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COMMITTED LAWYERS FOR NATURE AND HUMAN RIGHTS DEFENDERS

COMMISSION'S PROPOSAL FOR A REGULATION ON PLANTS OBTAINED BY CERTAIN NEW GENOMIC TECHNIQUES, THEIR PRODUCTS, AND THEIR FOOD AND FEED

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Let's Liberate Diversity! Conference
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Category 1 – NGT plants equivalent to conventional

- Verification procedure based on objective criteria
- Subject to the rules applicable to conventionally bred plants
- Seeds labelled as NGT
- Information available in a public database and variety catalogues

Category 2 – NGT plants not equivalent to conventional

- Authorisation procedure with adapted risk assessment and detection method requirements
- Traceability and labelling as GMO.
  Voluntary statement on purpose of modification
- Regulatory incentives for NGT plants with desirable traits
- Mandatory coexistence measures

Monitoring and reporting

Prohibition in organic production

European Commission

DEFINITIONS AND DISTINCTIONS PROPOSED

ANNEX I

Criteria of equivalence of NGT plants to conventional plants

A NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than 20 genetic modifications of the types referred to in points 1 to 5, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.

(1) substitution or insertion of no more than 20 nucleotides;

(2) deletion of any number of nucleotides;

(3) on the condition that the genetic modification does not interrupt an endogenous gene:

  (a) targeted insertion of a contiguous DNA sequence existing in the breeder's gene pool;

  (b) targeted substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool;

(4) targeted inversion of a sequence of any number of nucleotides;

(5) any other targeted modification of any size, on the condition that the resulting DNA sequences already occur (possibly with modifications as accepted under points (1) and/or (2)) in a species from the breeders' gene pool.

NGT plants

« Genetically modified plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the condition that it does not contain any genetic material originating from outside the breeders' gene pool that temporarily may have been inserted during the development of the NGT plant".

Category 1

Plants which fulfil the criteria of equivalence set out in Annex I (modifiable by the Commission through delegated acts)

Annex I sets out criteria of equivalence regarding technical scientific operations

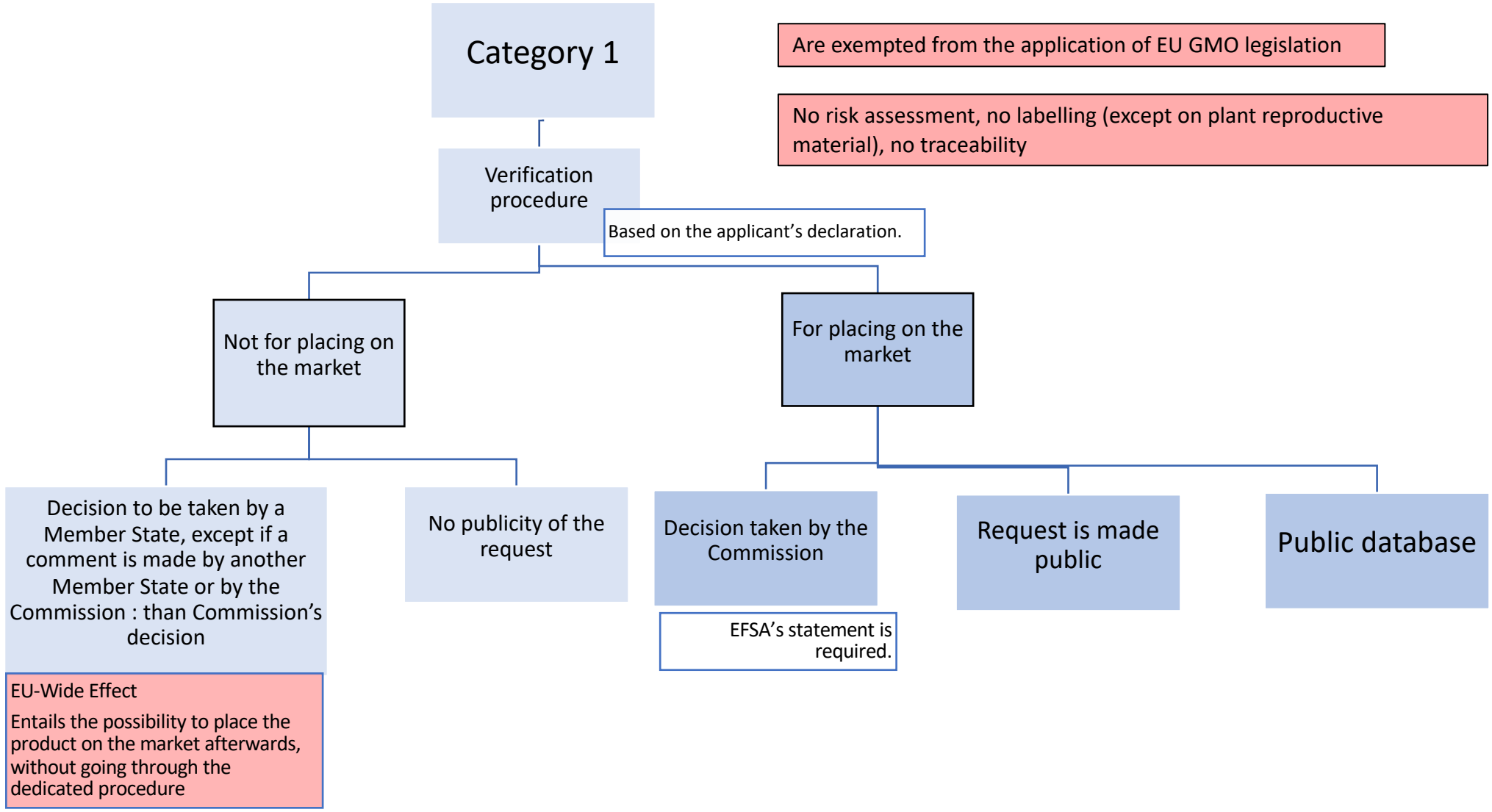
OR
the progeny of an NGT plant, including progeny derived by crossing of such plants

Progeny obtained by conventional breeding techniques are considered Cat 1 without the applicant having to demonstrate compliance with the equivalence criteria

Category 2

Covers all other NGT plants than Category 1

RULES TO BE APPLIED TO ‘CATEGORY 1 NGT PLANTS’



RULES TO BE APPLIED TO ‘CATEGORY 2 NGT PLANTS’

EU GMO legislation applies to Cat 2 NGT, insofar as it is not derogated from by the Proposal. GMO traceability and labelling rules apply.
EU GMO legislation is *lex generalis* / NGT legislation is *lex specialis*.

Category 2

Not for placing on the market

Notification procedure

To the competent authority of the Member State where the NGT will be released

For placing on the market for **other purpose than food or feed**

Notification procedure

Written consent given by MS authority shall specify monitoring, if necessary, and labelling requirements

Placing on the **market for food or feed**

Authorization procedure

Advisory opinion of EFSA about the application and the conformity of the particulars and document submitted

+ Incentives (pre-submission advice, financial advantage) for NGT with sustainability traits. Not for herbicide tolerant traits.

The summary of the notification or authorisation file is made public, as is the decision.

Once notification or authorization is renewed, it will be valid for an unlimited period of time.
No refusal or withdrawal is foreseen.

Environmental and safety risk assessments shall be carried out in all cases, but the type and amount of information shall be adapted to the risk profile. Hazard identification and characterisation only in the plausible risk hypothesis. (double modulation)

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Main problems

General

- **Objective pursued** and legal basis of the proposal (Art. 114 TFEU)
- Very large definition of the **breeder's gene pool**: allows for the introduction of a wide range of foreign genes into NGT plants
- the **criteria of equivalence** (Annex I) are purely arbitrary / have no rational or scientific fundament
- progenies of Cat 1 NGT plants could easily violate Annex 1 and criteria of equivalence
- the right for the Commission to adopt delegated acts amending the criteria of equivalence violates article 290 TFEU

Category 1 NGT plants

- No information for consumers nor for farmers (only seed packages + a useless public register)
- Co-existence impossible due to lack of information and absence of detection methods and monitoring
- Absence of risk assessment and traceability : impossible to know the risk and monitor effects on the ground and in the food chain
- Criteria of equivalence arbitrary and unlimited possibilities to intervene on the genome of plants
- Verification procedure:
    - very quick for MS (30 days)
    - verification request never public
    - Art. 6 procedure (other than placing of the market) will exempt from passing Art. 7 procedure afterwards (placing on the market) : no publication whatsoever

Category 2 NGT plants

- Safety and environmental risk assessments adapted to the “risk profile” + specific information on “hazard identification and characterization”, only required in the “plausible risk hypothesis” (not defined anywhere)
- administrative decisions to be unlimited after a first renewal.

What does the Commission proposal mean for consumers, farmers, and the seed sector?

Claire Robinson

Let's Liberate Diversity! Conference, Dublin 27 October 2023

Which GM plants would be deregulated under the Commission's proposal?

- The proposal will deregulate plants made with new GM techniques such as gene editing. The most commonly used gene editing technique is CRISPR/Cas.
- Other new GM techniques could also be included in the deregulation, such as gene silencing (RNAi or RNA interference) techniques.

For Category 1 new GM plants (about 94% of all new GM plants) the proposal means:

- No risk assessment for human and animal health and the environment
- No traceability of these GMOs throughout the agricultural and food and feed supply chains
  - ❖Traceability will be restricted to seeds, which Commission proposes will be labelled Cat 1 NGT (even this may be removed if pro-GMO people in Parliament succeed in their aims)
- No GMO labelling for consumers, ending the choice to buy and eat GMO-free food
- No way for farmers to know if neighbours are growing new GMOs
  - ❖No way to protect crops from GMO contamination
  - ❖New GMOs may have traits unwanted by the farmer whose crop is contaminated.

Category 1 (continued)

- No publicly available detection methods, so no possibility of monitoring effects on health, the environment, or farming.
- In addition to no traceability, no liability is established – so it's not clear who is legally responsible if something goes wrong, e.g.
  - ❖Consumer has an allergic or toxic reaction to a new GM food
  - ❖Breeders have their germplasm contaminated with GMOs
  - ❖Farmers' crops are found to be contaminated with new GMOs
  - ❖Food producers and retailers' produce is found to be contaminated with new GMOs.
- It will be difficult or impossible to ensure that organic and non-GMO foods and crops remain free from GMO contamination.
- Costs of segregation will be borne by organic/non-GMO sector.

For Category 2 GM plants:

- Adapted (weakened) risk assessment according to the expected "risk profile".
- This is useless, as risks, by their nature, are often unexpected, so you should do certain basic tests on all GMOs to ensure that nothing unexpected and harmful pops up (as are done on all GMOs under current laws).
- GMO labelling and traceability requirements will still apply.
- However, traceability will be difficult to achieve if no detection method is supplied by the developer – the Commission proposes that requirement for detection method can be waived if the applicant says it's not feasible to supply it. **Note, however, that documentation-based traceability (as with organic products, centre of origin labelling, welfare of egg-laying chickens, etc.) is possible and this should be demanded**.
- A "sustainability" label is possible, if the plant has a trait that is claimed to be able to contribute to sustainability – but
  - ❖No evidence appears to be required for sustainability claims.

Risks to consumers

Category 1 GM foods won't be labelled. So:

- Consumers won't be able to choose to buy and eat non-GM foods, even though polls show that most consumers want to keep labelling for all GMOs.
- Consumers will no longer have the assurance that food safety risks from GMOs have been checked.
- The risks of all GM plants are unexpected toxicity or allergenicity.
- These risks are recognised by many scientists and regulators across the world.
- Studies on 1st generation GM foods have found that they can be unexpectedly toxic or allergenic.
- There is no reason to believe that new GMOs are any safer/less risky than older-style established GMOs. The research hasn't been done!

The patents problem

- All old and new GMOs are patented – patents apply to both the individual GMOs and the technologies used to produce them, such as the gene editing technique called CRISPR/Cas.
- Far from democratising plant breeding and putting it in the hands of small- and medium-sized breeders, as is often claimed, **new GM techniques are owned and controlled by large agribusiness corporations through patent ownership.**
- The patent landscape in agricultural gene editing is dominated by Corteva (formerly Dow DuPont) and Bayer (which acquired Monsanto), followed by KWS, Calyxt, BASF, Keygene, and Syngenta.

Patent-related risks to plant breeders and farmers

- Deregulation of new GMOs would increase the risk that small- and medium-sized plant breeders and farmers will be trapped in a "patent thicket" – a dense web of overlapping patents – which would make it challenging for them to operate without infringing on existing patents.
- Plant breeders would find it increasingly difficult or impossible to access genetic resources that are crucial for creating new plant varieties.
- Deregulation would enable major seed companies to increase their dominance, pushing out smaller and medium-sized breeding companies.
- This matters because we need to preserve and develop crop diversity in the face of climate and biodiversity challenges.

How farmers and breeders will suffer

- More GMOs coming onto the market in the EU will increase breeder and farmer dependence on patented seed and technology.
- Breeders and farmers will have to pay licence fees and royalties to patent owners.
- Fees are charged through various pathways: e.g. increased seed costs, licence agreements that must be signed by farmers and breeders, and/or royalties that can be claimed by patent owners at various stages of the production process.
- Farmers are generally not allowed to save and replant patented GM seeds – they must buy new seed each year. If they save seed without permission and payment, patent owners can sue them for infringement.
- Multinationals do not only patent GMOs, but also their descendants: If a GM plant fertilises a conventionally bred plant in a neighbouring field, the neighbour risks being sued for infringement.
- In 2012 Monsanto took over 450 farmers to court, resulting in 142 lawsuits, 70 of which won the company $23 million.

Organic and non-GMO farmers and producers would not be able to keep GMO-free status

- Organic standards do not allow the use of GM plants and the Commission's proposal excludes NGTs from being used in organic farming.
- To enable farmers to avoid inadvertently planting Category 1 GM seeds and breeders to avoid using them, the Commission proposes that these GM seeds should be labelled "Category 1 NGT". The variety would be entered as NGT in a public register.
- However, this labelling would stop with the seeds – foods produced using Category 1 new GM techniques would not be labelled.
- Organic and non-GMO farmers could have their crops contaminated by new GMOs through cross-pollination and through mixing and spillover during transport, storage, and processing.

GMO patent owners have the power Farmers and producers bear the risk

- Without a publicly available detection method, the only body that would be able to prove contamination or its absence would be the applicant for GMO authorisation – the GMO developer company or individual.
- The implications of this power imbalance are huge. Companies can allege that a farmer's crop illegally contains their patented GMO and farmers won't be able to do their own testing to challenge the accusation. The patent owner can then claim royalties from the farmer. There is a precedent (Monsanto's GM soy in Brazil).
- The absence of a "polluter pays" principle in the Commission's proposal means that the onus would be on farmers and food producers to put measures in place to avoid contamination. So those who wish to provide GMO-free food would have to pay the cost of segregation.

How does the Commission justify its proposal?

The Commission claims that the existing GMO regulations have failed to keep up with scientific progress and that they are “disproportionate” when applied to certain new GMOs (Category 1), as they are no more risky than conventional plants.

It also claims that new GMOs are needed

- to achieve the sustainability and food security goals of the European Green Deal’s Farm to Fork Strategy
- to reduce pesticide use.

Do the Commission's arguments stack up?

- There's no evidence that new GMOs can improve sustainability or reduce pesticide use.
- A peer-reviewed scientific analysis examined the research on gene-edited crop plants in research and development stages for evidence that their intended traits could fulfil the EU's sustainability goals, focusing on fungal pathogen and drought resistance. The conclusion: There are no such plants close to commercialisation and a variety of agricultural methods need to be used to improve sustainability (Hüdig M et al, 2022).
- A report by the Commission's Joint Research Centre (JRC) found that of the new GM plants that were close to commercialisation, the largest trait group – six out of 16 plants – was herbicide-tolerant (Parisi C, Rodriguez Cerezo E, 2021).
- These GM plants will continue the toxic trajectory of older-style GM herbicide-tolerant crops, which have increased herbicide use (Benbrook C, 2012).
- A report by Foodwatch investigated the pesticide reduction claim for new GMOs and found it baseless. It concludes, "When it comes to pesticide reduction in the European Union, the potential of these genetic engineering technologies seems to be currently nearly zero" (Neumeister L, 2023).

Why new GM techniques such as gene editing should not be deregulated: The scientific reasons

Prof Michael Antoniou

King's College London

Let's Liberate Diversity

Dublin, October 27, 2023

What is gene editing?

Targeted alteration to the DNA of an organism:

- Small base unit changes (deletions/insertions)
- Large deletions
- Small/large insertions

Arguments of advocates of gene editing deregulation in agriculture

- Gene editing ***mimics what may occur naturally through breeding and random mutation***. **[NOTE: contradiction when claiming patents.]**
- Only the ***end product*** of the gene-editing event(s), whether a plant or animal, should be considered by regulators, rather than the ***process*** by which the genetic change was obtained.
- Intended changes in a gene(s) are "***precise***" and no unintended gene alterations occur in the target organism.
- The outcome of the gene-editing event(s) is ***totally predictable*** and thus the products derived from this process are ***safe***.

Are these claims supported by the scientific evidence that underpins this technology?

Gene editing: how does it work?

CRISPR-Cas

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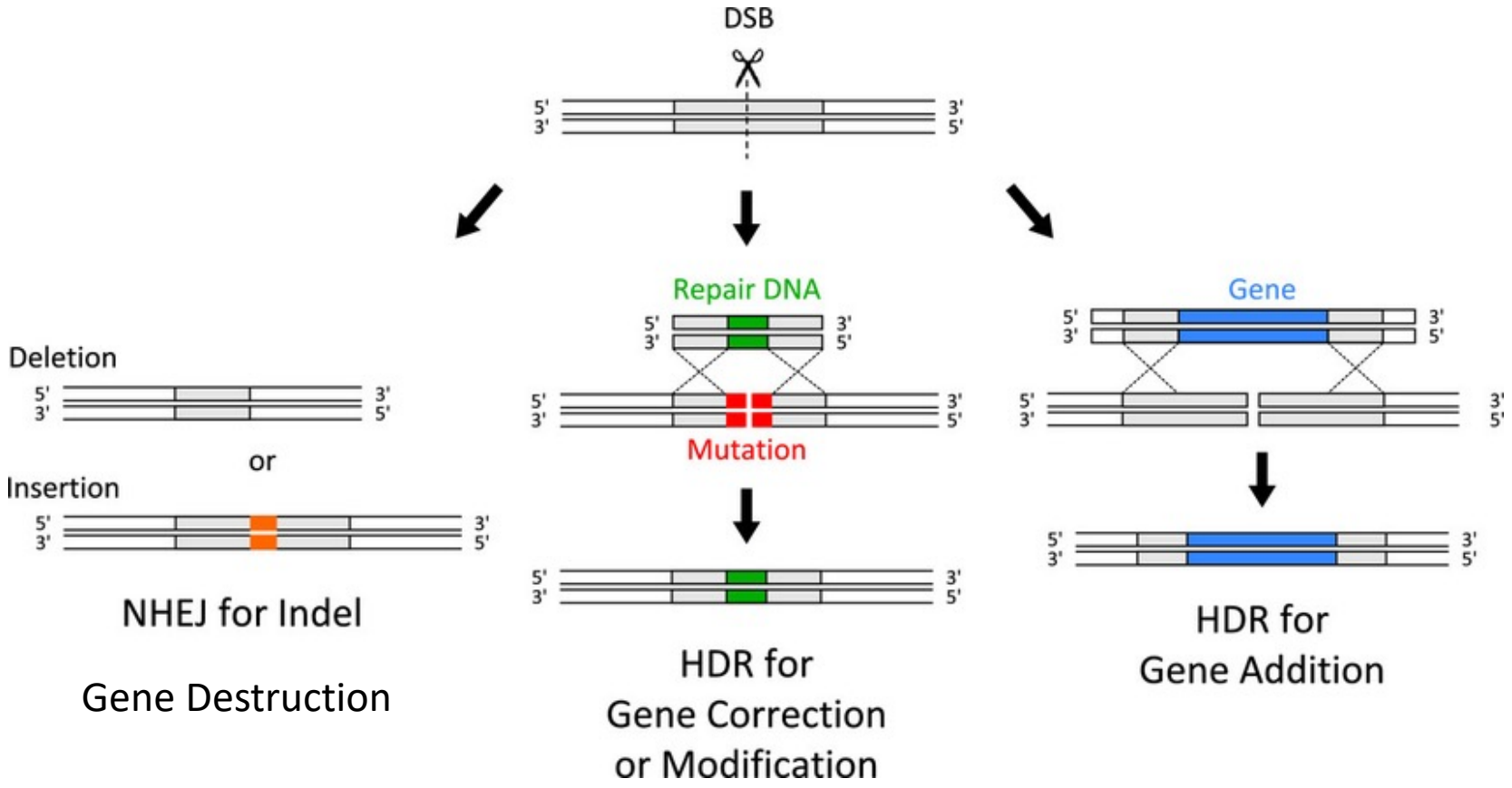
Produce double-strand break in DNA at pre-determined site



Process of gene editing a plant: laboratory-based GM procedure

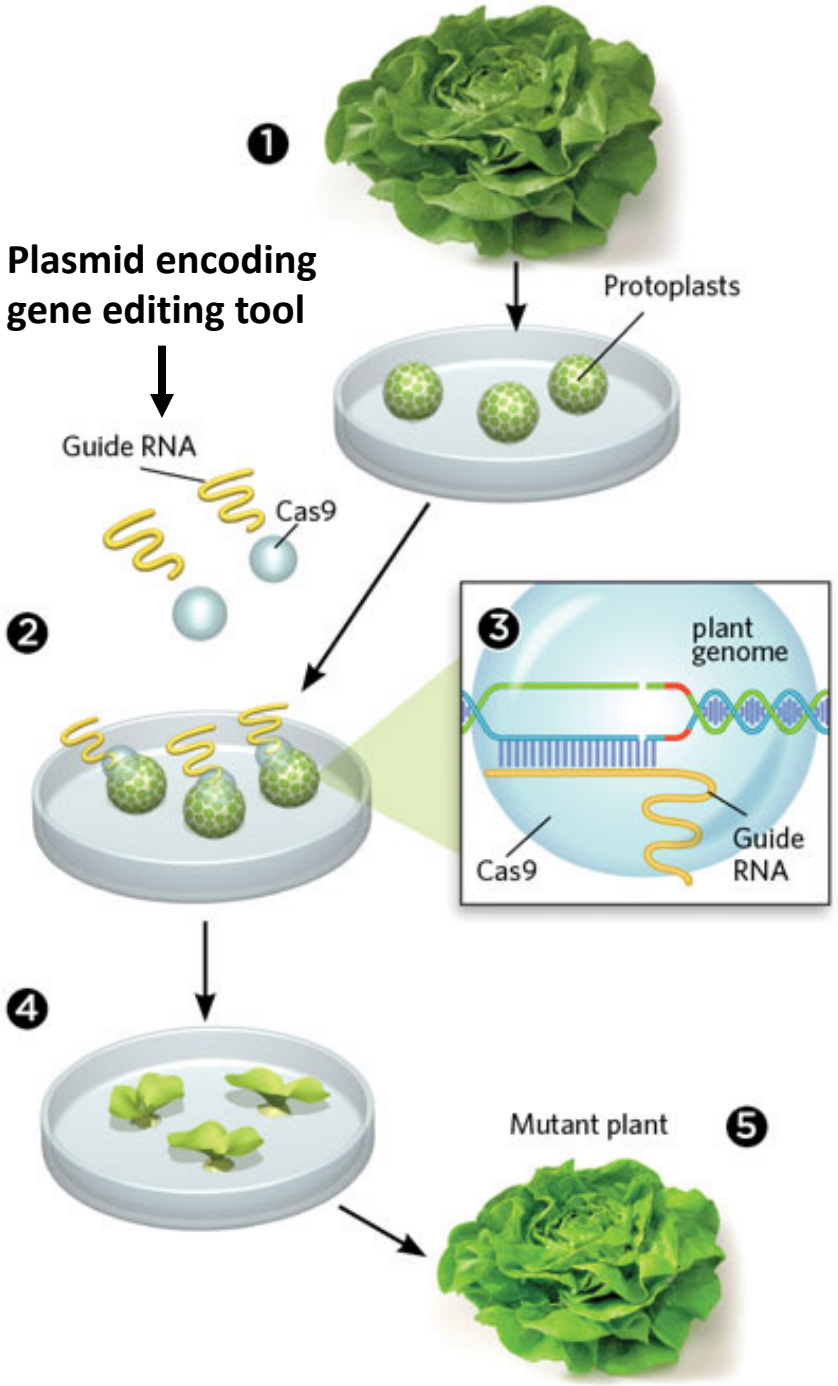
1. Cells (as protoplasts) from plant to be gene edited are grown on dishes – plant tissue culture.

2-3. Gene-editing tool (CRISPR/Cas) is introduced into plant cells, usually encoded on plasmid DNA molecules.

4-5. Whole plants are grown from gene-edited plant cells.

Then plants are screened for gene-edited trait and viability.

NOT NATURAL!



Gene editing can markedly modify plant biochemistry and composition

Gene editing can be used to modify one gene or multiple genes simultaneously and/or sequentially.

Gene editing can be used to radically alter an organism, completely changing biochemical pathways.

Such products require stringent regulation.

Examples of gene-edited crops

- **Calyxt (US):**

(i) Altered fat soybean (commercialised)

(ii) Low gluten wheat (under development)

- **Corteva (formerly DowDuPont) (US):** CRISPR gene-edited altered starch “Waxy” maize (approved in US, Canada, Argentina, Brazil and Chile but not yet commercialised)
- **Penn State University (US):** CRISPR gene-edited non-browning mushroom
- **Japan:** high sedative GABA tomatoes (commercialised)
- **John Innes Centre (UK):** vitamin D precursor-producing tomato
- **Cibus:** Herbicide-tolerant canola

Are claims of precision and predictability of gene editing supported by the evidence?

The claim that gene editing-induced gene changes are similar to what may occur naturally is unproven.
Presently this constitutes at best an untested hypothesis.

What is known is that these techniques are prone to unpredictable "off-target" and "on-target" mutational (DNA damaging) effects.

Currently recognized gene editing unintended mutational effects

Recognized gene editing <u>off-target</u> mutational effects:

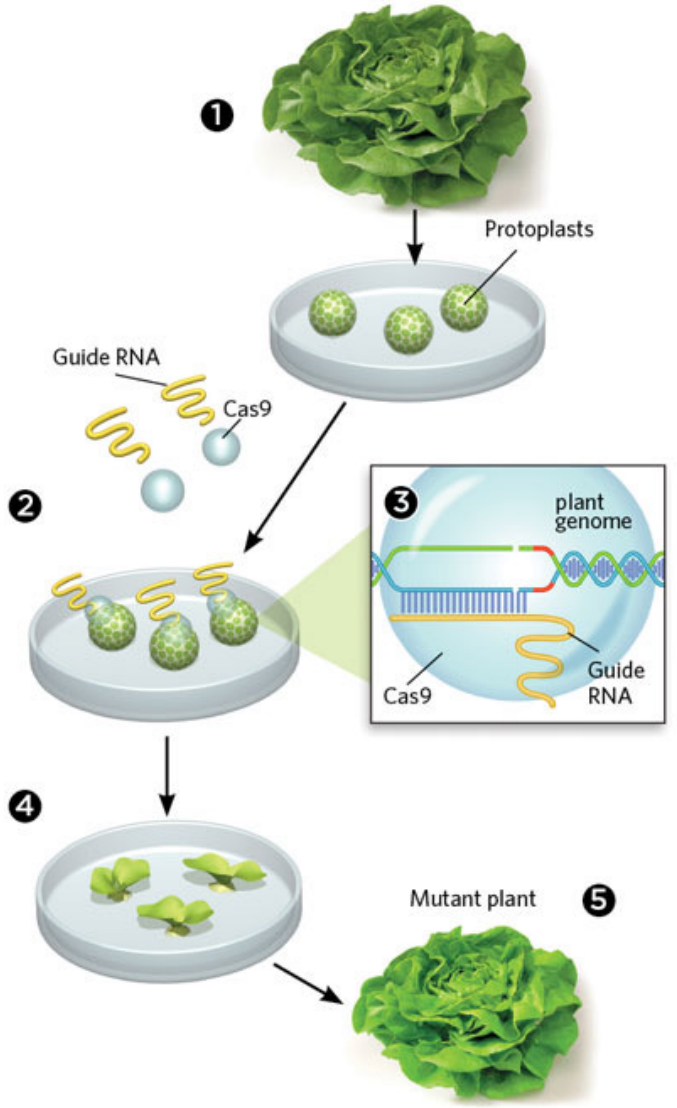
- **Unintended alterations or mutations to other genes in addition to the target gene(s).** Includes mutations from plant tissue culture.

Recognized gene editing <u>on-target</u> mutational effects:

- **Unintended side-effects from the intended alteration;** e.g., alteration in enzyme activity can result in chemical reactions other than those that are intended.
- **Large DNA deletions affecting more than one gene.**
- **Large DNA rearrangements affecting multiple gene functions.**
- **Creation of new gene sequences resulting in new RNA and proteins.**
- **Insertion of foreign DNA (even when foreign DNA is not intended to be inserted).**

Multiple types and large number of unpredictable, unintended mutations from gene editing

Mutations from plant tissue culture and transformation process



Off-target and on-target mutations

Consequences of unpredictable off-target and on-target mutations from gene editing

- **Can lead to alterations in patterns of gene function, leading to unintended changes in the biochemistry of the organism.** In edited plant foods, these changes could include production of **unexpected toxins or allergens**, or altered or compromised nutritional value.

On-target mutations:

- **occur after gene-editing tool has completed its task**
- **are at the mercy of the cell's DNA repair mechanisms and machinery**

Therefore, no matter how precisely the initial editing tool DNA cut may be targeted, unintended on-target mutations can still take place.

Differences between gene editing and conventional breeding

Conventional breeding:

Sexual reproduction (cross-pollination, animal mating)

Asexual reproduction (e.g. vegetative propagation; potatoes and bananas)

Combines only genetic material already present within the species

Develops new plant varieties by a process of *selection*

Does not involve direct human intervention in the genome (the total genetic material of the organism)

Combines pre-existing families of genes (genomes)

Brings about novel combinations of **genetically complex** pre-existing characteristics or **traits**.

Genetic variation arising from rounds of natural sexual reproduction is not random

CRISPR gene editing:

Invented 2012

Artificial laboratory procedure

No conventional breeding

Involves direct human intervention in the genetic sequence of the organism

Manipulates one or a few genes at a given time; combining families of genes not possible

Cannot bring about genetically complex traits

Most applications to date are gene disruption

Procedure as a whole brings about unintended non-random and random modification of the plant's genome; no region is spared

Commission's criteria of equivalence of Category I NGT plants to conventional plants

An NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by **no more than 20 genetic modifications** of certain types, in any DNA sequence similar to the targeted site that **can be predicted by computer bioinformatic tools**.

- Permitted genetic modifications includes small (up to 20 DNA base unit) changes, large deletions, large insertions, large rearrangements

BUT:

- There is no evidence that a new GM plant with less than 20 genetic modifications is any safer/less risky than a new GM plant with more than 20 genetic modifications. The number 20 is totally arbitrary.
- Safety/risk does not depend on the number of genetic modifications, but on what they do.
- Even a small change to a single base pair (smallest unit of genetic information) can make a normally safe plant toxic or allergenic.

AND:

- **The Commission's criteria totally ignore the inevitable wide-scale unintended DNA damage (there will be far more than 20 of these damages but they won't be counted).**
- **The criteria have no sound scientific basis.**

Process-based and product-based regulation must be applied

Given that gene editing is a GM procedure, which

- Uses laboratory-based, artificial DNA modification procedures
- Does not in itself involve natural cross-breeding
- Results in functional alterations of one or more DNA sequences
- Causes unintended and unpredictable off-target and on-target effects at DNA, RNA and protein levels

– regulations applied to gene-edited products should be process-based as well as product-based.
The Commission's deregulation proposal ignores process and focuses only on the intended final product (product-based).
All unintended effects of the GM processes used would be ignored.

Evidence of harm from gene editing?

- **No studies conducted to date**
- **Claims of safety are hypothetical**
- **Numerous studies show evidence of harm from consumption of old-style transgenic GM crops**
- **Consumers, farmers and breeders must continue to be informed via traceability and labelling which foods and seeds are produced using new GM techniques like gene editing.**

What can we do? (1)

- We all need to oppose the Commission's proposal and we need to ACT FAST. The debate in the EU Parliament's Environment Committee is scheduled for 9 Nov. Supporters of GMO deregulation are trying to push through the new legislation by first half of 2024.
- **Contact your MEP** and ask them to ensure that:
  - risk assessments, seed-to-fork traceability **(via detection methods and/or documentation)** and GMO labelling are preserved for ALL GMOs, including new ones.
  - the GMO deregulation and the new pesticide reduction rules are de-linked. The official reason why the Renew Group ("liberals" in the EU Parliament) and its allies are pushing the fast schedule is alignment with the new pesticide reduction rules – they are claiming that a major way to reduce pesticide use is to enable faster and easier approvals of new GMOs!

What can we do? (2)

- Emphasise to your MEP that new GM seeds from Bayer & Co will be designed to go with high pesticide and fertilizer use, even if they are marketed as "fungal disease resistant" or similar.
- Say that seeds should be produced for low input systems. This is a message that MEPs and others are unlikely to hear normally. They only hear Bayer & Co's promises of "sustainable traits".
- Protect your own production and keep it as GMO-free as you can. Save seed. Talk to neighbour farmers and growers and tell them about the risks.
- Keep up to date: Subscribe to our free newsletters at GMWatch.org – "Subscribe to News". Follow us on Twitter @GMWatch