Towards a scientifically justified, differentiated regulation of genome edited plants in the EU

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German National Academy of Sciences Leopoldina
Union of German Academies of Sciences and Humanities
German Research Foundation

Expert hearing
AGRI Committee of the European Parliament
30 November 2021

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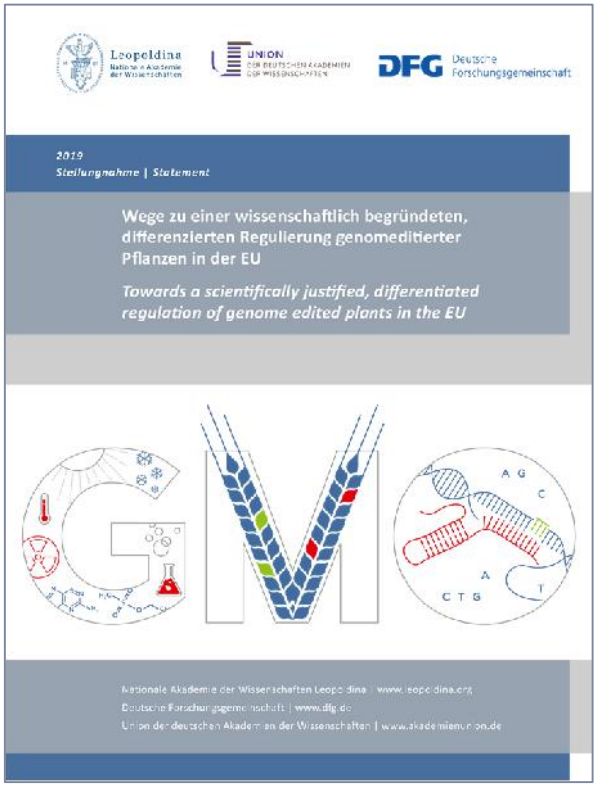
Science-based advice to policy-makers and citizens

1. **Idea and concept:** scientists identify a relevant topic and submit it to so-called presidential committees;
2. **Strategic approach:** committees decide on setting up a working group;
3. **Detailed planning:** selection and appointment of working group members, design of a working schedule;
4. **Workflow:** group meetings, workshops, expert hearings, text drafting etc.;
5. **External review:** selection of independent reviewers, reviewing process;
6. **Publication:** online and print release, media presentation, assessment of feedback;
7. **Follow-up:** monitoring scientific debate/findings.



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Breeding and genome editing: brief intro

1. Breeding relies on **genetic changes** (mutations).

2. **Spontaneous mutations** occur all the time, yet are too rare to allow for efficient breeding of new varieties.

3. Breeders accelerate the process by chemical or physical treatments (**mutagenesis**).

   - treatment with mutation-inducing chemicals
   - treatment with high doses of radioactive radiation

These treatments induce **thousands of mutations**. The (very few) **desired** ones must subsequently be identified, and the thousands of **undesired** ones must be crossed out. This takes many years.

Radiation breeding ("atomic gardening")

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Breeding and genome editing: brief intro

4. **Genome editing** is another mutagenesis method, but differs in 3 important aspects:
   a. **mutations are not induced randomly in the genome** → only in the desired place (the target gene)
   b. the mutation-inducing chemical is a **protein** (or a protein + a small RNA)
   c. the **method is much faster and more efficient** than conventional chemical or radioactive mutagenesis

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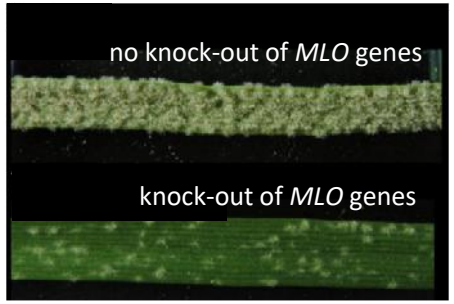
Genome editing: new opportunities in plant breeding

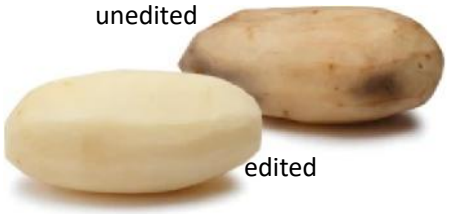
Reduction of harvest losses through disease resistance

- 6 genes for mildew sensitivity in wheat
- inactivation by genome editing produced mildew-resistant wheat variety
- new opportunities, especially for organic farming and SMEs!



Healthier food

- frying of potatoes produces toxic and carcinogenic acrylamide
- targeting of up to four enzyme genes by genome editing: no bruising, less acrylamide
- also: canola (oilseed rape) with healthier fatty acid composition (more unsaturated fatty acids)



GE: safety, risk assessment and traceability

Perceived risk vs. scientific facts Q&A

Q: Some genome editing techniques use recombinant DNA – isn‘t this potentially dangerous?

A: If used, the recombinant DNA is crossed out and **not present** in the final plant variety. This can be easily verified.

Q: With genome editing, many genes can be targeted – is this a potential risk?

A: **No**, this is the big attraction of the technology. Classical breeding also changes many genes, but this can take dozens or hundreds of years.

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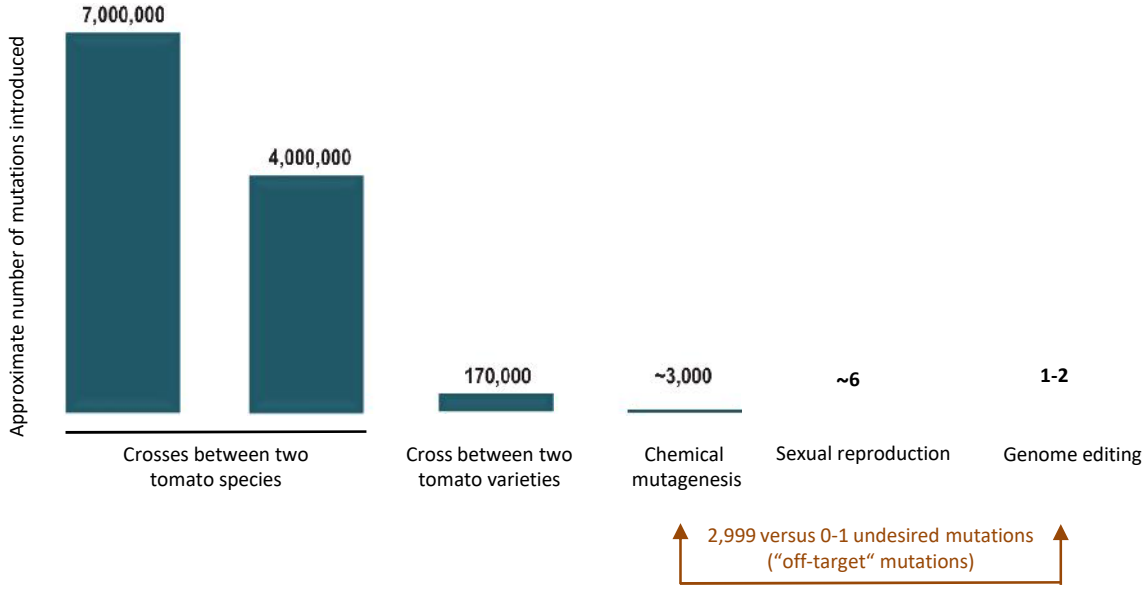
GE: safety, risk assessment and traceability Q&A

Q: Can genome editing introduce undesired mutations, so-called "off-target" mutations? Is this a potential risk?

A: If at all, genome editing causes **far fewer off-target mutations** than any other breeding method.



Source: Graham, N., et al., *Plant Physiol.*, 2020

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GE: safety, risk assessment and traceability Q&A

Q: Isn‘t more research needed into the safety of genome-edited crop varieties?

A: There are **no recognisable new risks**. Genome editing is like any other mutagenesis technique – just faster, cheaper and more precise.

The products of genome editing should be evaluated like other products of breeding or genetic engineering: on a **case-by-case basis**, by looking at the new trait(s).

Q: Can you develop analytical methods to detect genome-edited crops in food or feed?

A: No. If genome editing is used to introduce one or a few mutations into the genome, the resulting plant varieties will be **indistinguishable** from the products of conventional breeding. It is not possible to determine the origin of a mutation *ex post*.

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GE: safety, risk assessment and traceability Q&A

Q: What are the risks of NOT using genome editing and other new breeding technologies?

A: Many problems related to **food security, climate change and the environmental footprint of agriculture** will remain unaddressed (or progress will be very slow).

EU breeders will have a serious **disadvantage** compared to their competitors in the rest of the world (where genome-edited plants are not regulated as GMOs).

Basic research in the EU will be seriously disadvantaged, and EU researchers will need to “export” their field experiments to non-EU countries. This is already happening.

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Regulation of genome edited plants in the EU

Applicability of the existing EU legal framework on GMOs?

- GMO definition = “front door”

→ GMO = “organism […] in which the genetic material has been altered in a way that does not occur naturally”

- Exemption clause = “back door”

→ Exempted = “mutagenesis”

CJEU, Case C-528/16, Confédération paysanne and Others

- GMO definition → GMO = all organisms obtained by mutagenesis
- Exemption clause → mutagenesis which has conventionally been used in a number of applications and has a long safety record

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Regulation of genome edited plants in the EU

Consequence

→ Genome edited organisms (GEOs) = GMOs, not exempted

Problems

→ Deliberate Release

- Public registry

→ Placing on the market

- Authorisation procedure
- Authorisation requirement “description of identification and detection techniques”

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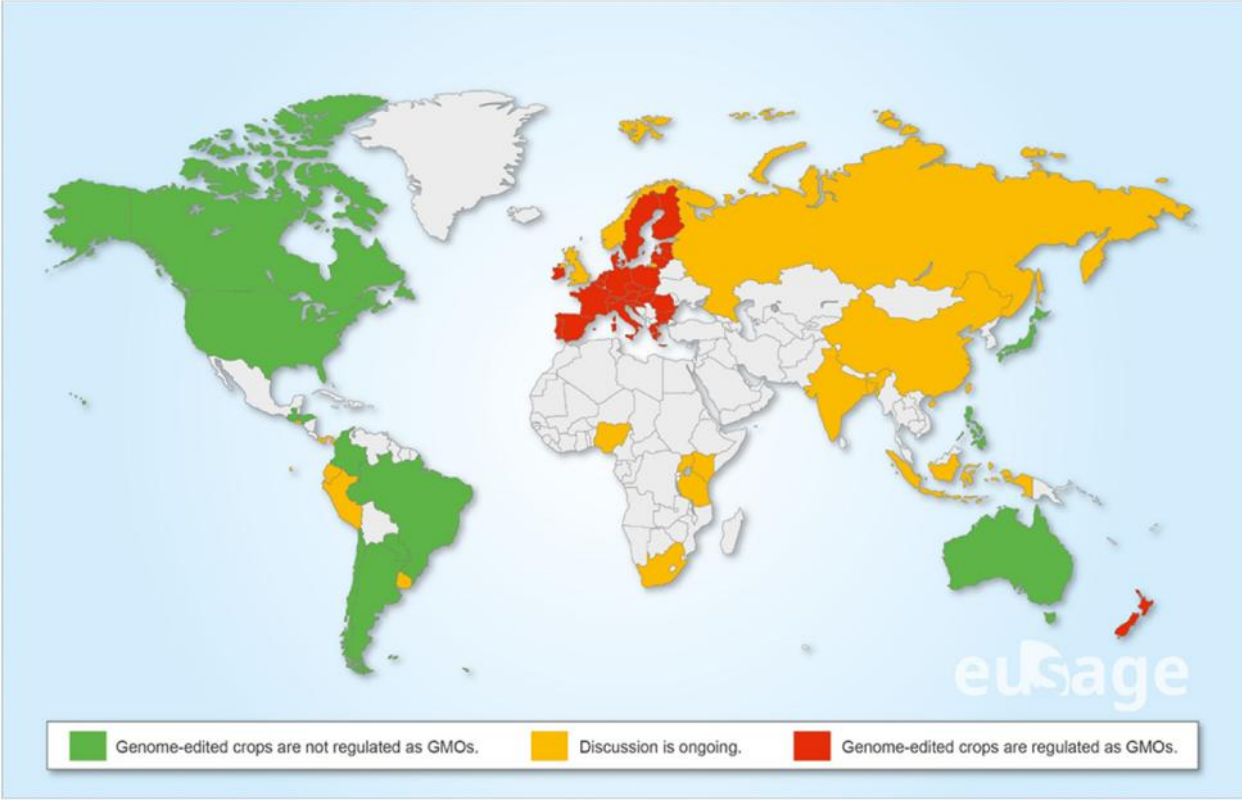
Status quo regulatory implications

→ Regulatory asymmetry

- E.g.: Canada, USA, Argentina

→ WTO Law

- Consistency



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Recommendations on regulation of GE plants in the EU

Recommendation #1

→ Fundamentally new legal framework: “novel trait”-based

Recommendation #2

→ Minor amendments to the existing legal framework

→ Objective: exemption of GEOs

- No foreign DNA
- Genetic Modification could have occurred naturally or been obtained through traditional breeding methods

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Recommendations on regulation of GE plants in the EU

Ways to implement

→ Narrowing “front door”: amendment to GMO definition

- Option 1: general definition
- Option 2: list of non-GM techniques

→ Broadening “back door”: amendment to exemption clause

- Option 3: list of exempted techniques

→ Mandatory preliminary examination procedure

- Case-by-case