



**BIODYNAMIC  
FEDERATION** demeter

**POSITION PAPER  
NEW GENETIC  
ENGINEERING TECHNIQUES**

No solution for a sustainable future

## Introduction

Since the introduction of the first Genetically Modified Organisms (GMO) in the 1990s, their release in the environment has been strictly regulated in the European Union. All GMOs or derived products from GMOs require risk assessment, traceability, and clear labelling before being placed on the market. But in the past few years, several new genetic engineering techniques have been developed which can be used in plant breeding, and their legal status is now being raised as a question.

With the pending climate crisis and increasing biodiversity loss our agriculture systems are under a lot of pressure. Various stakeholders see these new genetic engineering techniques as a powerful tool to address the different problems agriculture is facing and are arguing that they should be excluded from the scope of the current European Union's regulation on GMOs.

The Biodynamic Federation Demeter International sees a real danger in a potential deregulation of these new techniques. Not only because they represent a threat to human health and to our environment but also because they are so invasive that one cannot guarantee the production of seeds and food that are free from GMOs in the long run. Such drastic consequences would be especially problematic when it comes to organic farming. Therefore, the Federation strongly supports to keep the new genetic engineering techniques under the scope of the current GMO legislations.

## New genetic engineering techniques: a definition

The new genetic engineering techniques include a wide variety of procedures. Many of the new techniques are not actually new but correspond to techniques that have been developed over the past 20 years since the first GMOs began with transgenesis in the 1990s. However, both old and new techniques alter genetic material in organisms at the molecular level. Their aim is to directly modify the genome, meaning to alter the genetic material of an organism by introducing either genetic material or material that enacts a change to genetic material into the cell.<sup>1</sup> The main difference is that the new genome editing techniques increase the possibilities and the speed of such modifications in the genetic material of organisms.

GMO defenders usually call them 'new breeding techniques' to relate them with traditional breeding and minimise their impact. GMO opponents consider it more appropriate to designate them as 'new engineering techniques' since they edit the genome of an organism.<sup>2</sup>

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1 Broadening the GMO risk assessment in the EU for genome editing technologies in agriculture, Environmental Sciences Europe, August 2020,

<https://enveurope.springeropen.com/articles/10.1186/s12302-020-00361-2>

2 Generation 'unknown', FOEE, December 2020,

<https://friendsoftheearth.eu/wp-content/uploads/2021/01/Generation-Unknown-English.pdf>

New genetic engineering approaches are continuously being developed leading to a diversity of techniques such as CRISPR-Cas 9, Cisgenesis and intragenesis, reverse breeding, etc. which can be used in combination with one another in both plants and animals<sup>3</sup>. They open new possibilities that previous methods of genetic engineering and conventional breeding cannot offer. Currently, the focus lies on the CRISPR-Cas 9 technique.

CRISPR-Cas is used to edit a genome at specific sites, using zinc finger nucleases that work like scissors that help to 're-write' parts of the genome by deleting, substituting, or adding DNA sequences in predefined locations.<sup>4</sup> This makes it more precise than the older genetic modification in which foreign DNA is randomly introduced in the genome with a low rate of success. In contrast to conventional breeding, the CRISPR-Cas method can directly interact with the genome, meaning that the entire genome can be 'edited', resulting in deep changes in the biological characteristics of organisms without the introduction of additional DNA sequences.<sup>5</sup>

So far only two plants produced by CRISPR-Cas are being cultivated: SU Canola, an oilseed rape developed by Cibus, an American gene-editing company and Calyno, a soya oil commercialised by Calyxt, a plant-based American technology company, although work on more crops is in process (maize and potatoes).

## New genetic engineering techniques: legislative state of play

In the European Union, GMOs have so far been regulated by EC Directive 18/2001 on the deliberate release into the environment of genetically modified organisms, EC Regulation 1829/2003 and EC Regulation 1830/2003.<sup>6</sup> None of these regulations prohibits the release in the environment of GMOs or GMO derived products, but they ensure that GMOs are subject to risk assessments and authorisation before coming on the market and to mandatory traceability and labelling once on the market. The EU has authorised more than 60 genetically modified crops for import but only one genetically modified crop has been authorised for cultivation (Monsanto's MON810 maize). As of today, no genetically modified animals have been authorised.<sup>7</sup>

As much as the legal status of GMOs is clear, the situation is different for new genetic engineering techniques. Indeed, the question remains as to whether these processes should be considered genetic modification. If not, then they will not fall under the scope of the GMO legislation meaning that they will not be subject to prior risk assessment and authorisation, traceability, and labelling.

3 New techniques of genetic engineering, FOEE, February 2017, [https://friendsoftheearth.eu/wp-content/uploads/2018/01/new\\_gm\\_techniques\\_joint\\_position\\_paper.pdf](https://friendsoftheearth.eu/wp-content/uploads/2018/01/new_gm_techniques_joint_position_paper.pdf)

4 Ibid.

5 Why 'New GE' needs to be regulated, Testbiotech, October 2020, [https://www.testbiotech.org/sites/default/files/Frequently\\_asked\\_questions\\_about\\_CRISPR\\_and\\_Co.pdf](https://www.testbiotech.org/sites/default/files/Frequently_asked_questions_about_CRISPR_and_Co.pdf)

6 EC Directive 18/2001, [https://eur-lex.europa.eu/resource.html?uri=cellar:303dd4fa-07a8-4d20-86a8-0baaf0518d22.0004.02/DOC\\_1&format=PDF](https://eur-lex.europa.eu/resource.html?uri=cellar:303dd4fa-07a8-4d20-86a8-0baaf0518d22.0004.02/DOC_1&format=PDF); <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003R1829&from=EN>; EC Regulation 1830/2003 <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003R1830&from=EN>

7 New techniques of genetic engineering, FOEE, February 2017, [https://friendsoftheearth.eu/wp-content/uploads/2018/01/new\\_gm\\_techniques\\_joint\\_position\\_paper.pdf](https://friendsoftheearth.eu/wp-content/uploads/2018/01/new_gm_techniques_joint_position_paper.pdf)

However, a Ruling of the European Court of Justice released in 2018 already provided some clarity as to the status of genome editing processes in the case of the use of mutagenesis techniques.<sup>8</sup> Although the Court reasserts that these mutagenesis techniques are indeed excluded from the scope of EC Directive 18/2001, it also immediately states that this exemption does not concern techniques or methods that have a long enough safety record and that have been used sufficiently, which is not the case for mutagenesis techniques. Indeed, if these new genetic techniques would be excluded from the scope of the Directive it would “compromise the objective of protection pursued by the Directive and would fail to respect the precautionary principle which it seeks to implement”.<sup>9</sup>

In the framework of the Farm to Fork Strategy, published in May 2020, the European Commission states that it is currently carrying out “a study which will look at the potential of new genomic techniques to improve sustainability along the food supply chain”<sup>10</sup>. However, any easing of the current regulatory requirements for new genetic engineering techniques would put in jeopardy the high food safety standards of the EU but also go against the EU’s precautionary principle. Therefore, the Federation insists on the importance to fully implement the Court’s ruling, taking into consideration the inherent risks and threats of these new techniques.

## Risks and threats of new genetic engineering techniques

### Inherent risks of genetic engineering

Interactions between genes and other elements are incredibly complex, which means that any genetic engineering intervention in the genome can have unforeseeable and unintended consequences. Studies on the matter are ongoing but the scientific community does not yet understand it all. A new study of the Environmental Sciences Europe Revue precisely shows the risks associated with the use of new genetic engineering in plants and animals.<sup>11</sup> Even if the genetic engineering intervention proceeds as planned, it is still possible that unexpected biological effects are triggered in the plant and unintentional plant properties are influenced.<sup>12</sup>

A few examples include modified plants synthesising modified proteins which may trigger allergies. Or if changes in the plant lead to an ecological advantage, the potential environmental impact could be devastating for existing wildlife. In fact, genetic engineering always means that there is the possibility of changes occurring beyond the intended edits in the genome, therefore producing unforeseen effects on human health and ecosystems.

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8 ECJ Ruling, July 2018  
<https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-07/cp18011en.pdf>

9 Ibid.

10 Farm to Fork Strategy, European Commission, May 2020,  
[https://ec.europa.eu/food/sites/food/files/safety/docs/f2f\\_action-plan\\_2020\\_strategy-info\\_en.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/f2f_action-plan_2020_strategy-info_en.pdf)

11 Broadening the GMO risk assessment in the EU for genome editing technologies in agriculture, Environmental Sciences Europe, August 2020,  
<https://enveurope.springeropen.com/articles/10.1186/s12302-020-00361-2>

12 Ibid.

The issue is that the knowledge about the effects of genetic engineering is very limited as there is not enough research carried out independent from the industry's interests. Often access is not granted to the material needed for the study and the incentives provided by industry are very high. Therefore, it is essential to strictly apply the precautionary principle, as well as systematic risk assessments and independent research. It is the European Commission's responsibility to ensure the safety of the products placed on the market and to invest in real risk analysis.<sup>13</sup>

## Genetic engineering: no solution

The seed industry and biotechnology companies see huge potential in genetic engineering. They argue that it is needed to ensure sustainable and sufficient food production. But genetic engineering has not yet realised any of these potentials. So far only two products are on the market but neither of them can be considered as more resistant with a reduced need for pesticides. We know from experience of the first generation of GMOs that the ambitious aims that were stated from the beginning have not been realised: the crops are by no means more robust and the use of pesticides remains the same.

Some errors already occurred while using new genetic engineering methods which greatly impact our safety.<sup>14</sup> Even if these issues concern mostly medical applications, there is no reason to think that the same errors won't happen in the agricultural field. Therefore, promises made by the seed industry need careful consideration. It is still unclear if new genetic engineering techniques when applied to agriculture can provide any real benefit for the environment and society. On the contrary, as a central component and driver of industrial agriculture, which is already harming the environment and the climate, agricultural genetic engineering exacerbates rather than solves the problems which already exist.

Most farmers worldwide are small farmers: 85 percent of farmers have less than two hectares of farmland.<sup>15</sup> Our food sufficiency is greatly dependent on these small farmers. Industrial and specialised agriculture, of which agro-genetic engineering is part, does not support small-scale farming structures. Only larger companies can afford to increase their productivity by replacing human labour with machines and by increasing the means of production in buying genetically modified seeds, fertilisers and pesticides. So far, Corteva controls most of the patents for the CRISPR-Cas technology providing them with a dominant market position leaving little margin for manoeuvre for other actors.<sup>16</sup>

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13 Risk assessment of GE plants in the EU: Taking a look at the 'dark side of the moon', Testbiotech, January 2021, [https://www.testbiotech.org/sites/default/files/Testbiotech\\_dark\\_side\\_of\\_the\\_moon.pdf](https://www.testbiotech.org/sites/default/files/Testbiotech_dark_side_of_the_moon.pdf)

14 An EU Perspective on Biosafety Considerations for Plants Developed by Genome Editing and Other New Genetic Modification Techniques (nGMs), Frontiers in Bioengineering and Biotechnology, march 2019, <https://www.frontiersin.org/articles/10.3389/fbioe.2019.00031/full>

15 Schöne neue Gentechnik, IG Saatgut, July 2020, [https://www.ig-saatgut.de/media/ig\\_broschuere\\_2020-07-24\\_web\\_einzelseiten.pdf](https://www.ig-saatgut.de/media/ig_broschuere_2020-07-24_web_einzelseiten.pdf)

16 Patent cartel for the large companies, Testbiotech, June 2019, <https://www.testbiotech.org/en/news/patent-cartel-large-companies>

## Genetic engineering contradicts the principles of organic farming

Organic farming opposes genetic engineering. In 2017, IFOAM Organics International, the organic agriculture movement, stated that the new genetic engineering techniques are not compatible with the principles of organic farming and should be regulated as GMOs.<sup>17</sup> Similarly, the Federation prohibits any use of genetically modified organisms. Seed, propagation, and plant material produced by new plant breeding techniques (NPBTs) are not authorised in production on a Demeter enterprise. This includes all NPBTs considered by IFOAM EU as techniques of genetic modification leading to GMOs according to the existing EU legal definition.<sup>18</sup>

Indeed, organic farming takes a precautionary approach to the changes made in our genetic heritage and planetary biodiversity.<sup>19</sup> It aims to respect the intrinsic value of all living organisms which is why it rejects patents on life. Instead, organic farming promotes free access to genetic resources and the preservation and availability of diversity for subsequent generations. Due to the invasiveness of the genome editing technology, once it is deregulated, it becomes nearly impossible to guarantee the integrity of whole system organisms. This means that gene edited products could be found in seeds varieties or traditional livestock breeds without any disclosure which would jeopardize the integrity of organic products.<sup>20</sup> Farmers and consumers have the right to know how and where their food comes from. This is essential not only to respect the high standards of organic production but also to preserve the integrity of our resources.

At a time when the European Commission aims to increase the EU's agricultural land under organic production to at least 25% by 2030, as stated in the Farm to Fork Strategy<sup>21</sup> and proclaims that the EU has the highest standards in food safety, a deregulation of the genetic engineering techniques appears even more contradictory. The focus and strength of the EU should remain the production of sustainable and healthy food rather than risking any unintended consequences.

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17 Genetic engineering and genetically modified organisms, IFOAM Organics International, November 2016, [https://www.ifoam.bio/sites/default/files/2020-03/position\\_genetic\\_engineering\\_and\\_gmos.pdf](https://www.ifoam.bio/sites/default/files/2020-03/position_genetic_engineering_and_gmos.pdf)

18 Production, Processing and labelling Standards, Biodynamic Federation Demeter International, January 2021, [https://www.demeter.net/sites/default/files/20201204\\_bfdi\\_standard\\_for2021\\_final\\_sc.pdf](https://www.demeter.net/sites/default/files/20201204_bfdi_standard_for2021_final_sc.pdf)

19 Genetic engineering and genetically modified organisms, IFOAM Organics International, November 2016, [https://www.ifoam.bio/sites/default/files/2020-03/position\\_genetic\\_engineering\\_and\\_gmos.pdf](https://www.ifoam.bio/sites/default/files/2020-03/position_genetic_engineering_and_gmos.pdf)

20 Genome Editing, Star and Furrow, October 2020, <https://www.biodynamic.org.uk/wp-content/uploads/2020/10/Genome-Editing-Lawrence-Woodward-Article-in-Star-and-Furrow-no-134-Oct-2020.pdf>

21 Farm to Fork Strategy, European Commission, May 2020, [https://ec.europa.eu/food/sites/food/files/safety/docs/f2f\\_action-plan\\_2020\\_strategy-info\\_en.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/f2f_action-plan_2020_strategy-info_en.pdf)

## Conclusion

Taking all these aspects into consideration, it is clear that the new genetic engineering techniques should be regulated as GMOs and fall under the scope of EC Directive 18/2001. Prior risk assessment and authorisation, as well as traceability and labelling, are essential for all products on the market to limit the risks on our health and environment but also to ensure the freedom of choice for both farmers and consumers. Contrary to what is often claimed, new genetic engineering techniques do not provide a solution to the challenges' agriculture is currently facing, they only come with more risks and threats.

Instead of pursuing an intensive and specialised agricultural model, our efforts must go towards sustainable practices that have proven their efficiency such as organic and biodynamic farming. It is time that the European Union takes a clear stand and announces its distance with the further development of these new techniques. The focus should lie in the EU Green Deal objectives by encouraging sustainable farming practices protecting our environment, biodiversity, and health.

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