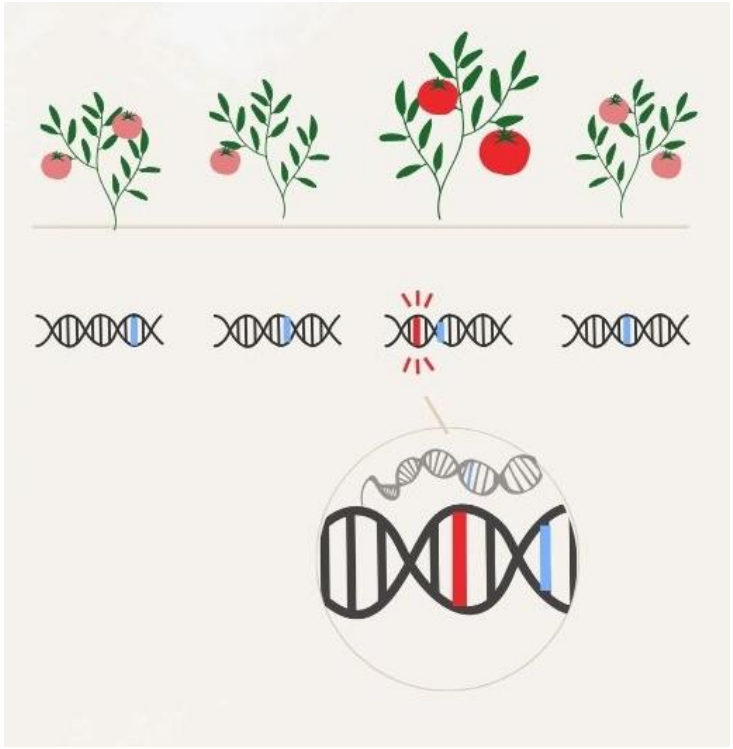
Gene Editing Regulation in the European Union

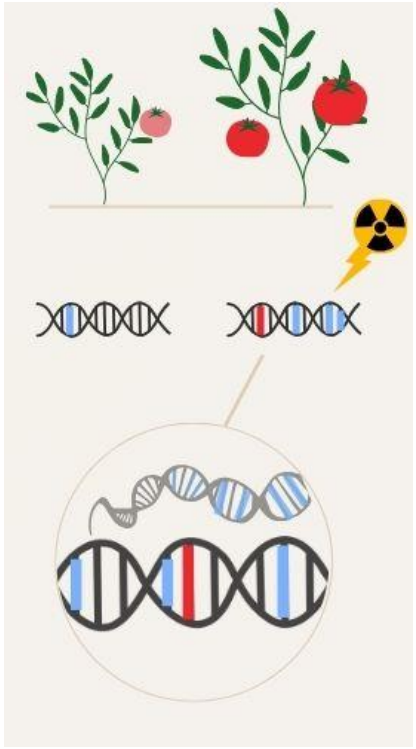
Opportunities and Challenges

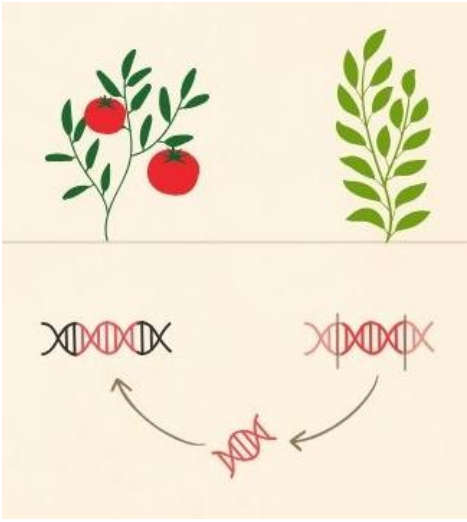
20261112 | Ania Lukasiewicz

WAGENINGEN
UNIVERSITY & RESEARCH

New Genomic Techniques - Regulation







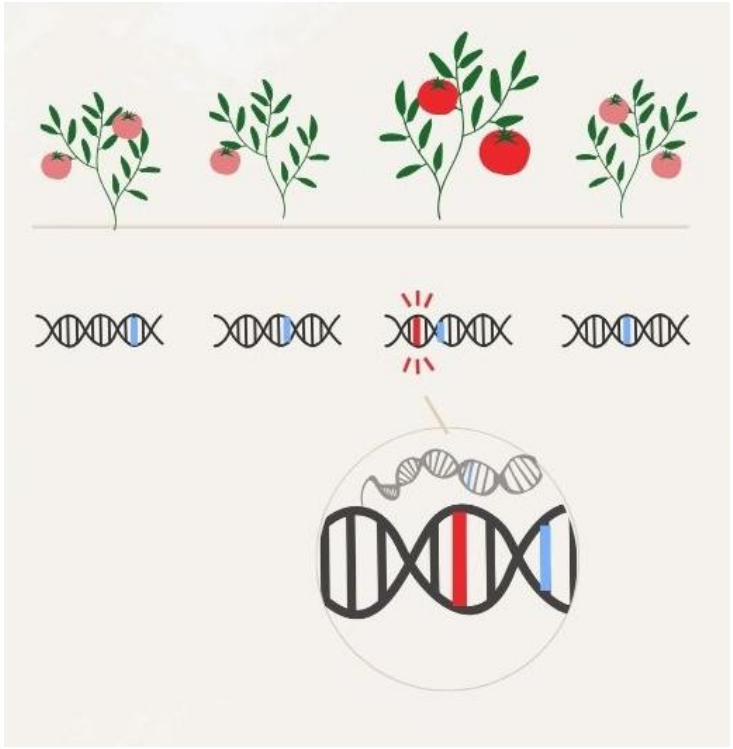
Conventional breeding

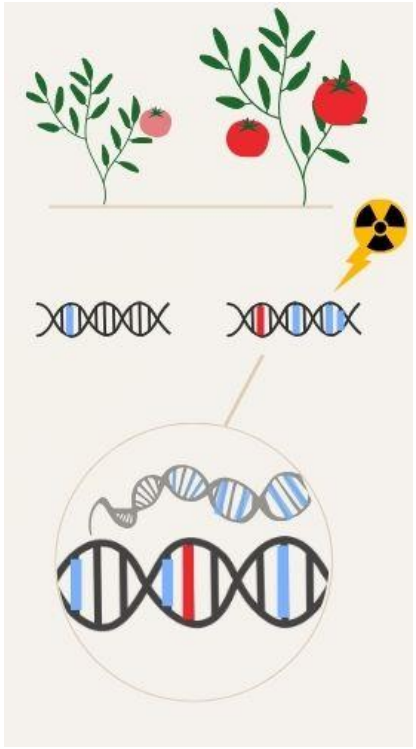
Random mutagenesis
(*in vivo and in vitro*)

Genetically Modified
Organisms (GMOs)

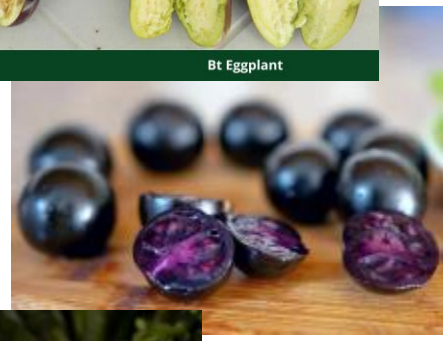
(CRAG CC-BY license)

New Genomic Techniques - Regulation



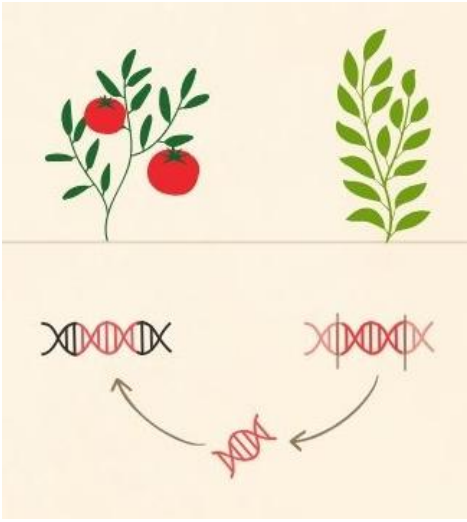












Conventional breeding

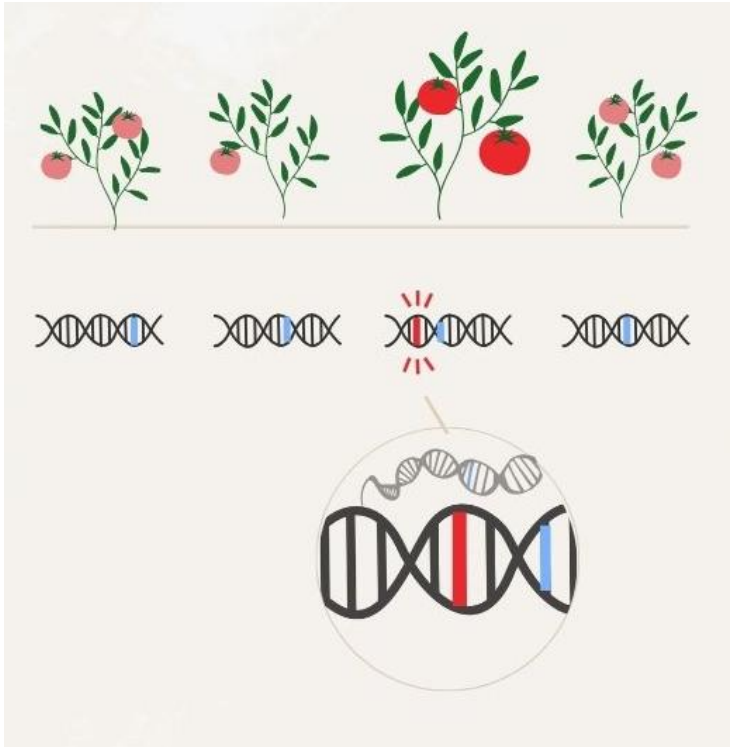
Random m
(*in vivo a*

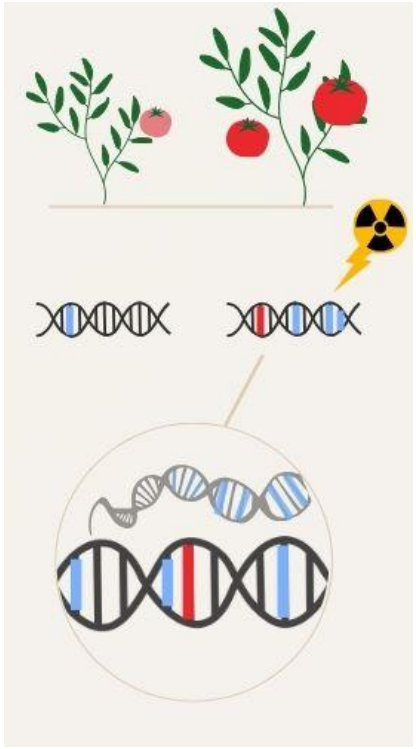


Genetically Modified Organisms (GMOs)

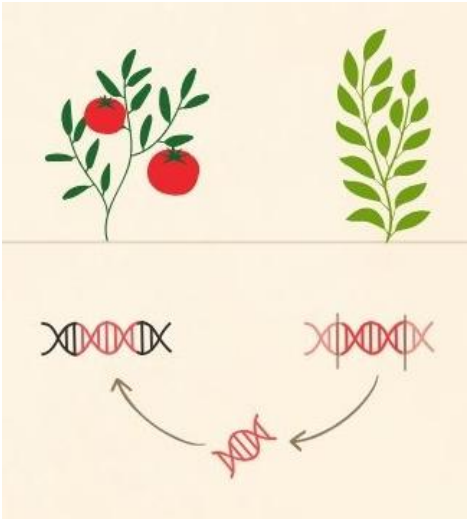
(CRAG CC-BY license)

New Genomic Techniques - Regulation









Conventional breeding

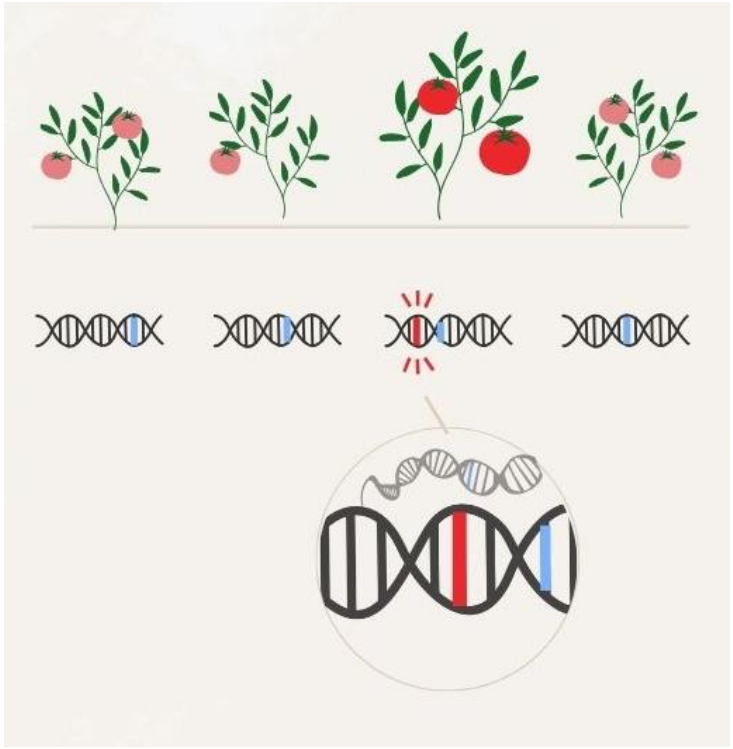
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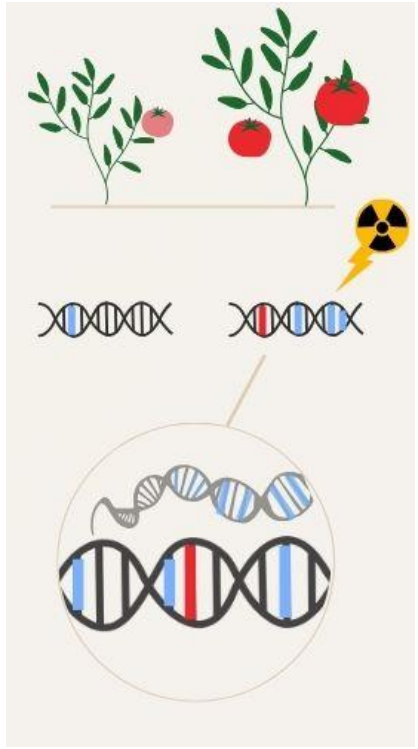
Targeted mutagenesis

Genetically Modified Organisms (GMOs)

(CRAG CC-BY license)

New Genomic Techniques - Regulation













Conventional breeding

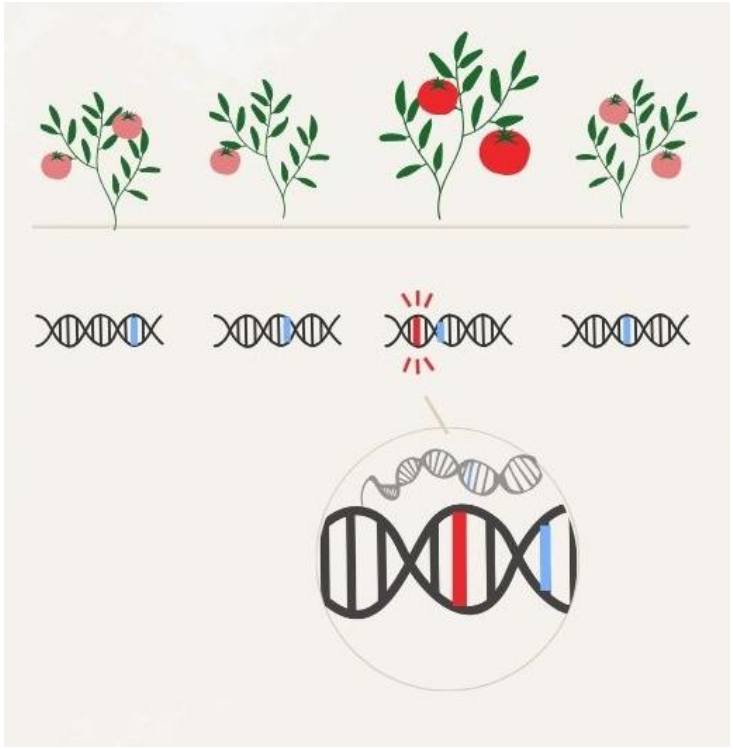
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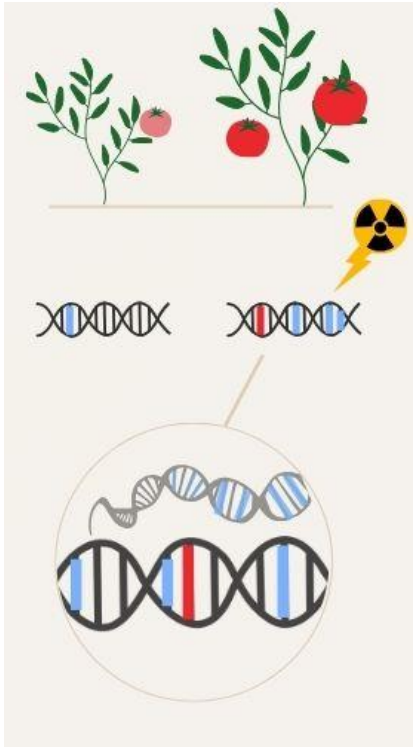
Targeted mutagenesis

(CRAG CC-BY license)

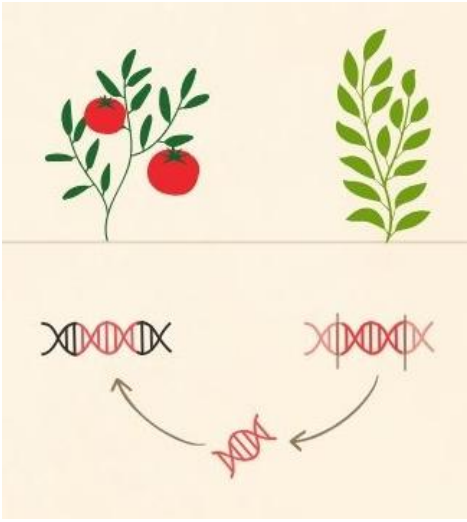
New Genomic Techniques - Regulation

GMO Directive 2001/18/EC









Conventional breeding

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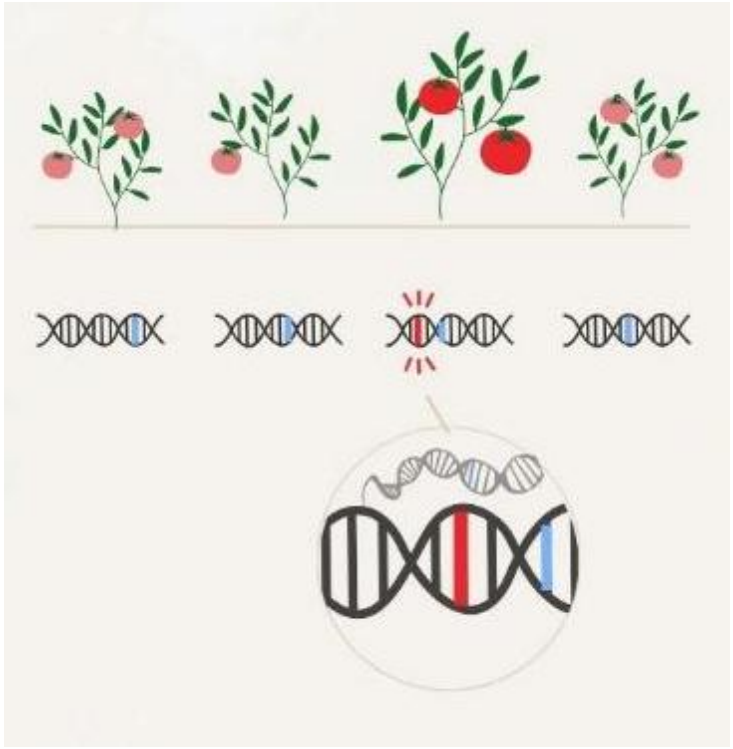
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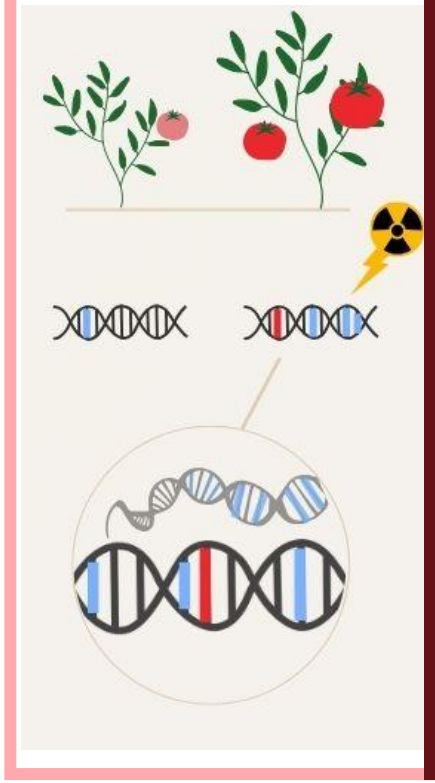
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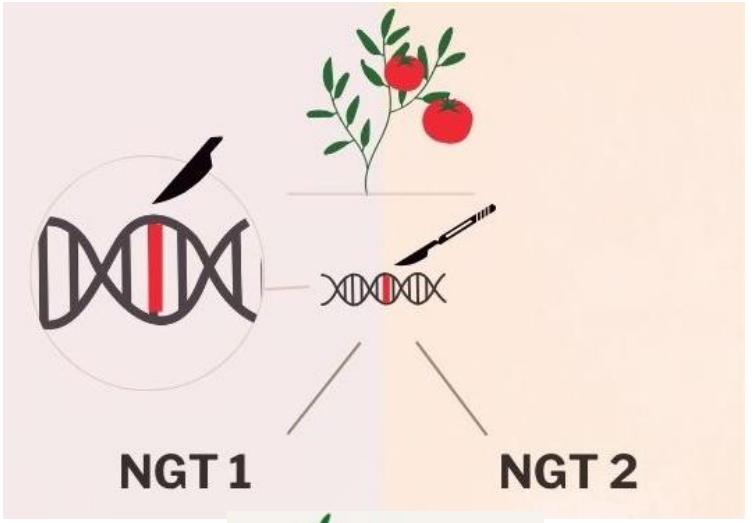
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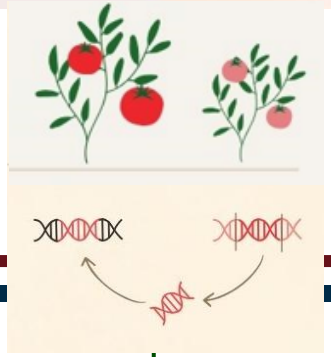
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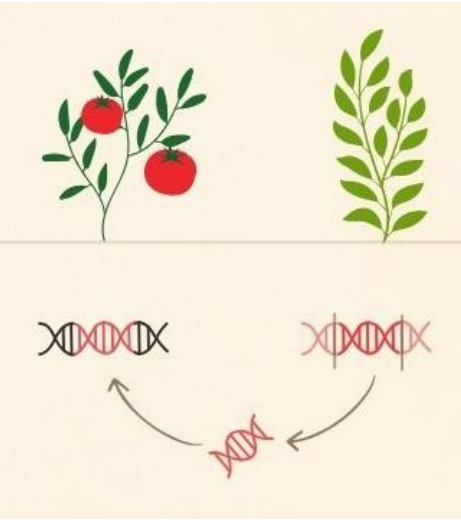
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Conventional breeding

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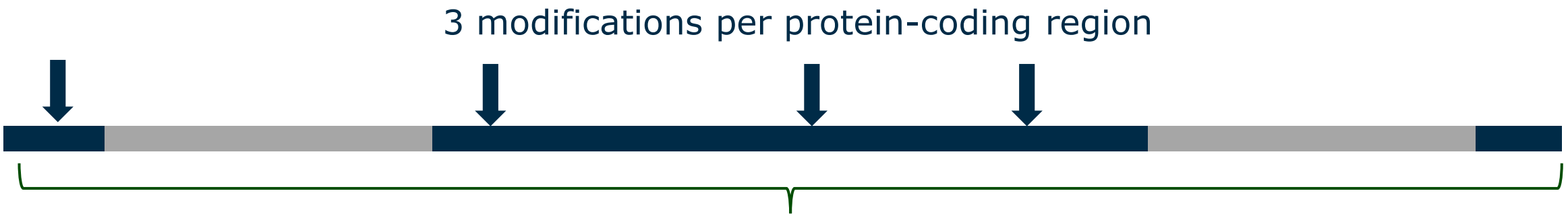
Genetically Modified Organisms (GMOs)

Exempted

Adapted regulation

(CRAG CC-BY license)

What is an NGT1 plant?



- Untargeted **cisgenesis** when combination is present in the **breeder's gene pool** and/or no endogenous gene is interrupted, including no formation of a chimeric protein
- **Herbicide-tolerant** plants and plants producing a "known **insecticidal substance**" excluded from NGT cat. 1
- Provide information on existing and pending **patents**
- **Labelling** of seed and reproductive material of NGT cat. 1 (also after crossing)
- Not for **organic** agriculture

Overview of new GGO framework

Requirements GGO Directive 2001/18/EC

	Conventional breeding	Exempted (random mutagenesis protoplast fusion, etc.	cat. 1 NGT	cat. 2 NGT	GMO (transgenic)
Risk assessment	−	−	−	+	+
Detection method	−	−	−	+	+
Labelling	−	−	+ (only PRM)	+ (+ trait)	+
Coexistence	−	−	−	+	+
Opt-out cultivation	−	−	−	+	+
Organic agriculture	✓	(✓)	✗	✗	✗

Research and market approval

Registration from July 2028

Decision-making process NGT in the EU

European Commission



Council of the EU



European Parliament



2001
EU GMO Directive
2001/18/EC

July 2018
CJEU ruling

Discussion on cisgenesis

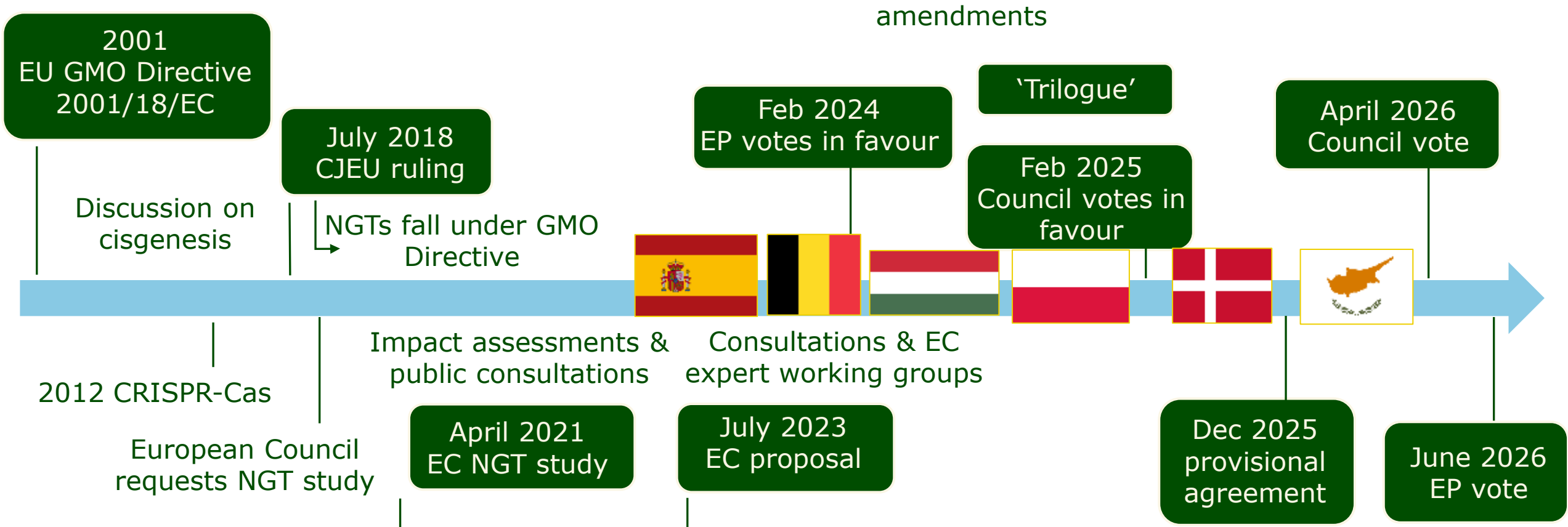
NGTs fall under GMO Directive

2012 CRISPR-Cas

European Council requests NGT study

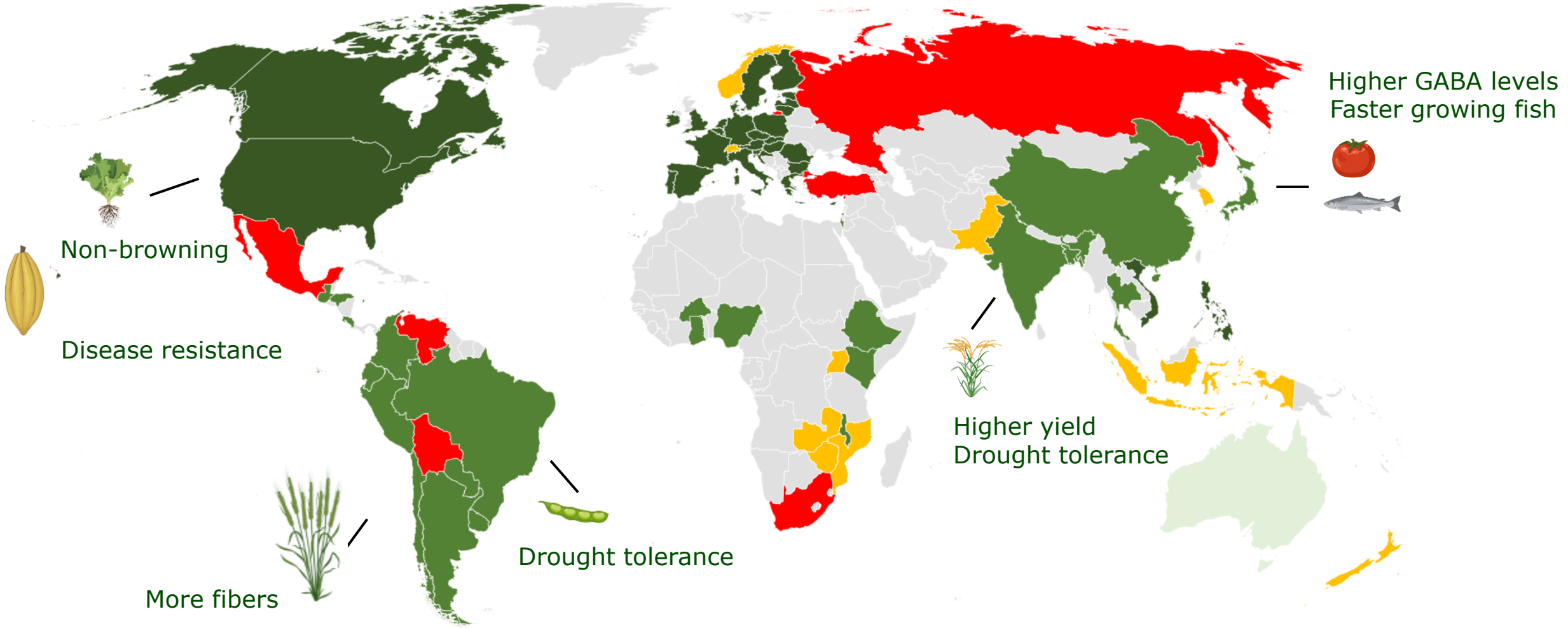
EC = European Commission
EP = European Parliament
Council = Council of the EU

Decision-making process NGT in the EU



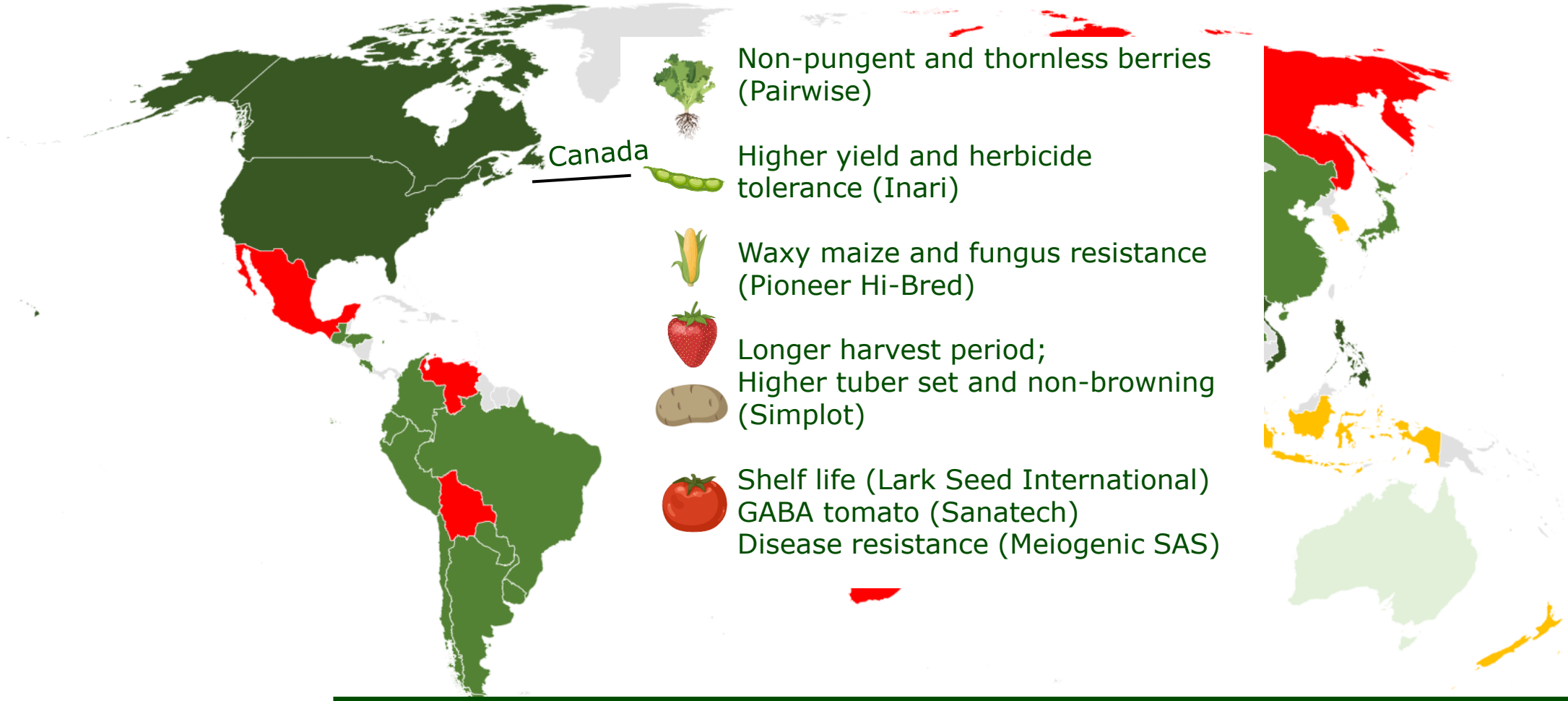
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Gene editing regulation worldwide



→ https://cropgeregulations.com/maps

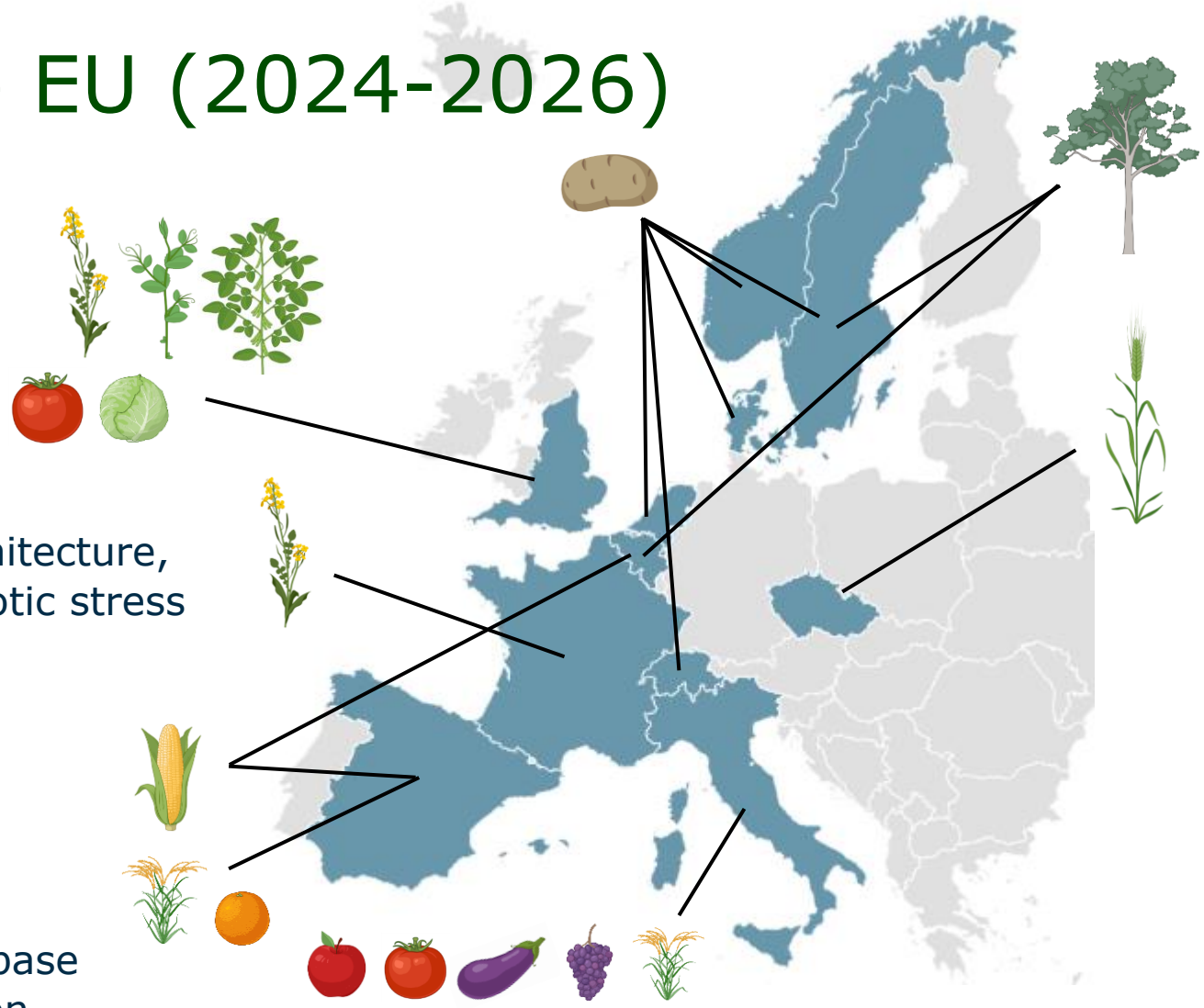
Gene editing regulation worldwide



→ Health Canada database; List of non-novel products of plant breeding for food use

Field trials in the EU (2024-2026)

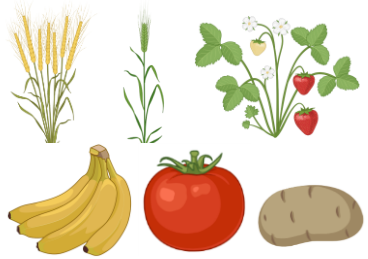
And the UK (2026)



→ Disease resistance, plant architecture, nutrient composition/levels, abiotic stress resistance (drought)

→ Experimental Releases Database European Commission; Precision Breeding Registry (UK)

Marketing notices UK (2026)





- **bread wheat** – reduced asparagine concentration in the grain
- **barley** – higher lipid content for animal feed
- **banana** – longer shelf life (non-browning)
- **tomato** – increased accumulation of pro-Vitamin D in leaves and fruits
- **strawberry** – longer harvest period
- **potato** – disease resistance (*Phytophthora* and viruses)

→ Precision Breeding Registry (UK)

Field trial 2026





Field trial 2026









DuRPh project: field trials 2005-2015

Durable resistance against *Phytophthora*

Untreated + 1 R gene Chemical protection

Aveka

Desiree

Premiere



Consumer acceptance of gene editing technologies

Norwegian study 2022

Most have not heard about gene editing…



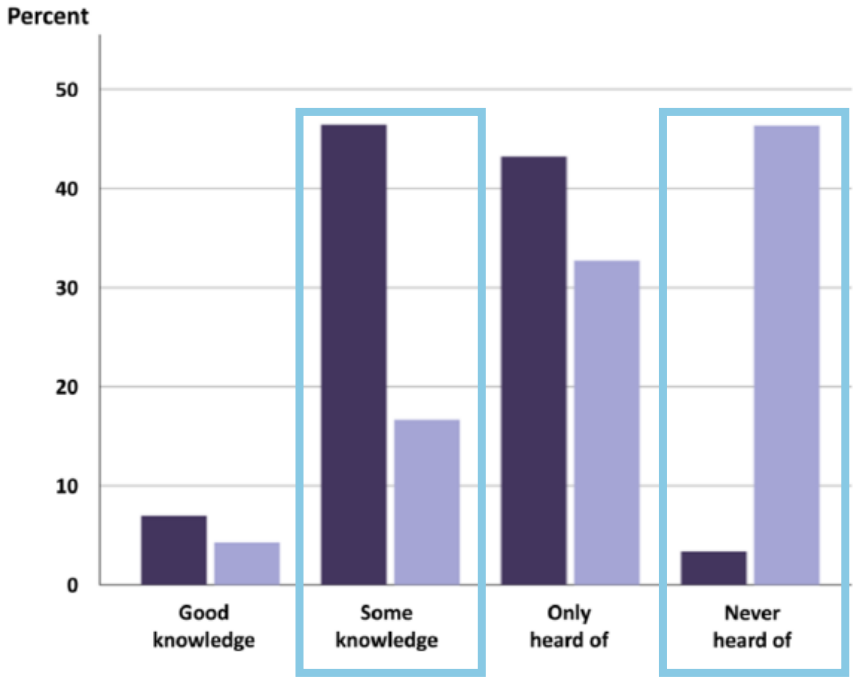
Figure 1: Consumers' knowledge of genetically modified food is significantly better than their knowledge of gene editing (CRISPR). Results from the total sample, N=2016.

(Norwegian Biotechnology Advisory Board)

Consumer acceptance of gene editing technologies

Norwegian study 2022

Most have <u>not</u> heard about gene editing…



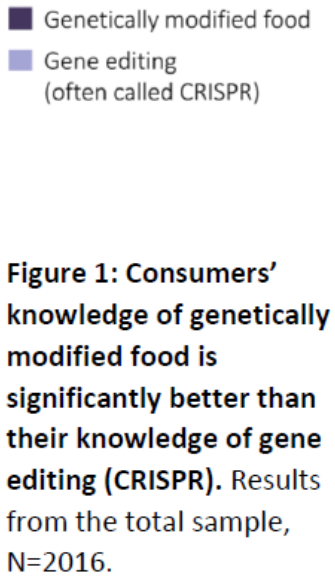
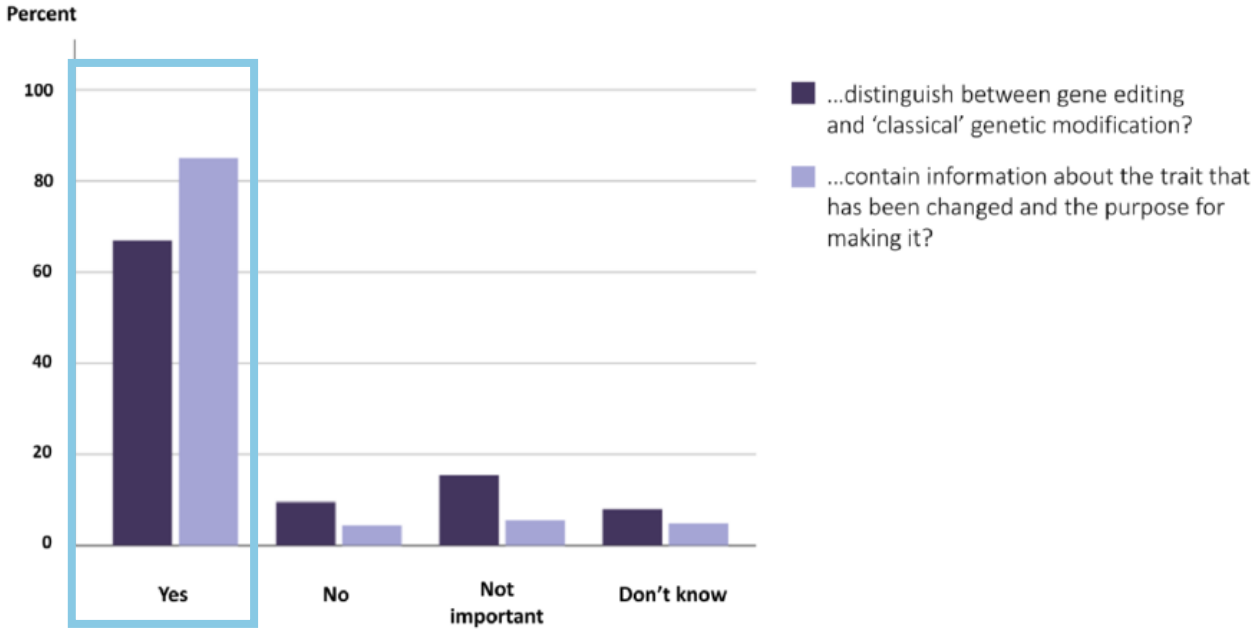


Figure 1: Consumers' knowledge of genetically modified food is significantly better than their knowledge of gene editing (CRISPR). Results from the total sample, N=2016.

They <u>do</u> want the products to be labelled

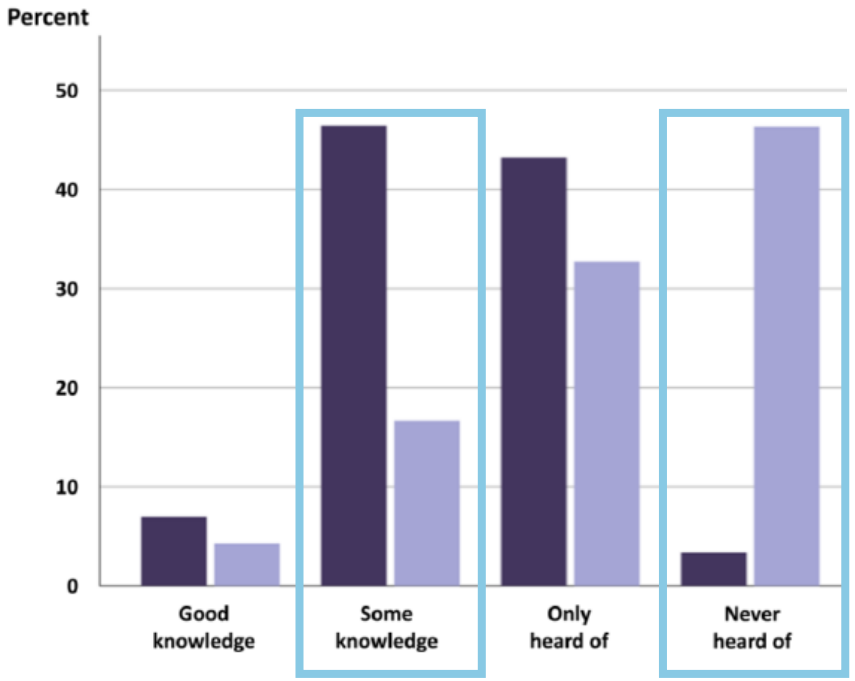


(Norwegian Biotechnology Advisory Board)

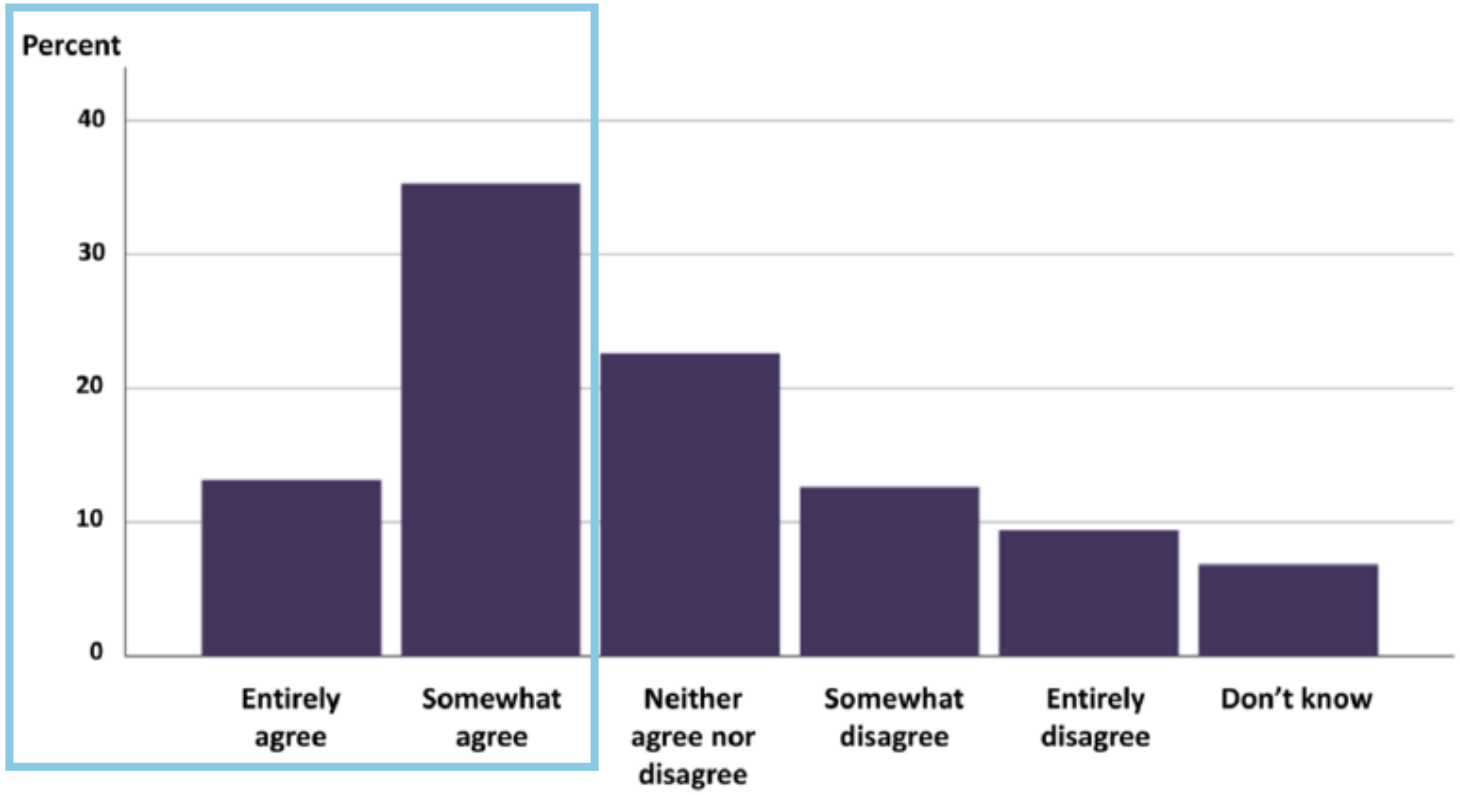
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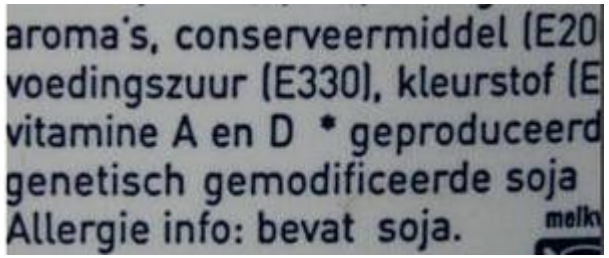
To what extent do you agree or disagree with the following statement: It can be unethical not to use gene editing in crop plants and livestock if it can contribute towards solving important societal challenges, such as climate adaptation of crops.



(Norwegian Biotechnology Advisory Board)

Labelling of genetically modified food

GMO-labels


aroma's, conserveermiddel (E20
voedingszuur (E330), kleurstof (E
vitamine A en D * geproduceerd
genetisch gemodificeerde soja
Allergie info: bevat soja.

GMO-labelling in the Netherlands



Non-GMO labelling (DE)



Bioengineered label (VS)
→ for GMOs!



Organic labelling (EU)

Databases: USDA (list of bioengineered food = GMO); Health Canada (list of non-novel food); EC experimental releases database; Precision Breeding Register (UK)

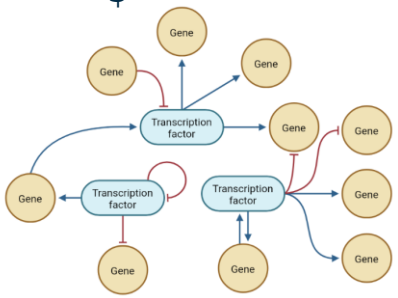
What are the challenges?



Gene editing is often the "easy" part

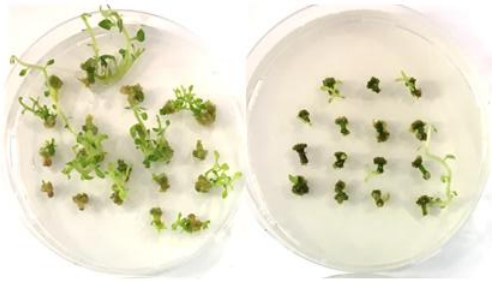
Licenses on the CRISPR technology

→ Develop your own enzyme or buy a license



Which genes do you need to modify?

→ Gene networks are involved in complex traits



Regeneration of plant cells after gene editing

→ Variation in regeneration between crops and within crop



Plant Variety Rights (EDVs) or patent rights?

→ How do you protect the new trait?

(Seed World)

Thema: ingrediënten

Verborgen [redacted] ingrediënten

Etiketteer genetisch gemodificeerd voedsel!

Het Europese debat rondom genetisch gemodificeerde gewassen

'Verknipt' of ziekteresistent voedsel?

De Europese Raad stemde afgelopen april met een gekwalificeerde meerderheid in met de geplande versoepeling van de regels rondom 'Nieuwe Genomische Technieken' (NGT) voor landbouwgewassen. De definitieve stemming in het Europees Parlement moet nog plaatsvinden.

Genetisch gemodificeerd voedsel in de supermarkt: Ja of nee? Het wetsvoorstel voor de versoepeling ligt al een paar jaar op de plank en heeft veel losgemaakt in Europa. Na jarenlang onderhandelen, lobbyen, tegenprotesten en campagnevoeren, lijkt die versoepeling er dan toch te komen. Een WUR-onderzoeker en de directeur van het biologisch dynamische keurmerk Demeter delen hun uiteenlopende kijk op de wet en mogelijke consequenties voor consument, zaadveredelaar en bedrijf.

modificaties. Grote aanpassingen waarbij vreemd dna wordt gebruikt om nieuwe gewassen te maken, transgene ggo's genoemd, blijven onder de strenge ggo-regelgeving vallen. De versoepeling maakt het makkelijker om vooral NGT-1-planten en producten in Europese supermarkten te introduceren. Dit kan nu ook voor ggo ge wassen, maar de aanvraag is een langdurig en prijzig traject. Slechts één ggo-gewas, insecten-resistente maïs, heeft op dit moment de autorisatie voor teelt in Europa. Er is wel import van ggo-gewassen en producten in de EU, voornamelijk bestemd voor veevoer.

tisch materiaal van planten gerichter aanpassen, waardoor veredeling sneller gaat."



FOTO: DAAN DE HOOP

▲ Ania Lukasiewicz leidt een veldproe
aardappelen met resistente genen veel minder pesticiden te spuiten."

Dangerous?

Organic farming?

Consumer acceptance?

Licensing (technology/trait)?





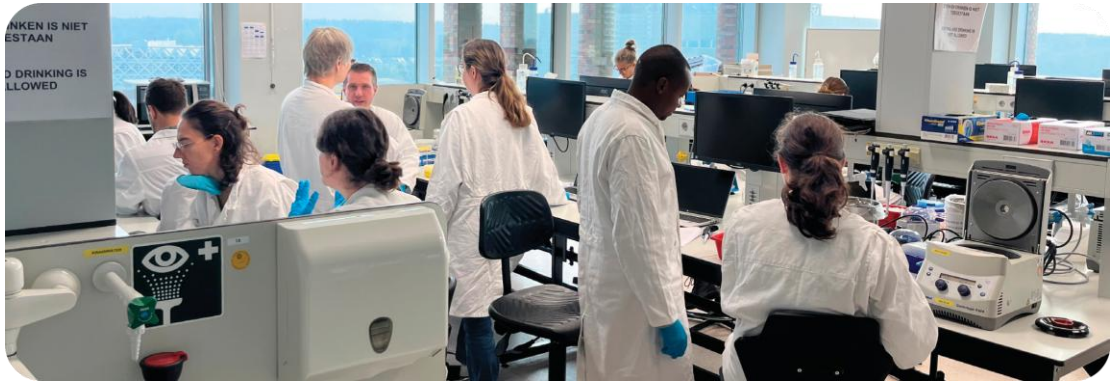
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Continuing Education @WUR
Hands-on Course CRISPR-Cas in Plants



Key details

- ✓ 6-days course on Wageningen Campus
- ✓ 27 Jan – 3 Feb 2027
- ✓ Lectures, hands-on practicals and group work on case studies based on your crop & traits
- ✓ Network with industry peers and experts from Wageningen Plant Research
- ✓ Awarded with Certificate

All steps needed for successful gene editing including Practical Lab Experience

More information & enrolment



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