

The debate about 'new genomic techniques' - facts, players and positions

Summary: The global seed industry is lobbying the EU to exclude certain genetically modified (GM) crops engineered with new GM technology from its GMO regulations, saying they are nothing else than traditionally bred varieties. Environmental groups, food retailers, small farmers and the organic industry oppose such a move, as this would mean that GM crops end up on our fields and plates untested and unlabelled. Scientific studies show that new GM technology changes the genetic makeup of organisms in ways that are fundamentally different to what happens in nature, and that it can have unintended, negative effects. At the end of April, the European Commission will set out its views on the matter.

Genetic modification by another name

Genetic engineering technology has evolved since the introduction of the first genetically modified (GM) crops more than 20 years ago. A set of new GM techniques has emerged that scientists collectively call 'gene editing'. Gene editing allows genetic engineers to modify existing genes rather than adding genes from other species - a hallmark of first generation GM technology. One of the gene editing tools is the CRISPR/Cas 'gene scissors' whose inventors were recently awarded the Nobel Prize.¹

Multinational seed producers like Bayer and Syngenta have claimed that these GM techniques do not produce GM organisms (GMOs). They initially used the term "new breeding techniques" to describe gene editing and other more recent GM techniques and methods.² They now use the term "breeding innovation" to conceal the fact that these are GM techniques resulting in GM organisms (GMOs).³ The EU Council of Ministers has introduced the term "novel genomic techniques",⁴ which the Commission subsequently turned into "new genomic techniques".⁵ It encompasses gene editing as well as other GM techniques.

Same producers as older-style GM crops

Most patent applications for agricultural crops engineered with gene editing have been filed by **Corteva** (former DowDupont) and **Bayer**.⁶ These companies belong to the Big Four agricultural corporations that dominate the global GM seed market today.⁷ However, they have so far not brought

¹ Royal Swedish Academy of Sciences, 2020, <u>The Nobel Prize in Chemistry 2020</u>

² New Breeding Techniques (NBT) Platform, New Breeding Techniques for Plants

³ Euroseeds, 2018, <u>Position on Plant Breeding Innovation</u> (updated 2019)

⁴ EU Council of Ministers, 2019, <u>Council Decision (EU) 2019/1904 of 8 November 2019</u> requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law

⁵ European Commission, <u>EC study on new genomic techniques</u>

⁶ Then, Christoph, 2019, Neue Gentechnikverfahren und Pflanzenzucht: Patente-Kartell für große Konzerne

⁷ IHS Markit, 2020, Analysis of sales and profitability within the seed sector

any gene-edited seed products to market. Corteva has announced a gene-edited 'waxy' maize that is approved in five countries but not commercialised.⁸

It is smaller companies that have ventured to market the first gene-edited GM crops. US company **Cibus** has cooperated with BASF to create a herbicide-tolerant oilseed rape that is grown in the US and Canada. **Calyxt**, a US-based company owned by French company Cellectis, has developed a soybean with altered oil content. In the EU, gene-edited crops are only grown on test fields, such as in Belgium, Spain and Sweden.⁹

Ongoing debate over EU regulation

In July 2018, the **European Court of Justice** confirmed that gene-edited organisms fall under the EU's GMO regulations. ¹⁰ The Court said that their exclusion from the GMO directive "would compromise the objective of protection pursued by the directive and would fail to respect the precautionary principle which it seeks to implement".

But the global **seed industry** wants to have gene-edited crops that do not contain any 'foreign' genes to be excluded from EU GMO regulations. This would encompass most gene-edited crops that are being researched, ¹¹ and also the two crops that are commercialised in the US and Canada.

Seed producers claim that gene editing produces DNA changes that could also occur in nature, and that it is necessary for the EU to achieve its green goals. They also say existing EU regulations cannot be enforced for gene-edited crops because they are too difficult to detect in the food chain. These claims are incorrect and misleading. Studies show that gene editing causes genetic changes that are different from those that happen in nature, and that the resulting products can be unsafe.¹²

Environmental groups,¹³ food retailers,¹⁴ small farmers¹⁵ and the organic industry¹⁶ want GMO regulations to be applied to ensure safety and respect farmers' and consumers' right to choose what they plant and eat. They say the EU must develop analytical methods to back up existing traceability schemes in order to enforce its laws.

The stakes are high. Essentially, if the EU excludes certain gene-edited products from its GMO regulations, they would no longer be subject to requirements for authorisation, traceability and GM labelling. EFSA would not carry out any safety evaluation and farmers, food producers and consumers would no longer be able to tell GM from non-GM crops and food.

⁸ Canadian Biotechnology Action Network, 2021, Product Profile - GM Waxy Corn

⁹ European Commission Joint Research Centre, <u>Deliberate release into the environment of plants GMOs for any</u> other purposes than placing on the market (experimental releases)

¹⁰ European Court of Justice ruling in case C-528/16, July 2018

¹¹ Menz, J., Modrzejewski, D., Hartung, F., Wilhelm, R., and Sprink, T., 2020, <u>Genome edited crops touch the market: a view on the global development and regulatory environment</u>. Front. Plant Sci. 11:586027. doi: 10.3389/fpls.2020.586027

¹² Greens/EFA, 2021, Gene editing myths and reality - a guide through the smokescreen

¹³ Friends of the Earth Europe, 2021, <u>Generation unknown: exposing the truth behind the new generation of GMOs</u>

¹⁴ VLOG, ARGE Gentechnik-frei, 2018, <u>Open letter from 75 GM-free food and feed companies</u>

¹⁵ European Coordination Via Campesina, 2017, Stop new GMOs!

¹⁶ IFOAM Organics Europe, 2021, <u>Civil society, farmers and business organizations: Vice-President Timmermans, don't deregulate GM crops & animals</u>

However, a recent opinion poll commissioned by our Group shows that, across the EU-27, almost 70 percent of respondents who have heard about new GM techniques such as gene editing want their products labelled as GM.¹⁷

What are scientists saying?

There are two camps, also among scientists. For example, in 2019, German science academy **Leopoldina** issued a statement making the same demand as the global seed industry. The statement asks that the EU GMO legislation be amended "within the current legislative period of the European Parliament" to exempt gene-edited organisms "if no foreign genetic information is inserted and/or if there is a combination of genetic material that could also result naturally or through traditional breeding methods." In 2020, the association of national academies of science in EU countries, Norway, Switzerland and the UK, **EASAC**, endorsed the statement. 19

The European Network of Scientists for Social and Environmental Responsibility, **ENSSER**, on the other hand, demands that gene-edited organisms should be regulated "at least as strictly as products of the older-style GM technologies". ENSSER has warned that new GM technologies, including gene editing, "can create unpredicted and unintended effects" and that their exclusion from GMO regulations would "place an unacceptable risk onto public health, the environment and trade". ²⁰

The EU's food safety agency, **EFSA**, has concluded that existing guidance for the risk assessment of GM plants was also "applicable" to gene-edited plants whose genome was modified without adding new DNA. At the same time, EFSA appears to question the need for GMO risk assessment altogether by saying gene editing did "not pose more hazards than conventional breeding or techniques that introduce new DNA into a plant".²¹

Selective reading of the evidence

The Greens/EFA Group has commissioned ENSSER to analyse the scientific foundations of the EASAC-endorsed Leopoldina statement.²² The analysis found that the Leopoldina statement is based on a limited selection of scientific publications and fails to reflect the findings of at least 200 highly relevant scientific studies. The Leopoldina statement ignores the evidence of harm arising from existing GM crops, as well as studies demonstrating the potential for negative outcomes of more recent genetic engineering tools. As a result, it endorses both old and new GM technology as safe and beneficial options of "science-based breeding", and proposes to also relax regulations for existing GM organisms.

An earlier analysis by German NGO Testbiotech revealed that five of the 16 authors of the Leopoldina statement had vested interests in gene editing applications, meaning either close affiliations to the biotech industry or relevant patent applications.²³

¹⁷ Greens/EFA, 2021, Opinion poll on the labelling of GM crops

¹⁸ Leopoldina, 2019, <u>Towards a scientifically justified, differentiated regulation of genome edited plants in the</u> EU

¹⁹ EASAC, 2020, <u>The regulation of genome-edited plants in the European Union</u>

²⁰ ENSSER, 2017, Products of new GM techniques should be strictly regulated as GMOs

²¹ EFSA, 2020, Existing guidance appropriate for assessment of genome editing in plants

²² ENSSER/CSS, 2021, Scientific critique of Leopoldina and EASAC statements on genome edited plants in the EU

²³ Testbiotech, 2020, <u>Testbiotech comment on the Statement</u> "Towards a scientifically justified, differentiated regulation of genome edited plants in the EU"

Upcoming Commission study

On 29 April, the Commission will present its **study on new genomic techniques**. The in-house report commissioned by EU ministers will set out the Commission's take on the safety, potential market applications and ethical consideration of these GM techniques, as well as the enforcement of current GMO law. It will draw on contributions from the Commission's scientific advisors, its Joint Research Centre (JRC), the European Food Safety Authority (EFSA), the European Group on Ethics EGE), the European Network of GMO Laboratories (ENGL), national governments and stakeholders. The Commission is not expected to present any policy options at this stage.

To gauge the views of governments and stakeholders, the Commission had asked these groups to fill out a dedicated questionnaire.²⁴ Friends of the Earth has criticised the stakeholder survey as biased because it sought input mostly from agri-industry bodies and asked many more questions about potential benefits than risks.²⁵

Greens/EFA position

The Greens/EFA Group in the European Parliament believes that GM technology is a costly and potentially dangerous distraction from the real advances needed to make our food and farming system more sustainable. We are under no illusion that these advances will come from the corporations that benefit most from the existing, chemical-heavy industrial farming system.

In our opinion, the EU should not look to the Big Four agricultural corporations (Bayer, Corteva, Syngenta and BASF) for advice on how to 'green' the farming sector, or advice on how to regulate their products. It should look instead to agro-ecological and organic farmers and scientists supporting their approaches.

The ENSSER analysis of the Leopoldina statement shows that older GM technology has not delivered on its promises, and that there is no reason to believe that new GM technology will. It shows that GM crops grown today have been associated with increasing chemical use, leading to environmental damage and ill health, among other things. It also points out that a series of widely accepted expert reports have called for a rapid shift away from input-intensive industrial agriculture, towards agroecological farming methods.

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²⁴ European Commission, <u>EC study on new genomic techniques - Stakeholders' consultation</u>

²⁵ Friends of the Earth Europe, 2021, Green light for new GMOs?