Annex

Greens/EFA response to the European Commission Consultation on New Genomic Techniques

As Greens/EFA, we oppose the introduction of separate legislation for products of new genetic modification (GM) techniques such as targeted mutagenesis (i.e. SDN-1, SDN-2 and ODM) and cisgenesis.[1]

In this submission, we outline why products resulting from these techniques, as for all GM products, must be subject to the essential requirements under the existing legislation on GMOs (genetically modified organisms): risk assessment, traceablity and labelling. We also consider the European Commission's policy scenario's as set out in the 'targeted survey for the impact assessment', and respond to the Commission's proposal to take into account new GM plants' potential to deliver on 'sustainability'. Finally, we set out why we believe that the Commission's planned initiative runs counter to, instead of supporting a shift towards more nature and climate friendly farming.

Instead of "new genomic techniques" (NGTs), we use the term new genetic modification (GM) techniques. The European Court of Justice (ECJ) has clarified that these techniques result in GMOs, and that these GMOs should be regulated under EU GMO legislation, in order not to undermine the EU's Precautionary Principle.[2] According to the ECJ, GM techniques cannot be excluded from the scope of EU GMO legislation unless they have conventionally been used in a number of applications and have a long safety record. Since this is not the case for gene editing techniques, such as CRISPR, they are subject to the GMO legal requirements. As Greens/EFA, we fully support the Court's ruling.

Which GM techniques are covered by the Commission initiative?

The term "**targeted mutagenesis**" refers to some forms of gene editing, and specifically SDN-1, SDN-2 and ODM. Our submission focusses on SDN-1 and SDN-2, the most common forms of gene editing by which developers cut the double strand DNA at a specific location in the genome and the cell repairs the cut. SDN-2 differs from SDN-1 in that a template is used to direct the DNA repair.[3]

The term "**cisgenesis**" denotes the stable insertion of gene from a sexually compatible species (so-called "cisgene"). This is usually done in the same way that genes from non-sexually compatible species (so-called "transgenes") are inserted, i.e. via plasmids (i.e. circular molecules of DNA derived from bacteria) or biolistics (i.e. gene gun). It can also be done with gene editing (SDN-3). In this case the developer can target a specific place in the DNA for the insertion of the cisgene.

The need for a full and robust risk assessment

Old and new genetic modification techniques have more in common than proponents would have us believe. Of three steps involved in gene editing – gene delivery, gene editing, and whole plant regeneration in tissue culture – the first and last essentially remain the same.

The first step, delivery of foreign genetic material into the plant cells, makes it possible to have the plant cell itself produce the gene editing "machinery" (the 'gene scissors' and 'guide'). It is usually done with the help of small circular DNA molecules (plasmids) that are introduced into the cells using a soil bacterium or a method called particle bombardment. The plasmid inserts itself into the plant cell's DNA, creating an organism that carries 'foreign DNA'. The foreign DNA is supposed to be removed at the very end of the process, through several backcrosses of the gene-edited organism to the non-GM

[1] Greens/EFA, 2020, Genome editing in agriculture. A Greens/EFA perspective
[2] Court of Justice of the European Union, 2018, Judgment in Case C-528/16
[3] Broothaerts, W. et al, 2021, New Genomic Techniques: State-of-the-Art Review

parent variety, whilst the new characteristic remains. But developers usually do not use adequate screening methods to confirm that the final product is indeed free from foreign DNA.

When it comes to the "editing step", developers can determine the intended location (or "target site") of the DNA cut. But DNA cuts can also occur at locations other than the intended site, resulting in "off-target mutations". The subsequent "repair" is carried out by the cell's innate repair mechanisms and cannot be controlled by the genetic engineer. Different types of unintended mutations (DNA damage) can take place at the intended gene edit site ("on-target mutations"). The unintended off-target and on-target mutations include small and large deletions, insertions, and rearrangements of DNA.

The last step, again the same as for transgenic GMOs, is the generation of whole plants from the edited cells. This can cause additional unintended effects such as small and large deletions and insertions, duplications of DNA segments and rearrangements.[4]

The unintended DNA mutations in gene-edited plants can lead to alterations in the function of many genes, which in turn can lead to altered biochemistry of the plant, including the production of new toxins or allergens. Therefore, all gene-edited plants need to undergo a full risk assessment taking into account both intended and unintended genetic alterations and their consequences.[5] The EU cannot rely on developers' claims that their products are without danger to the environment and human health.

No market access without traceability and detection method

For the non-GMO and organic sectors, it is crucial that GM products are identifiable across the food supply chain. The EU should therefore demand transparency from GMO developers, and not allow them to hide their products from breeders, farmers, retailers and consumers.

The **traceability** of GM products is essential, and there is no reason that it cannot be delivered. Traceability is a cornerstone of organic production, safeguarding the credibility of the EU organic label. It is also required under the EU labels indicating the geographic origin of food products and the welfare of laying hens. In future, it may also be required under EU systems labelling other aspects of animal welfare. Traceability and consumer labelling are possible regardless whether laboratory methods can be used to determine the origin of a product.[6]

When it comes to **analytical detection methods** for new GM products, we need to distinguish two cases:

- **Detection methods for individual GM products**. Under EU legislation, developers have to submit a quantitative detection method for each GM product they wish to have authorised. There is no question that such methods can be developed for all GM seed products, including gene-edited plants.[7] For example, Cibus, the first company to commercialise a gene-edited crop plant, submitted a specific detection method for its GM rapeseed to Canadian authorities,

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[4] ENSSER/CSS, 2021, Genome edited plants in the EU. A scientific critique of Leopoldina and EASAC statements

[5] ENSSER/CSS, 2021, Genome edited plants in the EU; Kawall K, 2021, The generic risks and the potential of SDN-1 applications in crop plants. Plants 10(11): 2259 ; Kawall K et al, 2020, Broadening the GMO risk assessment in the EU for genome editing technologies in agriculture. Environmental Sciences Europe 32(1):106; BfN, 2020, Risk Assessment of Plants developed by new Genetic Modification Techniques (nGMs)

[6] Eleonora Evi, 2021, GM food can and must be labelled

[7] ENGL, 2019, Detection of food and feed plant products obtained by new mutagenesis techniques

which satisfied legal requirements.[8] Chinese researchers have developed a detection method for a gene-edited (SDN-1) rice variety.[9]

Importantly, under EU law, GMO detection methods need not show whether a GM method was used to create the plant. They only need to enable the fail-proof identification and quantification of a specific GMO event.

- **Detection strategies and methods for non-authorised GM products**. Given the GM "signature" of gene-edited products (see previous section) the development of such strategies and methods is first and foremost a matter of time and research effort. As with the first generation of GM crops, specific research efforts are needed to achieve this. MEPs have asked the Commission to use the EU's Horizon 2020 programme to fund and coordinate such efforts.[10]

  The fact that unauthorised GM products cannot be detected in the laboratory is not a new phenomenon. Already today, some GM products escape routine GMO testing because they do not include the common DNA sequences that screening methods rely on, or are highly processed (e.g. oil, sugar) so that these sequences are no longer present. The absence of agreed strategies and methods to detect unauthorised GM products cannot be a reason to exclude them from EU GMO regulations.

The EU must require both traceability and detection methods from GM developers who wish to market their products on the single market. The fact that analytical methods are not available today to differentiate certain products from similar plants produced with non-GM methods cannot be an excuse to weaken regulatory requirements.

Consumers' have a right to know

An opinion poll commissioned by the Greens/EFA and conducted across all 27 EU countries shows that consumers demand GMO labelling also for products of new GM techniques. Sixty-eight percent of respondents who have heard of new GM techniques, such as CRISPR, say that food produced with these techniques should be labelled as GM.[11]

This is also the position of the EU consumers association, BEUC. The association writes, with regard to the EU's Farm to Fork Strategy:

> *"As clarified by the EU Court of Justice, organisms obtained from new genomic techniques fall within the scope of the EU GMO legislation. As such, it is vital they continue to be required to undergo a thorough risk assessment and approval procedure before they can be marketed for food and/or feed use. Moreover, traceability and labelling of products produced using these techniques must guarantee consumers' right to know and freedom of choice. A lack of labelling of these products, on the other hand, would risk eroding consumer confidence in organic food – hence, running counter to the Strategy's objective to stimulate organic food production and consumption in the EU."*[12]

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[8] CFIA, 2020, DD 2013-100: Determination of the Safety of Cibus Canada Inc.'s Canola (Brassica napus L.) Event 5715

[9] Zhang, H.; Li, J.; Zhao, S.; Yan, X.; Si, N.; Gao, H.; Li, Y.; Zhai, S.; Xiao, F.; Wu, G.; et al. An EditingSite-Specific PCR Method for Detection and Quantification of CAO1-Edited Rice. Foods 2021, 10, 1209, doi:10.3390/foods10061209

[10] Martin Häusling et al, 2022, EU research on risks and detection methods related to new GM plants. Letter to the European Commission

[11] Greens/EFA, 2021, Opinion poll on the labelling of GM crops

[12] BEUC, 2020, Towards greener and healthier food for European consumers: BEUC's take on the Farm to Fork strategy

Consumers have the right to know how their food is produced and the EU cannot leave them in the dark on whether GM methods were used. The EU should maintain the well-established distinction between GM and non-GM food, and provide consumers with an easy-to-access label on the final product to inform their choice.

GM crops that "could occur naturally"?

Several of the Commission's proposed policy scenarios are based on an assumption that some GM plants "could also be obtained naturally or by conventional breeding".[13] Under these scenarios, the EU would no longer require any risk assessment, traceability, consumer labelling or detection methods for such GM plants.

To our knowledge, such "nature-identical" GM plants do not exist. Gene editing causes both intended and unintended changes in the genome, and the nature of these changes can be very different from those that happen in the absence of gene editing. For example, gene editing can be used to modify multiple copies of a gene, or to modify areas of the genome that are usually protected from mutations.[14]

Claims that gene editing can produce organisms that could arise in nature or through mutation breeding remain entirely theoretical. No one has proven that any given gene-edited organism is the same as a naturally occurring or mutation bred organism, either at the level of the genome or in terms of its molecular composition (the proteins and natural chemicals that make up the structure and function of the organism).[15]

The proposed category of "nature-identical" GM plants belongs to realm of marketing, not serious policymaking. Such a category, based on completely unfounded claims, cannot be the basis for science-based regulation.

Misleading sustainability claims

The sustainability of our food system is not a matter of individual products. A plant trait in isolation, without considering the agricultural context in which the plant is grown, is insufficient to draw any meaningful conclusion. For example, a robust crop variety may be able to withstand certain pressures, such as pest attacks. It should still not be planted in monocultures. Sustainability is a function of an agricultural production system, not an individual plant. It will only be achieved with agronomic methods that provide for genetic diversity, and protect and sustain soil health.

The Commission's proposed sustainability analysis for GM plants is unlikely to render useful results. Generally, it will be hard to reconcile any sustainability claims with the fact that plants are genetically engineered. As a BEUC study from 2020 shows, "sustainable food" means for consumers that it has been produced "without pesticides and GMOs" and sourced from "local supply chains".[16]

The traits that the Commission suggests would make plants more "sustainable" include tolerance to pests and diseases, and to stresses like drought and salinity. Indeed, GM developers are studying ways to achieve these traits. However, it is doubtful that they will succeed.

Firstly, GM developers have promised such traits since the early days of genetic engineering. But until today, conventional breeding has consistently outstripped genetic engineering techniques (old and new) in producing crops tolerant to stresses such as drought, floods, pests, and diseases.

Secondly, these are genetically complex traits, meaning that they are the product of many genes working together in a precisely regulated way. Such traits will be extremely difficult or impossible to achieve by manipulating one or a few genes, which is all that gene editing and genetic modification in

[13] Technopolis Group, 2022, Targeted survey for the impact assessment of new legislation on New Genomic Techniques.

[14] ENSSER, 2021, Genome edited plants in the EU, pp 31ff

[15] Greens/EFA, 2021, Gene editing myths and reality, pp 21ff

[16] BEUC, 2020, One bite at a time: Consumers and the transition to sustainable food

general can achieve, even using multiplex approaches.[17] For example, at least 60 genes have been linked to drought tolerance, further mediated by environmental conditions, making any functioning and sustainable genetic engineering solution highly unlikely.[18]

Genetic engineering has produced crops with genetically simple traits such as herbicide tolerance or the ability to express an insecticide. Gene editing is set to continue on the same path. Indeed, many of the new GM plants that the Commission has identified as at “pre-commercial stage” have been engineered to tolerate spraying with broad-spectrum herbicides.[19]

Of the three new GM plants commercialised so far, none can be said to increase resistance against biotic or abiotic pressures. The first such plant was a herbicide-tolerant rapeseed developed by Cibus. Two others, a soybean from Calyxt and a tomato from Sanatech, have been engineered for an altered nutrient profile with no tangible benefits. People who eat a varied and healthy diet have no need for such foods.

When it comes to solving challenges of pests, diseases, or climate change, it is crucial to look at whole farming systems rather than employing a reductionist approach that only looks at genes, especially genetic engineering approaches that only manipulate one or a few genes. As well as robust crops providing stable yields under adverse conditions, we need resilient farming systems that cope with a variety of environmental stresses.

Claims that GM plants will contribute to improved EU food systems are not supported by the evidence. The EU should not weaken its GMO regulations to accommodate empty promises of “sustainable” GM plants.

Jeopardising the agroecological transition

As Greens/EFA we support a transition towards a social and agro-ecological model of farming: one which delivers sufficient amounts of healthy, nutritious, quality food to all, respects social and labour rights of agricultural workers and migrants, ensures a fair income for farmers and supports micro, small and medium sized farms, while maintaining long term fertility, productivity and efficient resource use.

Instead of solving any of the problems created by industrial farming systems, the Commission’s plan to introduce a separate light-touch regulatory regime for certain GM plants could create new problems, and exacerbate existing ones.

If the Commission succeeds in easing market access for these products, this will increase the range and number of **patented seeds**. Indeed, experience with genetic engineering to date shows that patent law has been the driving force behind development. With new GM techniques, this is set to continue. Already, a few multinational corporations such as Corteva and Bayer/Monsanto control large parts of the seed market. They also dominate the patent applications on gene-edited plants,[20] as patented GM techniques such as CRISPR/Cas help them extend and deepen control over the commercial seed market.[21]

As a result breeders and farmers risk “losing access to traditional cultivars that might be displaced with expanded markets in new biotech crops, or mined as genetic resources for breeding gene-edited varieties”.[22] Farmers could be forced to pay for access to gene-edited seeds and breeds, but lose access to non-GM seeds and breeds in the process.

[17] Greens/EFA, 2021, Gene editing myths and reality, pp 54ff
[18] ENSSER/CSS, 2021, Genome edited plants in the EU
[19] JRC, undated, New genomic techniques
[20] Testbiotech, 2021, Increasing number of patents on food plants and New GE
[21] Greens/EFA, 2021, Gene editing myths and reality, pp 41ff
[22] Montenegro de Wit, M., 2020, Democratizing CRISPR? Stories, practices, and politics of science and governance on the agricultural gene editing frontier. Kapuscinski AR, Fitting E, eds. Elementa: Science of the Anthropocene. 2020;8(9). doi:10.1525/elementa.405

The increased presence of GM crops will also hamper **organic production** in many other ways. If the EU organic label no longer stands for GMO-free food, this will undermine consumer confidence in the label. If the traceability requirement is abolished, organic producers may be unable to avoid the unintended presence of GMOs and have no legal cover in cases of GM contamination. To protect the organic and non-GM production from economic losses, governments would need to put in place systems (e.g. mandatory insurance for GM producers) to compensate farmers.

Allowing more patented GM seeds and products on the market would counter efforts to expand locally adapted and organic agricultural production. By reducing access to traditional cultivars, driving up seed prices and burdening peasant and organic farmers, it would jeopardise the much-needed transition to agro-ecological farming systems.