



Julius Kühn-Institut

Bundesforschungsinstitut für Kulturpflanzen
Federal Research Centre for Cultivated Plants

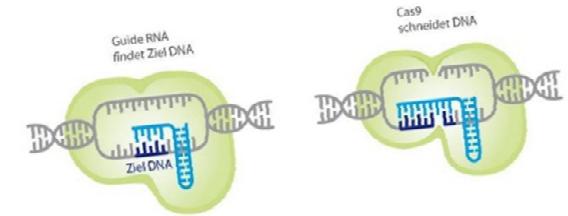
Wie CRISPR ist die Zukunft der Pflanzenzüchtung?

Ralf Wilhelm, Frank Hartung, Thorben Sprink



Fortschritte in der Krankheitsbekämpfung und Resistenzzüchtung bei landwirtschaftlichen Kulturpflanzen
11. bis 12. April 2022 im Kolpinghaus in Fulda





JKI

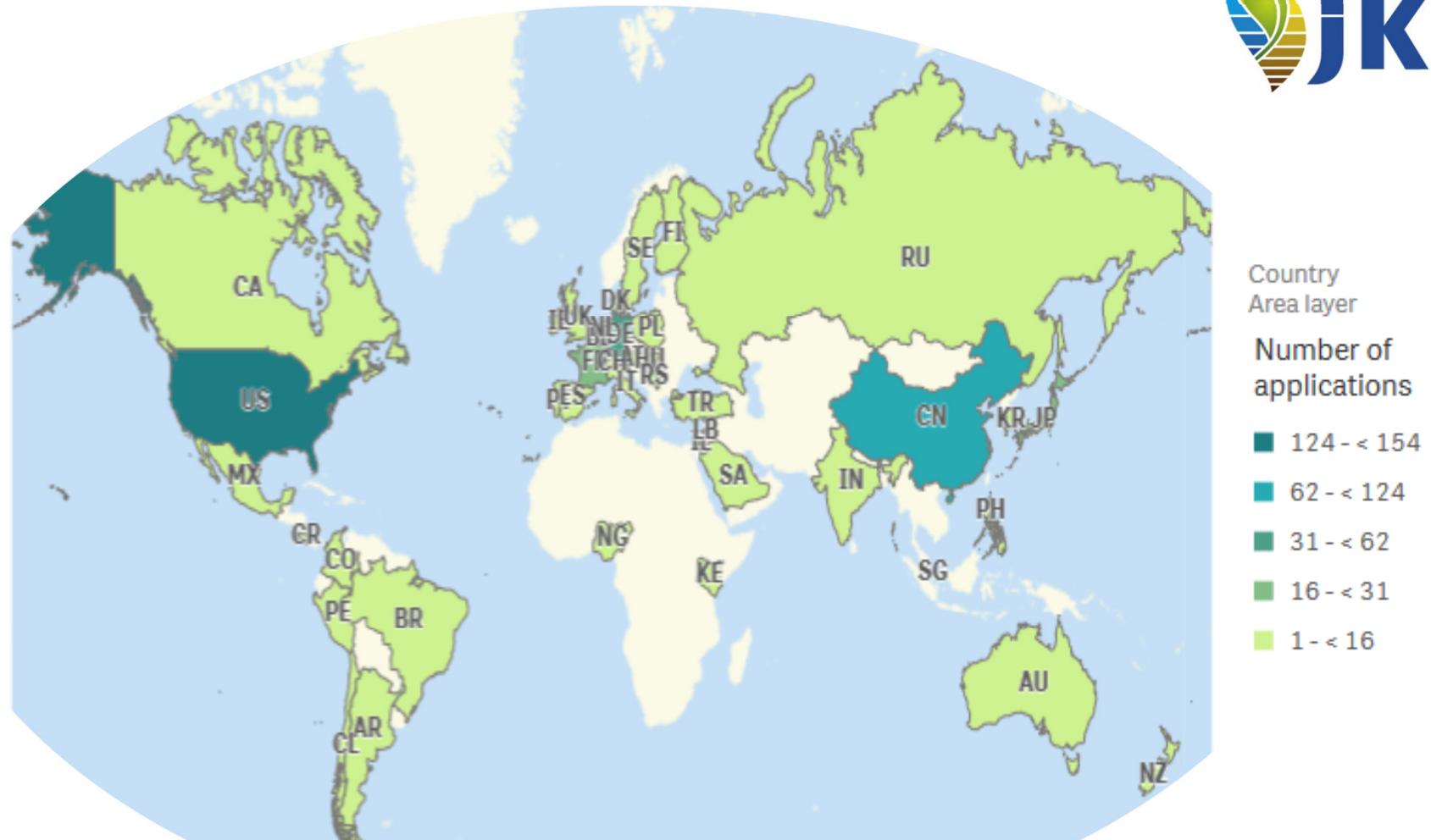


gpz
Gesellschaft für Pflanzenzüchtung e.V.

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DPG

The genome editing landscape 2021: 427 applications on plants

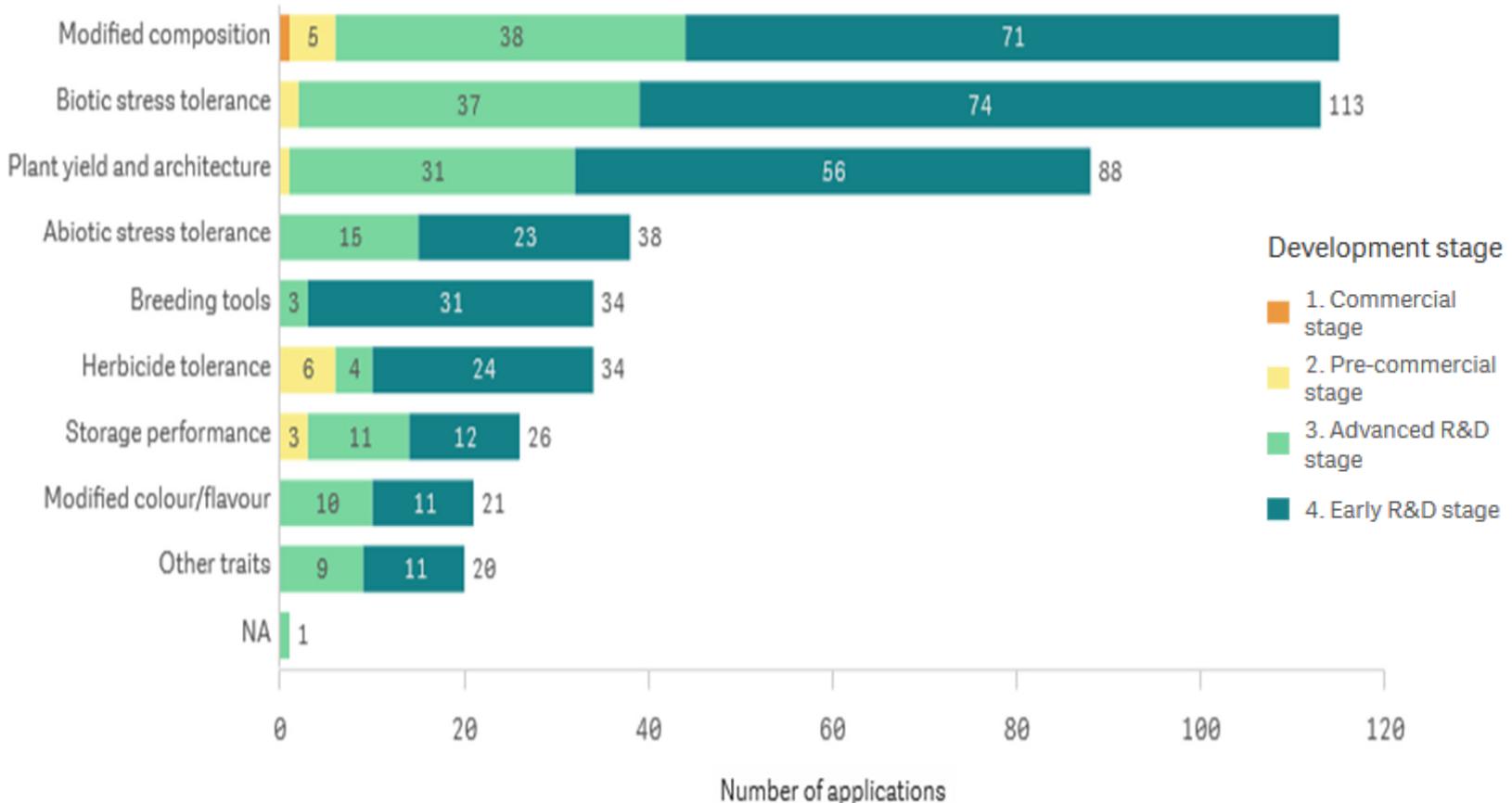


Web dashboard at this link:

https://datam.jrc.ec.europa.eu/datam/embed/NEW_GENOMIC_TECHNIQUES/

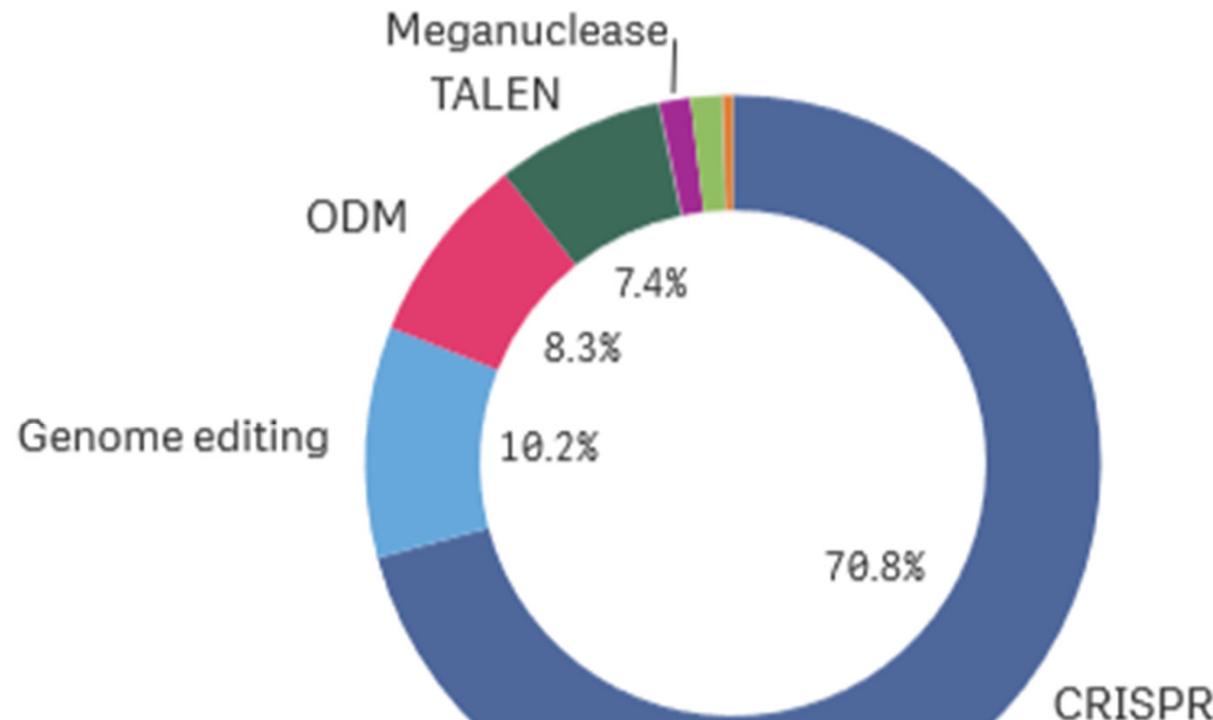
427 applications on plants

Traits and development stage

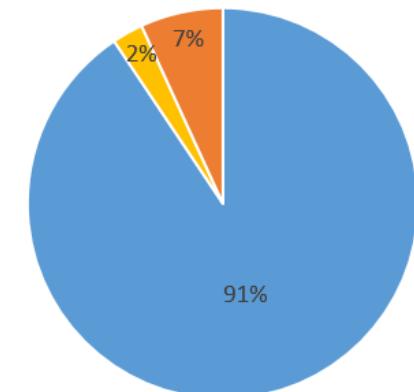


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Technique share 2021: 427 applications on plants



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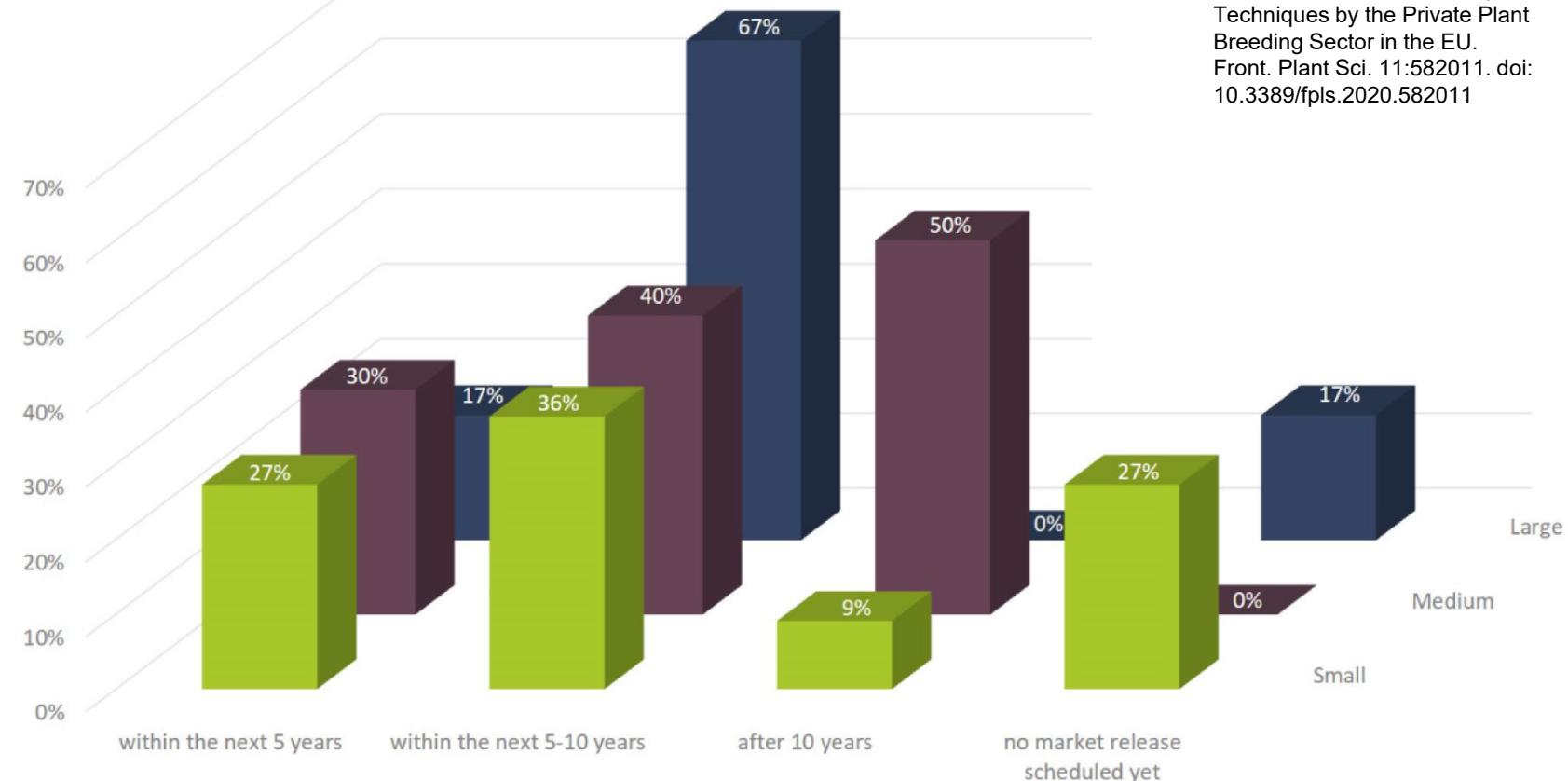


(2019, Modrzejewski et al.)

The pipeline (2020)

A

When will your company most likely bring varieties resulting from NBTs to the market (globally)?



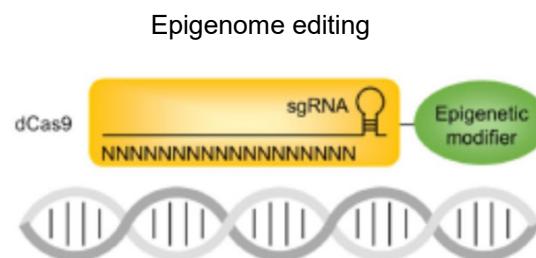
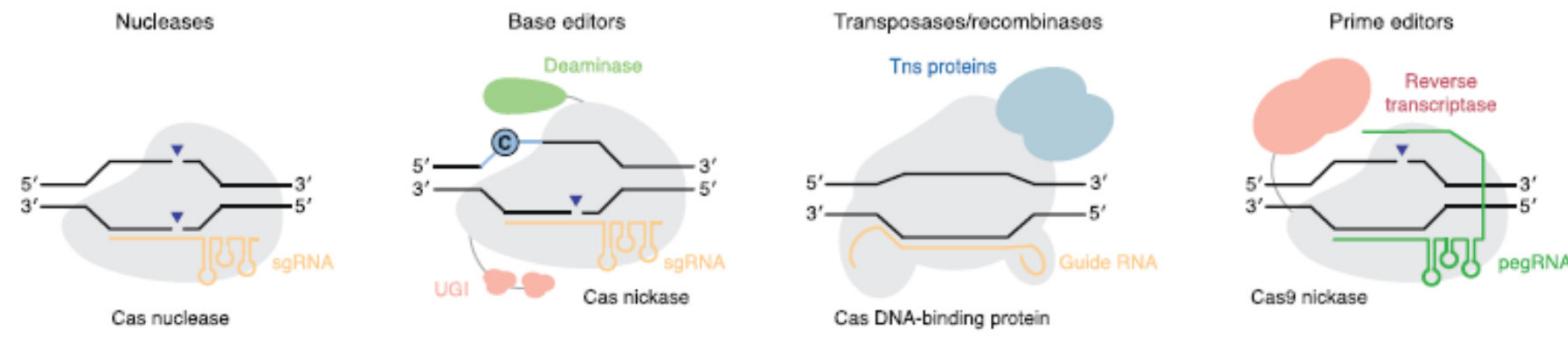
Jorasch P (2020) Potential, Challenges, and Threats for the Application of New Breeding Techniques by the Private Plant Breeding Sector in the EU.
Front. Plant Sci. 11:582011. doi: 10.3389/fpls.2020.582011

Field releases of genome edited plants in Europe (2022)



- | | | |
|---------------------|----------|--|
| 1) UK (2019): | Cabbage | S-Metabolism |
| 2) Belgium (2019): | Maize | DNA-repair ko |
| 3) UK (2019): | Camelina | fatty acid metabolism (CRISPR/Cas and transgenesis) |
| 4) Sweden (2019): | Potato | reduced amylose |
| 5) Spain (2020): | Tobacco | delayed flowering |
| 6) Sweden (2020): | Potato | fungi resistance (S genes) |
| 7) Spain (2021): | Tobacco | flowering, prolonged juvenile phase, alkaloids reduction |
| 8) Sweden (2021): | Potato | fungi resistance (S genes) |
| 9) UK (2021): | Wheat | reduced asparagine |
| 10) Sweden (2022): | Poplar | reduced lignin content |
| 11) Spain (2022): | Broccoli | stress tolerance to salinity and drought |
| 12) Belgium (2022): | Maize | growth under stress |
| 13) Belgium (2022): | Maize | reduced lignin content |
| 14) Belgium (2022): | Maize | drought tolerance |

CRISPR/Cas-Evolution



- ⇒ more precise
- ⇒ more flexible use
- ⇒ broader applications

Breeding – time afforts - application and applicability of genome editing

Plants	Conventional breeding	Biotechnology in plant breeding (T= Transgenesis only/classical GMP)				*) „introgression“ of a beneficial trait in a target genome for further breeding
		Time effort*	Applicability	Time effort*	Climate	
Wheat	8-15 years	X		2 - 3 years	X	X
Rye	8-15 years	-		-	-	-
Potato	[10–15 years]	X		3 - 4 years	X	X
Canola	8-20 years	X		2 - 3 years		X
Pea	3-6 years	X		2 - 3 years		T
Grapevine	10-20 years	X		2 - 3 years		X
Apple	20-40 years	T, x ⁺		2-3 years; T/FB: 8-11 years		T, FB
Sour cherry	15-30 years	-		-	-	-
Asparagus	10-15 years	X		4+? years		
Tomato	3-6 years	X		2-3 years		X

Berichte aus dem JKI 215 (2021)

Ruling of the Court of Justice of the EU, 25th July, 2018



Picture: Court of Justice of the European Union

- All organismen generated by mutagenesis are GMO.
- Organisms generated by targeted mutagenesis underly the strict regulations and are not exempted from any obligations.

Ruling of the Court of Justice of the EU, 25th July, 2018



Picture: Court of Justice of the European Union

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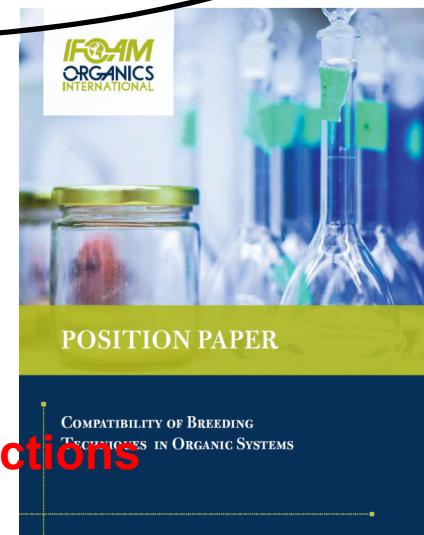


Reactions

Suggestions to **modify regulation asap**
(science organisations, some MS)

or

keep **strict legal restrictions**
(organic sector, some MS)



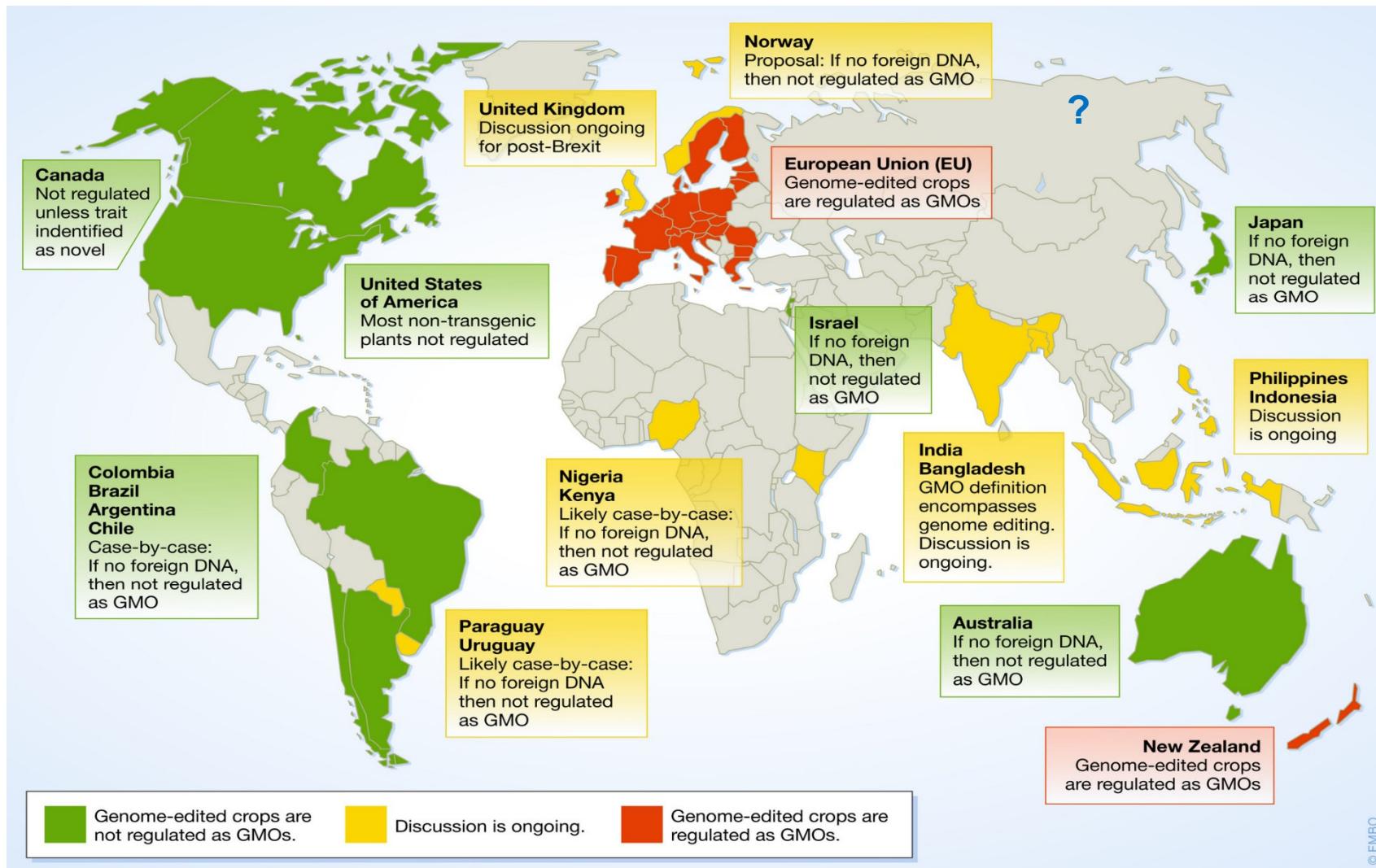
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The regulatory landscape for genome editing in plants (2020)



EMBO Rep, Volume: 21, Issue: 6, First published: 19 May 2020, DOI: (10.1525/embr.202050680)



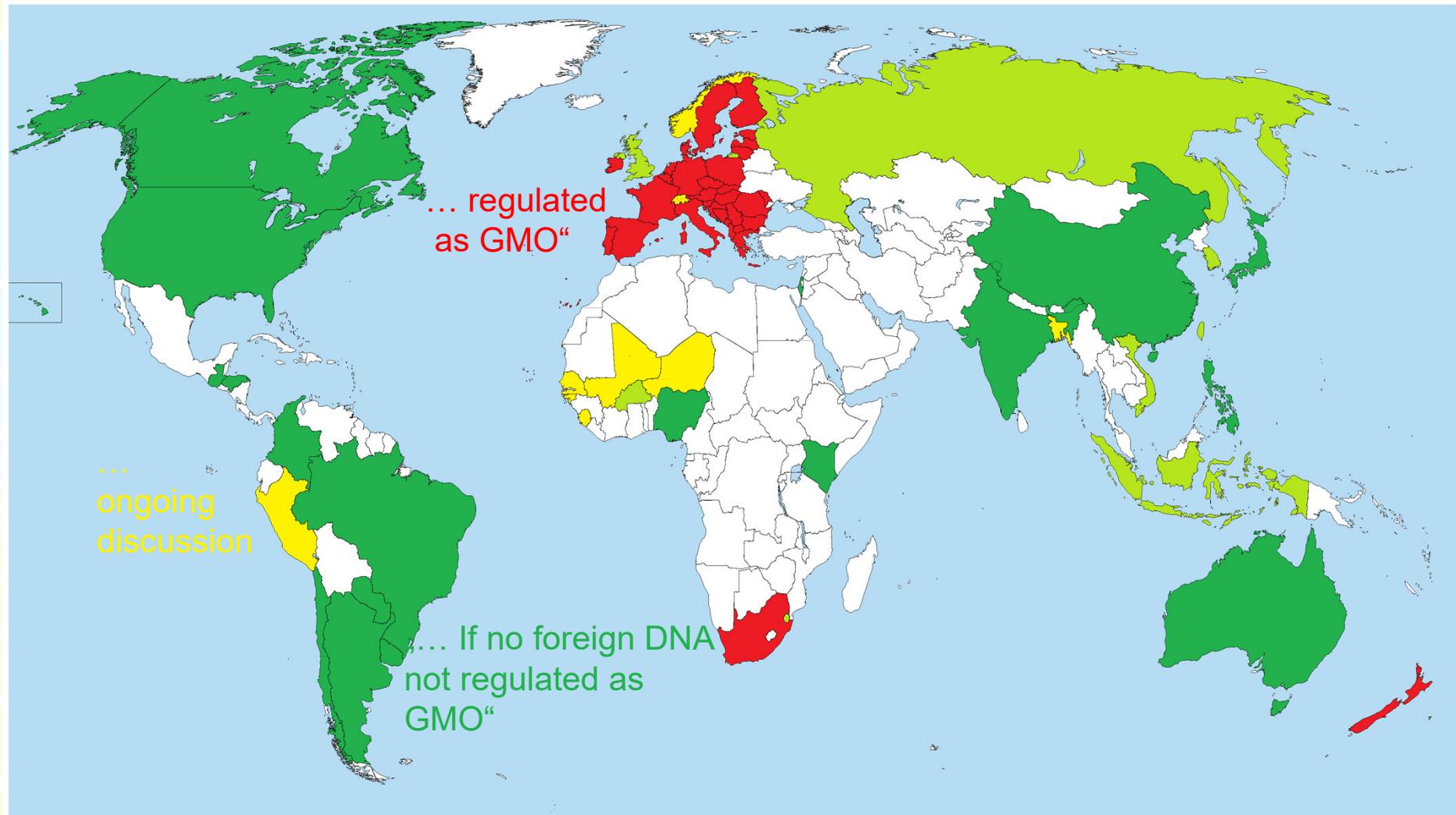
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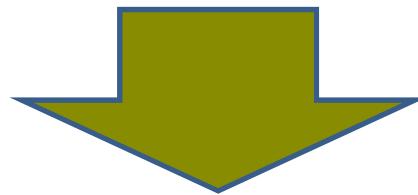
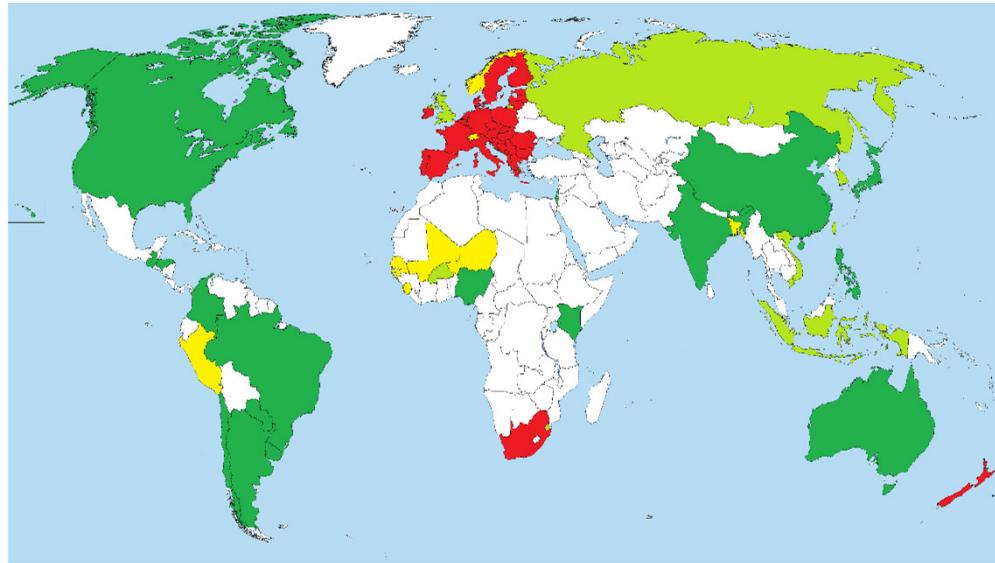


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The regulatory landscape for genome editing in plants (March 2022)





Challenge to EU-law enforcement in international trade:

- Detection of un-authorised imports.



Assessment of the Real-Time PCR Method Claiming to be Specific for Detection and Quantification of the First Commercialised Genome-Edited Plant

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Received: 10 November 2021 / Accepted: 21 February 2022

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Abstract

A real-time PCR method was recently published with a claim to be specific for the detection and identification of some genome-edited oilseed rape (OSR) lines commercialised in North America. The method was designed to detect a single base mutation in the AHAS1C gene, which confers herbicide tolerance. The authors claim that the method is event-specific for the genome-edited OSR line 5715 and fulfils all requirements for GMO analytical methods according to EU regulations. We have thoroughly assessed the method in relation to the minimum performance requirements (MPR) established by the European Network of GMO Laboratories (ENGL). The method was found to be sufficiently sensitive and robust when tested with pure genomic DNA of the OSR line 40 K. However, our results show that the method is not event-specific and detects also OSR lines carrying the same point mutation caused by somaclonal variation. Moreover, impaired robustness was observed using non-modified genomic DNA at the amount specified in the original protocol. Significant non-specific PCR amplifications with PCR products as non-target template DNA and with genomic DNA from numerous OSR varieties as well as from wild radish were found by three ISO/IEC 17025 accredited reference laboratories in tests using different master mixes and PCR cycler models. The assessment shows that the method does not meet the MPR for qualitative PCR methods and therefore is not fit-for-purpose for official controls of genetically modified products in the EU. Suggestions are provided for conditions under which analytical methods for genome-edited organisms should be validated.

Keywords Genome editing · Official control · SU canola · Oilseed rape (OSR) · GMO · Detection

Study of the European Commission about the impact of the CJEU ruling



Conclusions on possible follow-up

- ✓ Confirm whether and how adaptation is needed in order for the legislation to be resilient, future-proof and uniformly applied.
- ✓ Aim at enabling NGT products to contribute to sustainability, in line with the objectives of the European Green Deal, the Farm to Fork and Biodiversity Strategies, while addressing concerns.
- ✓ The Commission plans to initiate policy action on plants derived from targeted mutagenesis and cisgenesis.
- ✓ NGT applications in the agricultural sector should not undermine other aspects of sustainable food production, e.g. as regards organic agriculture.
- ✓ Address knowledge gaps identified in this study. More effort should be made to inform and engage with the public and assess their views.

Policy initiative by COM to Change the GMO regulation

Study of the European Commission about the impact of the CJEU ruling

Inception Impact Assessment (Roadmap)

Public consultation

Impact assessment of policy options

Public consultation

Impact assessment of policy options & Legislative proposal

2023

30.4.
2021

24.9.
2021

24.9.-
22.10.
2021

Q2
2022

Q2
2023

Questionnaire;
Consultation probably
April/May 22

Actual legislative proposal

Steadily increasing application of genome editing
in plant research and breeding



Progressive international legal liberation

Gain field data about promoted applications/use cases.

Substantially more market releases expected in the next 5 to 10 years

... challenges European GMO law (enforcement)
... and organic certification or value chains

Current policy actions by EU-COM for

- Legislation for plants produced by certain new genomic techniques
- Legislative framework for sustainable food systems
- Revision of the plant and forest reproductive material legislation