

Q&A / Why does the EU want to change the rules for the new generation of GMOs?

> How are GMOs - from all generations - currently regulated?

So far, all generations of genetically modified food, feed and seeds are regulated in the same way. They need to get an authorisation before they can be imported and placed on the EU market, a process which includes checks on potential risks for nature, human and animal health, as well as the provision of a detection method¹. Once the authorisation has been granted, the products are traced and labelled along the whole food chain, and monitoring is required. With the current EU GMO rules, any food with ingredients like rapeseed oil made of GM rapeseed, or cornflakes made of GM maize, must be labelled as containing or being made of GMOs.ⁱⁱ

In case of cultivation, national GMO laws enable neighbouring farmers and national authorities to know where the GM crops were grown, and some countries have rules to ensure compensation for contamination of harvests.

At the moment, 74 variations of GM food and feed (1 sugar beet, 21 soybeans, 8 rapeseeds, 46 maizes, 6 cotton)ⁱⁱⁱ are authorised for imports to the EU, but the GM crops failed to convince farmers. Since 2015, their cultivation has been banned in 17 member states^{iv} and only one GM crop is being grown in Spain.

It means that new GMOs are not banned, they just need to undergo the authorisation procedure.

> What are the main changes in the new law to deregulate new GMOs?

The European Commissions draft law, which was not subject to substantive changes from the European Parliament and Council of the EU, suggests to fully deregulate most new GMOs^v. This means that **pre-marketing authorisation, safety checks, traceability, labelling and monitoring would no longer apply for them**.^{vi} It also means that consumers, farmers, and the whole food chain would no longer know whether the seeds, ingredients and final food products they buy contain new GMOs or not.

Moreover, **the new GMO definition remains vague**. This is highly problematic as only one national authority checks whether the product fits the blurry definition, and if so, grants producers infinite rights to market or grow new GMOs.

How are new GMOs presented by the industry?

A long-term campaign by a handful of biotech corporations^{vii} aimed to rebrand these new GMOs, replacing the term 'genetically-modified' with 'precision' or 'new plant breeding' **to avoid GM labelling on food products**.^{viii}

In parallel, these same corporations have been promoting plants that are currently still in the research pipeline as magic solutions and sustainable solutions for all kind of challenges - without any concrete proof. The first new GMO to have been engineered, a rapeseed called Cibus, **eventually flopped and was withdrawn in the USA.**

Why does a wide range of stakeholders and authorities reject deregulation of new GMOs?

The assumption that the new generation would be the same as conventional plants has **not been supported by various national authorities**.^{ix} Many civil society organisations, farmers and breeders raised their concerns that the best and most efficient way to ensure freedom of choice, protect the



environment and an independent breeding sectors is still unresolved (Feb Letter 2025). Actually, the environmental impact of releasing new GMOs into fields has **not been assessed through independent research** (ANSES 2)[×]

> About the patent controversy in the Council of the EU

The European Commission **bypassed the topic of how patents on new GMOs could impact the farming and breeding sector**, and instead suggests to publish a study in a few years' time. The European Parliament amended this part of the proposal, specifying that new GMOs, along with their "plants, plant material, parts thereof, genetic information and the process features they contain shall not be patentable".^{xi}

In 2024, the Belgian Council presidency followed a similar approach but failed to secure a majority for it.^{xii} In 2025, the Polish presidency compiled two attempts, with its current proposal mirroring the Belgian one and calling for a **voluntary corporate statement** on patents, which could allow other breeders to use the genetic material on new GMOs for a fee.^{xiii}

What is the problem?

While patented seeds have played a limited role in Europe's breeding and farming sectors, this is now changing with the development of new GMOs as they will **further strengthen corporate control over farmers and breeders.**

Not only patented seeds will limit the availability of diverse seeds, particularly to those that rely on traditional breeding practices, but they also often come with contractual restrictions. These contracts deepen farmers' dependence on corporations for yearly seed purchases, **increasing their costs and reducing their autonomy.**

Unless the EU and the European Patent office address the issue of patents on essential biological process and implement specific restrictions on new GMO patents, any push to deregulate these new GMOs **will limit farmers' access to seeds capable of adapting to new challenges**, like extreme weather. Breeders will be forced into lengthy negotiations with a handful of powerful biotech corporations to maintain the right to work with genetic material, whether developed through conventional breeding or gene-editing.^{xiv}

Process:

- July 2023: The EU Commission publishes its draft legislation^{xv}
- February 2024: The EU Parliament votes on its position and confirmed it in April^{xvi}
- February 2024: Blocking minority of Member States under the Belgian Council presidency
- February 2025: The Polish Council presidency presents a proposal similar to the Belgian one.
- If there is an agreement at a Coreper meeting or in the Council, the so called 'trilogue' can start

How can farming adapt to current and new challenges in more efficient and sustainable ways?

New GMOs may or may not produce varieties with interesting traits in a few years' time, but so far, they have not delivered on their promises in countries where they are widely deregulated. Farmers are already struggling with extreme weather conditions and nature destruction, which impact crops health and, to some extent, yields.



Friends of the Earth Europe calls on the EU to:

- Focus on real solutions by strongly pushing for research on sustaining crop production during prolonged droughts or excessively wet conditions. This requires rethinking arable farming, from breeding and new agriculture machinery to cultivating highly diverse crops on
- Implement policy measures to make healthy and more sustainable diets an easy and affordable choice for consumers
- Strictly **apply the relevant EU directive to block patent claims** on plants, animals and organisms that are not based on patented GMO technology.
- **Regulate the new generation of GMOs under existing GMO laws** to ensure freedom of choice for consumers, farmers and breeders, and for new technologies to go through stringent safety checks and labelling before being marketed.
- Reject the deregulation proposal

- https://ec.europa.eu/food/food-feed-portal/screen/gmo/search
- ^{iv} <u>https://food.ec.europa.eu/plants/genetically-modified-organisms/gmo-authorisation/gmo-authorisations-cultivation/restrictions-geographical-scope-gmo-applicationsauthorisations-eu-countries-demands-and-outcomes_en</u>
- ^v Bohle, F.; Schneider, R.; Mundorf, J.; Zühl, L.; Simon, S.; Engelhard, M. (2023): Where Does the EU-Path on NGTs Lead Us? Preprints 2023, 2023111897. <u>https://doi.org/10.20944/preprints202311.1897.v1</u>

vⁱ <u>https://food.ec.europa.eu/system/files/2023-09/gmo_biotech_ngt_proposal_2023-411_en.pdf</u> and the annex <u>https://food.ec.europa.eu/system/files/2023-09/gmo_biotech_ngt_proposal_2023-411_annex_en.pdf</u>

ⁱ <u>https://food.ec.europa.eu/plants/genetically-modified-organisms/gmo-authorisation/gmo-authorisations-food-and-feed_en</u>

ⁱⁱ See regulation 1829/2003 <u>https://eur-</u>

lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2003R1829:20080410:EN:PDF

^{vii} <u>https://www.amsem.ro/ImageHandler.ashx?UploadedFile=true&pg=d63ee450-0f3a-4e83-b811-</u> 127758e634a0&image=~/App_Data/UserImages/File/ESA/2021/PBI%20Advocacy%20Brief%20ESA.pdf

viii https://corporateeurope.org/en/2021/03/derailing-eu-rules-new-gmos

^{ix} Authorities from Austria, Poland, Italy, Germany and Switzerland contributed to this research: Eckerstorfer, M.F., Grabowski, M., Lener, M., Engelhard, M., Simon, S., Dolezel, M., Heissenberger, A., Lüthi, C. (2021) Biosafety of genome editing applications in plant breeding: Consideration for a focused case-specific risk assessment in the EU. biotech 10, <u>https://doi.org/10.3390/biotech10030010</u>

 ^x Koller, F. et al. (2023): The need for assessment of risks arising from interactions between NGT organisms from an EU perspective. Environmental Sciences Europe 35, 27. <u>https://doi.org/10.1186/s12302-023-00734-3</u>
^{xi} <u>https://www.europarl.europa.eu/doceo/document/TA-9-2024-0325_EN.html</u>

xii https://data.consilium.europa.eu/doc/document/ST-11318-2024-INIT/en/pdf

xiii version 19 February 2025 new paragraphs in articles 6 and 6: 2XXThe requester may submit a written declaration of a patent holder confirming his willingness to license the protected subject under fair, reasonable and non-discriminatory conditions, which is applicable within Union territory

xiv <u>https://friendsoftheearth.eu/publication/locked-seeds-who-wins-and-who-loses-when-new-gmos-get-patented/</u>

^{**} https://food.ec.europa.eu/system/files/2023-09/gmo_biotech_ngt_proposal_2023-411_en.pdf

^{xvi} <u>https://www.europarl.europa.eu/doceo/document/TA-9-2024-0325</u> EN.html



Overview of the EU institutions' position on the new GMOs file, and their impacts

	Current situation	EU Commission proposal	EU Parliament position	Council debate	Impacts of the deregulation
Definition	Clear definition of what a GMO is	Smokescreen definition	Smokescreen definition	Smokescreen definition	Deregulates 94% of new GMOs
Authorisation	Required	Abolished	Abolished	Abolished	With only one field trial, new GMOs can be marketed and grown infinitely. In case harm would be detected, marketing would be still possible.
Safety checks	Required	Abolished	Abolished	Abolished	Harm for the environment, humans and animals cannot be excluded.
Detection method	Required	Abolished	Abolished	Abolished	Impossible to monitor potential environmental or health impacts, to hold corporations accountable if any harm occurs, and to trace new GMOs along the food chain.
Labelling	Required along the whole chain	Only for seeds	Required along the whole chain	Only for seeds	Consumers won't know whether the food they buy and eat contains new GMOs. Food producers won't know whether they are using new GM ingredients. Retailers won't know whether the food they offer contains new GMOs.
Monitoring	Required	Abolished	Abolished	Abolished	Nobody will check the impacts on environment, human or animal health. They will remain undetected
Liability	Required	Abolished	Abolished	Abolished	In case food products or neighbouring fields are contaminated, or if any harm on nature is detected, nobody can be held accountable
Patents	Nothing	Nothing	Prohibited on new GMOs, but without checking mechanisms in case of violations	Voluntary corporate statements	Breeders will be forced into lengthy negotiations with powerful biotech corporations to maintain the right to work with genetic material