BIODYNAMIC FEDERATION demeter

BRIEFING PAPER

NEW GMOS: OLD CLAIMS AND FALSE PROMISES

Proposal on new genomic techniques

Introduction

Under the current EU legislative framework, all genetically modified organisms (GMOs) are subject to mandatory risk assessment, traceability, and labelling. These requirements guarantee freedom of choice for farmers, breeders, and consumers, while protecting our environment and health in line with the precautionary principle.

For more than a decade, new GMOs, produced using new GM techniques (also called new genomic techniques, NGTs), were developed. The agricultural biotech industry, as well as seed companies and international trade partners, are pushing to exempt GM products obtained by these techniques from the current GMO regulations. They claim these techniques are the solution to ensure food security and achieve sustainability in food and farming.

Following their lobbying pressure, the European Commission proposed a new legislative framework in July 2023 for certain categories of NGTs, aiming to facilitate their market access by lifting the current transparency and safety requirements applying to GMOs.[1]

Not only would such a new legislative framework put our health and environment at risk, but it would also impact the whole GMO-free food production, including biodynamic and organic farming, as well as the conventional GMO-free sector. The current regulatory framework must be maintained for all GMOs to ensure protection of health and the environment, as well as farmers' and consumers' freedom of choice regarding whether they want to grow or eat these new GMOs.

WHAT ARE NEW GMOS?

According to EU Directive 2001/18, the basis for GMO regulation in the EU, GMOs are "organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating or natural recombination".[2]

GM techniques are used to deliberately alter the genetic material of plants, microorganisms, or animals to confer certain desired traits. So far, GM crops are mainly modified to either withstand the spraying of weedkillers such as glyphosate, produce their own pesticide (BT toxins), or both. Most of the time, the desired trait is introduced with the use of DNA from another species ("foreign" DNA).

New GM techniques are now being promoted under a wide variety of names – new plant breeding techniques, new genomic techniques, and targeted mutagenesis – giving the impression that gene-edited organisms are not GMOs.

The main claim is that gene editing techniques, such as CRISPR, TALENs, ODM, or ZFNs, do not necessarily introduce DNA from a foreign organism and are able to target the change to a specific location of the organism's DNA. Gene editing aims either to destroy a gene function, to alter a gene function, or to introduce additional genes. The aim is to alter an existing trait (such as to prevent the browning of certain fruits or vegetables when cut) or to introduce a new trait (such as herbicide tolerance).[3]

Neither precise nor predictable

Gene editing is carried out by introducing a DNA cutting enzyme (technically known as a nuclease, which acts like a "gene scissors") into the organisms' cells. This makes a cut across the double helix of the DNA (double-strand break) at a targeted location. The cell then uses its own repair mechanism to repair the break in the DNA.

Gene editing techniques are often claimed to be safer and more precise than older-style GM techniques, on the claimed grounds that the "edit" can be targeted to a certain location in the genome and that no foreign genetic material is introduced.

But these claims are misleading. In fact, gene editing is not precise when the entire process by which it is undertaken is taken into account. While the initial DNA break can be precisely targeted to a certain region in the genome, what happens after that is not precise, predictable, or controllable.

Several things routinely go wrong. First, the gene editing tool or "gene scissors" can make cuts at locations in the genome other than the intended edit site, which are similar to the target site causing mutations (DNA damage) in genes that are not being targeted. Second, a wide range of different types of unintended DNA damage can occur even at the intended edit site, which can result in the unintended destruction or disturbance in the function of numerous genes. Third, the gene editing process, taken as a whole and including the obligatory plant cell tissue culture phase, causes hundreds or thousands of random mutations throughout the genome of the organism, some of which will unintentionally disturb the functioning of many genes.

Collectively, different types of mutations, both at the target edit site ("on-target") and at other sites in the genome ("off-target")[4], combine to alter the function of many gene functions in an uncontrolled and unpredictable manner, which can lead to biochemical and compositional changes in the organism – with unknown health and environmental consequences.

Difference from natural breeding

The mutations caused by gene editing are different from genetic variation that occurs from natural breeding. This is because certain areas of the genome that are protected from mutations in natural breeding are not protected in gene editing.[5] So unlike in natural breeding, it is likely that gene editing-induced mutations will occur in locations of the genome that contain active genes that are important to the normal, healthy functioning of the organism.

Also, the genetic variations that occur in natural breeding are not random – they are geared to helping the plant adapt to its environment.[6] In contrast, the intended and unintended mutations caused by gene editing will occur randomly across the entire genome.

GMO developers generally do not test properly for unexpected and potentially harmful genetic changes, suggesting that they will often be missed, and their consequences not investigated.[7] As long as the gene-edited plant looks acceptable and grows satisfactorily, other less obvious changes, such as changes in composition that can affect the health of the consumer or wildlife, can pass unnoticed.

Risks and threats

The mutations caused by gene editing processes carry risks. Gene editing-induced DNA damage can alter patterns of gene function, which can cause a plant's biochemistry to change in unintended ways. This is because an organism's genes work as an integrated network and not as isolated units of information. So, changing the function of just a single gene, let alone of many genes, can have major repercussions on the organism. For example, compositional changes can result, with the plant becoming unexpectedly toxic, allergenic, or harmful to wildlife.[8] These effects could also happen as unintended consequences of the intended "edit".

In addition, contrary to frequent claims in the media and by politicians that gene editing does not introduce foreign DNA into the genome of the edited organism, gene-edited organisms can and do contain foreign DNA[9] and even entire foreign genes.[10] These can either be intentionally introduced (in so-called SDN-3 or "gene insertion" gene editing) or inadvertently left behind from the gene editing process.[11] An example of the latter case is the gene-edited hornless cattle that were found to unexpectedly contain genes conferring resistance to three antibiotics.[12]

Even if no foreign genes are inserted, small changes in the genome can have large effects, including severe consequences for health or nature.[13] Ecosystems can be endangered by altering individual genes that exert a particular key function within a food web – for example, the "monarch fly".[14]

Another source of threat from gene editing techniques is that they increase the range of possibilities and speed with which the genetic material of organisms may be modified.[15] The resulting gene-edited organisms, with their spectrum of intended and unintended mutations, once authorised for marketing, are then rolled out at wide scale. In this way, the risk potential of gene editing is far greater than risks from genetic variations occurring in nature or from natural breeding.

In sum, it is well recognised that genetic integrity is vital for maintaining the health status of an organism and its harmonious, balanced integration within an ecosystem. Both the random unintended mutations and the unintended consequences of the intended genetic change brought about by gene editing processes violate the genetic integrity of an organism, which normally evolves through the non-random genetic variation arising through rounds of natural reproduction. The disruption of genetic integrity from gene editing processes can pose serious risks to biodiversity, human and animal health, and the environment. This is why new GMOs produced by gene editing techniques need to be regulated and closely monitored.

New techniques, old claims: false promises

The agricultural biotech industry presents new GMOs as indispensable to ensure food security and achieve a reduction in pesticide use (the EU Farm to Fork Strategy foresees a reduction by 50% of pesticide use by 2030).[16] They claim gene editing techniques will help to increase yields or the resistance to environmental stresses. But so far, with first-generation GMOs, only two main genetically engineered traits have been brought to market: herbicide resistance (especially to the total herbicide, glyphosate) and the production of insecticides (especially Bt toxins).[17]

Over twenty years of commercial GMO cultivation in North and South America resulted in an increase in pesticide use,[18] jeopardising our health and the environment. Will new GMOs be different, as is being promised? Probably not: According to a report by the Joint Research Centre, 16 new GM plants are at the pre-commercial stage worldwide, and 6 out of the 16 (the largest

group) are engineered for herbicide tolerance.[19] So far, only very few new GMOs are already on the market – most are still in research and development stage.[20] Some of those that have been commercialised seem to have rapidly disappeared from the market.[21] So new GMOs are far from being a market reality and their potential benefits still need to be demonstrated.

CURRENT EU GMO LEGISLATIVE FRAMEWORK

In the EU, Directive 2001/18, EC Regulation 1829/2003, and EC Regulation 1830/2003 regulate the release and use of GMOs.[22] According to the current legislative framework, all GMOs on the market are subject to the following requirements:

- Prior risk assessment of the GMO for health and environment. The developer must supply data to allow the regulator to check for toxicity and allergenicity, as well as the effects on nutrition and the potential consequences to the environment.
- Traceability allows the GMO to be traced in seeds, cultivated plants or grains, and in food and feed products. For analytical detection, "reference" samples of the GMO (e.g. seeds, plant material) must be submitted to the regulator, along with a detection method.
- Labelling to guarantee freedom of choice. All food and feed products in the EU containing GMOs must be labelled accordingly, with the exception of food derived from animals fed with GM feed. Labelling is key to enable consumers to choose wherever or not they would like to buy a GM product.

The current EU GMO legislative framework is process-based, meaning that if an organism is produced through a genetic modification process, the GMO regulations apply. It is based on the precautionary principle set out in the EU Treaties, as it recognises the potential unintended effects from all GM processes.[23] To date the EU has authorised more than 60 GM crops to be imported in the EU, but only one crop has a cultivation authorisation in Spain and Portugal (Monsanto's MON810 maize).

In 2018 the European Court of Justice confirmed that organisms obtained by new mutagenesis techniques (by which it is understood to mean new GM techniques such as gene editing) are to be considered as GMOs and are subject to the requirements laid down in the current GMO directive. The exception is if the techniques involved have been used in several applications and have a long safety record – something that doesn't apply to new GM techniques, which have little or no safety record. It reinstated the necessity to follow the precautionary principle considering the possible adverse effects on human health and the environment.[24]

Despite the ECJ Ruling, the biotech industry has continued to push new GMOs further on the political agenda, asking for a deregulation of new GMOs. This resulted in EU member states requesting the EU Commission to submit a study on the status of new GMOs. The Commission published a "staff working document" in April 2021, concluding that the current GMO legislation is not fit for purpose for certain NGTs and that a policy action on plants produced by targeted mutagenesis techniques (such as gene editing) and cisgenesis (the genetic modification of a plant with a gene from a crossable – sexually compatible – plant) is needed.[25]

New legislation on NGTs: What is at stake?

The working document published by the Commission initiated the first step of a new legislative framework for targeted mutagenesis and cisgenesis. It was followed by two rounds of public consultations (Sept-Oct 2021 and Apr-Jul 2022). The first gathered more than 60,000 citizens expressing their concerns towards a potential deregulation of new GMOs, while the second was heavily criticised for its biased approach.[26]

The objective of the new legislative framework is to lower the mandatory requirements for GM crops derived by certain categories of NGTs to simplify and speed up their market access. This would mean that GMOs could appear in our fields and on our plates without prior risk assessment, traceability, or labelling. Not only would such a proposal jeopardise freedom of choice for the consumer and put our health and environment at risk, but it would also increase the burden on organic, biodynamic, non-GMO, and conventional farmers and food producers to ensure GMO-free production.

Both organic and biodynamic farming prohibit the use of GMOs.[27] The obligation to conduct a comprehensive risk assessment, to ensure consistent labelling from the seed to the final product, and to provide working detection methods are intrinsically linked to the preservation of GMO-free production. The quality management to remain GMO-free is often linked with high cost for farmers and companies (buffer land strips, cleaning of transport and storage facilities, testing, etc.). Contamination can occur throughout all steps of the production chain, adding an additional burden on operators.[28]

Dismantling the EU's GMO regulations would also worsen the problems of patents on seeds, threatening farmers' rights to seeds, small and medium-sized breeders' access to seeds and plant material, and seed diversity. Contrary to conventional plant breeding, both the processes and the products of NGTs are patentable under the EU law. Exempting new GM seeds from EU's GMO regulations would therefore result in a flood of patented seeds on the market.[29] This will increase the consolidation and monopoly control of the seed industry,[30] while placing an onerous burden on most farmers and breeders, who will have to navigate the resulting "patent thicket". In this regard, traceability is indispensable to protect farmers, breeders, and producers from accusations of patent infringement, as well as enabling them to provide non-GMO products.

Consumers would also be concerned by a weakening of the EU GMO regulations. With a large group of diverse organisations, the Federation carried out an EU-wide petition calling on EU decision makers to keep new GMOs strictly regulated and labelled, meaning to maintain the mandatory risk assessment, traceability, and labelling. More than 420,000 signatures were collected, showing citizens' desire to make an informed decision on whether to buy and eat GM products.[31] Regardless of their opinion on new GMOs, labelling of all GMOs on the final product is decisive for consumers to guarantee their freedom of choice.

Instead of relying on the empty promises of the biotech industry and increasing the risks to our health and the environment, our efforts must go towards proven solutions such as organic, biodynamic and agroecological farming practices. Only such systems have the potential to make a real transition towards sustainability while tackling climate change. Agroecosystems rely on a complexity of interactions that cannot be narrowed down to specific traits or genes but require a holistic approach to farming.

Upcoming negotiations: Outlook

The European Commission published a new legislative framework for NGTs in July 2023. It is now up to the Council of the EU and the EU Parliament to discuss and amend this proposal before the last round of negotiations between all three institutions (called "trilogues"). According to the current schedule, the new legislation could rapidly enter into force, but with the upcoming EU elections in May 2024 the process could be delayed.

The following points must be carefully considered in the negotiations on the new legislative proposal:

- Mandatory labelling for all GM organisms and of the products made from or using these organisms along the entire food and feed supply chain.
- Mandatory traceability for GMOs in seeds, cultivated plants/grains, and final food products. The company that places a GM product on the market must provide detection methods as a prerequisite for the market introduction of plants developed with NGTs, as already occurs under the current GMO regulations.
- Mandatory coexistence regulations for production, processing, and trade, in accordance with the "polluter pays" principle, to ensure the protection of GMO-free products from contamination. A location registry for NGT crops must enable farmers to know if GMOs are grown around their farm and if they can expect a high risk of contamination. The burden for protective measures must lie with the users of GM organisms or products and not with the GMO-free sector.
- Investment in independent research to investigate the effects of new GMOs on our health and the environment, as well as the socio-economic impacts of GM production on the actors of organic and non-GM supply chains before lowering or lifting the current legal requirements for NGTs.
- To assure public access to genetic resources and to protect farmers from accusations of patent infringement, no patents should be granted on any form of life or its components that restrict the free access to genetic resources.
- Support ecological and holistic farming systems, such as organic and biodynamic farming, as well as peasant agroecology, that provide reliable and proven solutions to tackle the climate crisis and pave the way towards sustainability.

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ABOUT US

The Biodynamic Federation Demeter International is an umbrella organisation of 48 member organisations dedicated to biodynamic agriculture, active in 36 countries all over the world. It was founded three years ago to unite, promote, and support a worldwide sustainable agri-cultural impulse which will celebrate its centenary in 2024. It has built up a certification for biodynamic farming worldwide labelled with the Demeter brand. This brand is used by more than 7000 certified farms in 62 countries worldwide. More information at: www.demeter.net

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