European Parliament

New plant-breeding techniques

Applicability of EU GMO rules

SUMMARY

New plant genetic modification techniques, referred to as 'gene editing' or 'genome editing', have evolved rapidly in recent years, allowing much faster and more precise results than conventional plant-breeding techniques. They are seen as a promising innovative field for the agri-food industry, offering great technical potential. Consumers could benefit from enhanced nutritional quality or reduced allergenicity of food, for example, such as gluten-reduced wheat.

There is, however, considerable debate as to how these new techniques should be regulated, and whether some or all of them should fall within the scope of EU legislation on genetically modified organisms (GMOs). Those who take the view that the new techniques should be exempt from GMO legislation generally argue that the end product is very similar to products generated using conventional breeding techniques, or that similar changes could also occur naturally. Those who consider that the new techniques should fall within the scope of GMO legislation contend that the processes used mean that plants bred using the new techniques are in fact genetically modified.

In July 2018, the Court of Justice of the European Union ruled that genome-edited organisms fall under the scope of European GMO legislation. While welcomed by some, the judgment also sparked criticism and calls for the new European Commission to amend EU GMO legislation. In November 2019, the Council requested that the Commission submit a study in light of the Court of Justice judgment regarding the status of novel genomic techniques (NGTs), by 30 April 2021.

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Issue

EU legislation on genetically modified organisms dates back to 1990. It has been revised since then, but the definition of GMOs has remained unchanged.

In traditional plant breeding, mutations producing variations in the plant genome are introduced using radiation or chemicals. This way of modifying genetic material, called mutagenesis, is explicitly exempt from the scope of EU's GMO legislation on the basis that it has a long history of safe use. Many varieties of plant species cultivated today, including barley, wheat and grapefruit, were modified in this way.

New breeding and genetic modification techniques have evolved rapidly over the last decade, and biotechnologies are applied in plant breeding with the aim of introducing new traits bringing desirable characteristics to the plants. The objective is to achieve this in a precise and cost-effective manner, allowing rapid identification of plants carrying the desirable genotypes.

Potential applications of gene-edited plants

- Precise and rapid alteration of crops to boost yields
- Plants with herbicide tolerance
- Plants with pest or insect resistance
- Plants with drought or flood resistance
- Enhanced nutritional quality of food crops
- Changes in the composition of nutrients in plants, for example vitamins or fatty acids
- Food crops with reduced allergenicity (for example wheat low in gluten)

The first new plant varieties developed using new gene-editing techniques (for example herbicide-tolerant oilseed rape (canola), non-browning apples, and soybean oil made to be healthier) are already on the market in North America. In the United States and Canada, meanwhile, the first genetically modified animal, Atlantic salmon, modified to grow faster, has been approved for human consumption.

Some of the newest plant-breeding techniques are in an uncertain situation concerning their classification within legislation. There is considerable debate as to how these new techniques should be regulated and whether some or all of them should fall within the scope of EU legislation on GMOs.

The Member States have asked the Commission to issue guidance on the regulatory status of products generated using the new techniques. The Commission has stressed that it is the 'sole prerogative of the European Court of Justice to render a final and binding opinion on the interpretation of EC law'.

In July 2018, the Court of Justice of the European Union (CJEU) delivered a judgment in which it held that organisms obtained by the new techniques are GMOs and fall under the scope of EU legislation on GMOs. While welcomed by the environmentalists, the judgment has also sparked criticism and calls for the new Commission to change the EU's GMO legislation.

EU legal basis

The EU's GMO legislation stems from 1990 when the first two directives concerning GMOs[1] came into force. Both original directives have since been updated,[2] but the definition of a GMO has remained unchanged. This is causing problems for new techniques developed since then.

Under EU law, the definition of GMOs states that 'genetically modified organism (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination' – Directive 2001/18/EC, Article 2(2).

The annexes to the directive further define the techniques that (a) result in genetic modification (listed in Annex I A, Part 1), (b) are not considered to result in genetic modification (Annex I A, Part 2)

and (c) result in genetic modification but yield organisms that are excluded from the scope of the directive (Article 3 and Annex I B): these techniques are mutagenesis and cell fusion.

Recital 17 states that the directive 'should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record'. Mutagenesis – a method used in traditional plant breeding, where variations in the plant genome are introduced using radiation or chemicals – is explicitly exempt from the scope of GMO legislation, on the basis that it has a long history of safe use.

In replies to parliamentary questions, the European Commission has stressed that the decision to include or exclude a technique from the scope of Directives 2001/18/EC and 2009/41/EC depends only on the interpretation of the definition of genetically modified organisms and of the conditions for exemption provided for in the two directives. The Commission has also noted that the evaluation is complex, because the definition of a GMO under EU legislation refers both to the characteristics of the organism obtained and to the techniques used.

On 25 July 2018, at the request of the French Council of State (*Conseil d'État*), the CJEU delivered a judgment (Case C-528/16) in which it held that organisms obtained by the new mutagenesis techniques are GMOs and fall under the scope of the EU's GMO legislation (Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms). According to the ruling, organisms obtained by mutagenesis, a set of techniques that make it possible to alter the genome of a living species without the insertion of foreign DNA, are GMOs and are, in principle, subject to the obligations laid down by the relevant EU-wide authorisation, traceability and labelling rules. The Court took the view that organisms obtained by mutagenesis are GMOs, in so far as the techniques and methods alter the genetic material 'in a way that does not occur naturally'. However, organisms obtained by mutagenesis techniques which have conventionally been used in a number of applications and have a long safety record remain exempt from those obligations.

Background for regulating the new techniques

According to a 2011 study by the European Commission's Joint Research Centre (JRC), Europe's plant-breeding industry and researchers have been very active in the field of new plant-breeding techniques, and have carried out almost 50 % of the research done globally. These new techniques allow targeted gene modifications to be obtained more precisely and faster than by conventional plant-breeding techniques. The study notes that because the regulatory costs for plants classified as GMOs are much higher than those for non-GMO plants and because public acceptance of them is lower, biotechnology companies and plant breeders have been 'particularly concerned' by the legal uncertainty relating to the applicability of GMO rules to these new techniques.

At the request of the Member States, the European Commission set up a working group in 2007, composed of nationally appointed scientists, to assess whether or not a number of new breeding techniques should fall within the scope of GMO legislation.[3] The working group completed its work in 2012. The experts agreed that organisms developed through cisgenesis[4] and intragenesis[5] fell under Directive 2001/18/EC, but remained divided on the regulatory status of most of the other new techniques. In 2011, the JRC published a study on the potential of these technologies, and on detection and monitoring.

The European Food Safety Authority (EFSA) has issued two opinions on the safety assessment of new breeding techniques.[6] In its opinions, EFSA concluded that the existing guidelines for risk assessment applicable to genetically modified (GM) plants were also appropriate for cisgenic and intragenic plants, and for the ZFN-3 technique. EFSA also considered the hazards associated with cisgenic plants to be similar to those linked to conventionally bred plants, but that novel hazards could be associated with intragenic and transgenic[7] plants. All these breeding methods could, however, produce 'variable frequencies and severities of unintended effects, the frequency of which cannot be predicted and needs to be assessed case by case'.

In the past few years, a novel innovative technique for genome editing, CRISPR-Cas9, with wider potential and easier applicability, has rapidly advanced research and the development of applications for plant breeding. Nuclease-based genome editing is an effective genetic-engineering method that allows modification of genetic information by adding, altering or removing DNA sequences at a specific location in the genome in a targeted way. This is obtained using artificially engineered enzymes called nucleases that act as molecular scissors to split open the DNA double-stranded helix, then allowing the cell's own endogenous repair machinery to repair the break.[8] This technique is quick, precise and cheap to use, and experts say it has revolutionised gene-editing technology since 2012. In October 2020, the 2020 Nobel Prize in Chemistry was awarded to the developers of this technique, French microbiologist Emmanuelle Charpentier and American biochemist Jennifer A. Doudna.

In April 2017, the High-level Group of the Commission's Scientific Advice Mechanism (SAM) published an explanatory note on new techniques in agricultural biotechnology , providing an overview of new techniques and explaining differences and similarities with conventional breeding and established techniques of genetic modification.

EU legislation requires that GMOs be identifiable using detection methods.[9] Nevertheless, plants grown using many of the new methods can hardly, if at all, be distinguished from conventionally bred plants if no foreign DNA has been introduced. It is often impossible to tell whether the modification was natural or triggered by a new breeding technique.

In October 2018, the Commission asked the European Union Reference Laboratory for GM Food and Feed to elaborate a report on the detection of food and feed plant products obtained by new mutagenesis techniques. The report was published in March 2019. It highlights challenges and limitations relating to detection and identification, concluding that products of genome editing can only be readily detected in commodity products if prior knowledge of the altered genome sequence is available.

If the new techniques were to be exempted from GMO legislation, they would also then be exempt from the obligations of pre-market assessment and authorisation, as well as from labelling requirements concerning GMOs.

Developing new plant varieties or protecting old ones?

Innovation in agriculture and plant breeding can play a key role in responding to challenges such as feeding the growing world population, adapting to climate change and protecting natural resources. According to different estimates, food production will need to increase by anywhere from 25-70 % by 2050 to feed the world population, while the area suitable for agricultural cultivation is limited. As a result of climate change, the world may need plant varieties that can adapt to changing conditions.

At an international symposium on agricultural biotechnologies, hosted by the United Nations Food and Agriculture Organization (FAO) in 2016, stakeholders, scientists and representatives of governments as well as civil society and farmers' groups discussed the benefits of biotechnologies, such as improving crop and vegetable resource efficiency, building climate change resilience, increasing fruit and vegetable storability and shelf life, increasing yields, improving plants' nutritional qualities and transforming food systems so that they need fewer inputs and have less of an environmental impact.

Paradoxically, the intensification of plant-breeding activity may reduce biodiversity, and hence resilience. Plant genetic diversity is threatened by the loss of landraces (local varieties of plant species that have adapted over time to their ecological and cultural environments) and the domination of genetically uniform modern varieties in many agricultural production systems. The FAO points out that 'since the 1900s, some 75 % of plant genetic diversity has been lost as farmers worldwide have left their multiple local varieties and landraces for genetically uniform, high-yielding varieties'. Yet, according to the FAO, maintenance of genetic diversity is key to adapting to changing conditions. In Europe, only a few farmers cultivate locally adapted traditional crops and much of this genetic variation has been lost.

EU debate on regulating the new techniques

There are two sides to the debate on how the new techniques should be regulated. Those who take the view that new techniques should be exempt from GMO legislation generally argue that the end product is similar to products that could be generated using conventional cross-breeding techniques; and that mutations can also occur naturally, without human intervention. Those who take the opposing view contend that the processes used are similar to those used to generate GMOs, and that despite the claimed precision, unintended effects are still possible.

The case for exempting the new techniques from GMO legislation

In its 2018 statement on new breeding techniques, the European Academies' Science Advisory Council (EASAC), a body of national science academies of the EU Member States, argues that the products of genome editing should not fall under GMO legislation when they do not contain foreign DNA. EASAC takes the view that the EU should seek to regulate the trait and/or the product rather than the technology used. According to EASAC, when considering safety issues, the focus should be on assessing whether the novel attributes of the plant might represent a risk to the environment or human health, irrespective of the breeding technique employed.

The view that the safety of new crop varieties ought to be assessed according to their characteristics, rather than the method by which they are produced, is shared by a range of bodies, including the UK Biotechnology and Biological Sciences Research Council (BBSRC), the German Academies, the European Plant Science Organisation (EPSO) and the French High Council for Biotechnology (HCB).

The plant-breeding industry in general takes the view that new breeding techniques should not be subject to GMO legislation. Euroseeds, representing European seed businesses, argues that plant varieties developed through the latest breeding methods should not be subject to different or additional regulatory oversight if they could also be obtained through earlier breeding methods or result from spontaneous processes in nature. According to Euroseeds, the prohibitive compliance requirements of the GMO Directive relative to the value of commodity crops effectively cut Europe's breeders off from scientific progress and put them, as well as farmers, processors, traders and consumers, at a competitive disadvantage in relation to regions with more enabling regulations.

The case for classifying the new techniques under GMO legislation

A legal analysis of genome-editing technologies commissioned by the German Federal Agency for Nature Conservation (BfN) concluded that the organisms produced using the new techniques fall within the scope of the EU's GMO legislation. The analysis argues that the fact that mutations also occur naturally is of no importance in this context: most crucial is that the modifications are carried out purposefully and lead to the incorporation of material into a host organism in which these nucleic acid molecules do not occur naturally. In addition, these interventions can be applied many times over to the same plant, possibly leading to extensive modifications. Most importantly, the analysis highlights, the term mutagenesis used in Annex I B explicitly covers only conventional mutagenesis.

In a report on the assessment of the potential risks associated with crops obtained through new plant-breeding techniques, Environment Agency Austria points out that the individual new techniques differ widely in their approaches and characteristics. It further emphasises that these techniques are used mostly in combination. The potential risks are associated with the intended modifications, or with unintended effects resulting from application. This means that a case-specific risk assessment is necessary, as well as application of the precautionary principle.

EcoNexus, a not-for-profit public-interest research organisation, concludes that there is a scientific case for classifying all the new breeding techniques as GM. EcoNexus points out that all of these techniques, though claiming great precision, can also have unintended effects and unpredictable consequences. ENSSER, the European Network of Scientists for Social and Environmental

Responsibility, also stresses that products of new genetic modification techniques should be strictly regulated as GMOs, and points out that unexpected patterns of mutations induced by genome editing have recently been described. In cases of plant foods produced with these techniques, off-target effects can lead to unexpected toxins or allergens, ENSSER warns.

A legal analysis commissioned by several German agricultural and environmental associations concludes that both ODM and the CRISPR-Cas technique constitute GMO technology. The analysis takes the view that the classification of a specific technique does not depend on whether or not the modified organism can be distinguished from an organism that mutated naturally or with the help of traditional breeding, because Directive 2001/18 is process-oriented, not result-oriented.

A number of environmental NGOs published a joint position paper in February 2017, arguing that EU GMO law must be applied in full to the new plant-breeding techniques. If they were to escape EU regulations, any potential negative effects on food, feed or environmental safety would go unchecked.

European Parliament

In its resolution of February 2014 on 'Plant breeding: what options to increase quality and yields', Parliament noted that it was important to develop and use new plant-breeding techniques that respond to societal and agricultural demands and to be open to the technologies available. Parliament expressed concern at the Commission's delay in assessing new breeding techniques, and called on the Commission to clarify their regulatory status. Parliament stressed that in order to respond to forthcoming challenges, such as future food-supply needs and climate change, it was important to have an effective and competitive plant-breeding sector. It called on the Commission to use the Horizon 2020 framework programme to fund research that supported the development of new, innovative plant-breeding techniques such as accelerated breeding. In its March 2014 resolution on 'The future of Europe's horticulture sector – strategies for growth', Parliament called on the Commission to differentiate between cisgenic and transgenic plants and to create a different approval process for cisgenic plants.

On the other hand, during the 2014-2019 term, Parliament systematically objected to every authorisation of 'traditional' genetically modified food and feed, demanding the suspension of all GMO approvals until their authorisation process has been revised.

In recent years, Members of the European Parliament have put several questions to the Commission concerning progress on completing the legal analysis (such as P-003377/2015, P-014731/15 and P-005734-16), as well as the impacts of the Court of Justice ruling (E-000185-19, E-000219-19).

Reactions to the Court's ruling

The Group of Chief Scientific Advisors, tasked with providing the European Commission with scientific advice, took a view in its statement in November 2018 that 'in view of the Court's ruling, it becomes evident that the new scientific knowledge and recent technical developments have made the GMO Directive no longer fit for purpose' and recommended revising the existing directive in order to reflect current knowledge and scientific evidence, 'in particular on gene editing and established techniques of genetic modification'. The group also warned that, unless the EU 'improves the regulatory environment' for products of gene-editing, it will be left behind in this field, which could also diminish EU influence on ongoing debates at the international level.

In April 2019, over 20 EU business associations published an open letter calling upon Member States and the Commission to initiate a legislative change to ensure innovation-friendly rules on mutagenesis. They say that the Court's ruling will effectively deprive European farmers and consumers from the benefits of these products, cut the EU off from scientific progress and put it at competitive disadvantage compared to countries with regulations more conducive to innovation. According to the letter, the ruling is also virtually impossible to enforce, given that many gene-edited products may be indistinguishable from products changed by natural processes or with conventional breeding techniques.

Copa and Cogeca, representing European farmers and agri-cooperatives, emphasised in July 2019 that new breeding techniques (NBTs) should be a priority within the new Commission's work programme when it comes to agriculture. For Copa and Cogeca, it is a matter of urgency that a European strategy regarding these techniques be put in place.

In an answer to a parliamentary question, given in March 2019, the Commission explained that Member States are responsible for the enforcement of GMO legislation, and that the Commission and the Member States' competent authorities are discussing the implications of the Court ruling in terms of implementation, with a view to harmonised enforcement. According to the European Commission website, the Commission is working with EU countries and stakeholders to implement the Court's ruling and 'organises regular discussion with Member States during Regulatory Committees'. For example, a summary report of a joint working group on the implementation of the CJEU ruling was presented at a meeting held on 25 April 2019.

In a press interview in March 2019, EU Health and Food Safety Commissioner Vytenis Andriukaitis said that, in his personal view, a new regulatory framework was needed for new plant-breeding techniques, adding that this should be dealt with by the new European Commission after the European elections in May 2019.

At a meeting of EU agriculture ministers in May 2019, many Member States supported a common EU approach to new plant-breeding techniques and called for the revision of the EU's GMO legislation to be added to the next European Commission's work programme. After the meeting of EU agriculture ministers, then Agriculture Commissioner Phil Hogan said in an interview that the Commission has asked EU Member States to provide the necessary data in order to help the Commission to come up with a 'robust response' to the EU court's ruling and for the new Commission to draft a legislative response.

In July 2019, a European Citizens' Initiative (ECI) demanding revision of EU GMO Directive was registered by the Commission. The organisers have until 25 January 2021 to collect the one million signatures needed.

There are also views that oppose de-regulation of gene-editing, saying that gene-editing tools are still far from perfect, and stressing that the techniques are not as precise as claimed. According to these critics, they produce many unintended effects, not only at 'off-target' sites but also at the intended gene-edited site.

IFOAM EU, representing the organic food and farming sector, argues that any attempt to exclude new genetic engineering techniques from the GMO legislation would lead to the release of genetically modified organisms in the environment and the food chain without assessment, prior authorisation and traceability. This would make it almost impossible for organic farmers and conventional GMO-free farmers to exclude the presence of GMOs from their production process.[10] Several NGOs called on the new Commission to resist lobbying efforts to torpedo the existing GMO regulations.

It has also been claimed that the Court's ruling will create a dilemma for food-testing laboratories across Europe, as scientists struggle to know how to detect unauthorised gene-edited crops whose altered DNA can mimic natural mutations.

In the United Kingdom, Prime Minister Boris Johnson has suggested that his country should take a different approach to GMOs and genetic modification after leaving the EU, saying they should 'start to liberate the UK's bioscience sector from anti-genetic modification rules' and 'develop the blight-resistant crops that will feed the world'. While the biotech industry and some researchers have highlighted the opportunities of such a shift in approach, there are others who caution against 'liberating' the use of those techniques from regulation, pointing out that even with the latest genome modification techniques, such as CRISPR, it takes a great deal of work to make sure that only the desired changes have been induced, and that it is even more difficult to be sure that the only consequence of the change introduced is the one that was intended.

Regulation in some non-European countries

The United States Department of Agriculture (USDA) indicated in 2015 that crop varieties generated through genome editing do not constitute GMOs as they do not contain foreign DNA from plant pests.[11] In March 2018, the US Secretary of Agriculture Sonny Perdue issued a statement on plant-breeding innovation, clarifying that the US Department of Agriculture did not have plans to regulate plants 'produced through innovative new breeding techniques which include techniques called genome editing'. The United States Food and Drug Administration (FDA), for its part, offers a voluntary premarket consultation programme[12] for developers of new plant varieties to obtain early feedback on potential food safety considerations. In October 2018, the FDA announced its Plant and Animal Biotechnology Innovation Action Plan, reaffirming the FDA's commitment to promoting innovation in this area. In June 2019, President Donald Trump issued an executive order on modernising the regulatory framework for agricultural biotechnology products, to remove undue barriers that impede 'innovative and safe genome-edited-specialty-crop-plant products' from reaching the marketplace.[13]

In May 2020, a final rule was announced, updating and modernising the USDA biotechnology regulations under the Plant Protection Act. The 'Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient' (SECURE) rule is to 'bring USDA's plant biotechnology regulations into the 21st century by removing duplicative and antiquated processes in order to facilitate the development and availability of these technologies through a transparent, consistent, science-based, and risk-proportionate regulatory system'. The final rule puts in place a process to identify plants that would be subject to regulation, focusing on the properties of the plant rather than on its method of production. Some plants developed using genome editing techniques will be regulated if they pose a plausible plant pest risk. The SECURE rule was published in the Federal Register on 18 May 2020, and the provisions take effect on key dates over the following 18 months.

The Government of Canada regulates plants, animal feed and human food separately under different legislation. Therefore, the regulatory requirements for each are different. When a product is 'novel' (different from what is already available in Canada), the Canadian Food Inspection Agency (CFIA) and Health Canada carry out pre-market assessments. Some products developed using gene editing techniques may not meet the regulatory definition of 'novel'. If a product is not novel, it is considered equivalent to its existing counterparts, and no pre-market assessment is required. Regulatory oversight is based on the characteristics of the product, regardless of how it was developed. Developers using biotechnology are 'strongly encouraged' to request an opinion from the CFIA or to contact Health Canada to confirm whether their product is novel.

The Australian government announced in April 2019 that it will not regulate the use of gene-editing techniques that do not introduce new genetic material. Techniques for modifying genomes are grouped into three groups, based on the outcomes produced in the final product: 1) genome contains new DNA (techniques such as transgenesis and cisgenesis); 2) genome unchanged by gene technology (new DNA is used to accelerate the breeding process, but only organisms that have not inherited the new DNA are finally selected for food production purposes); and 3) genome changed but no new DNA (genome editing techniques such as CRISPR and ZFN, which involve deleting a specific piece of DNA or editing the DNA without adding new DNA). Food Standards Australia New Zealand (FSANZ) announced in April 2020 that they have been reviewing how the Food Standards Code applies to food derived using new breeding techniques. A final report on the review was released in December 2019, recommending that FSANZ prepares a proposal to revise and modernise current definitions in the Code to make them better able to accommodate emerging genetic technologies. The work to amend the definitions commenced in February 2020, but was stalled due to the coronavirus pandemic, and public consultation was postponed until later in the year.

In Argentina, a decision was published in May 2015, determining that all crops derived through new breeding techniques were to be reviewed on a case-by-case basis. All products obtained through any new plant-breeding techniques must be submitted to a prior consultation. If the product does

not contain a new combination of genetic material in the genome, the product does not fall under the GMO Resolution (Resolution 701/11 that regulates activities with GMOs for agricultural use). Researchers from Institute of Agricultural Technology of Argentina (INTA) have used CRISPR-Cas9 to develop potatoes that do not turn brown; milk that does not affect allergic consumers; and to increase alfalfa productivity and quality. Most South American countries have adopted a case-by-case approach based on the end product, and do not regulate genome-edited products as GMOs. This means that if gene-edited products are put on the market in those countries, neither information about the genetic change, nor a validated detection method might be available.

In Japan, an advisory panel for the Ministry of Health concluded in March 2019 that no safety assessment should be required, provided that the techniques used do not leave foreign genes or parts of genes in the target organism. The Ministry of Health, Labour and Welfare published final guidelines in 2020, stating that gene-edited plants and food can be sold to consumers without safety evaluations as long as the techniques involved meet certain criteria, but developers must send notification to the government. First field trials are ongoing with a rice, gene-edited to increase the size and number of grains.

Recent developments in the EU

In Council Decision (EU) 2019/1904 of 8 November 2019, the Council requested 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 (NGTs) under Union law, and a proposal, if appropriate in view of the outcomes of the study. The study should be submitted **by 30 April 2021**.

The Council notes in its decision that there has been substantial progress in the development of new breeding techniques, leading to uncertainty on whether those new techniques come under the definition of a GMO. According to the Council, the ruling of the Court of Justice brought legal clarity as to the status of new mutagenesis techniques, but also raised practical questions, which have consequences for the national competent authorities, the Union's industry, in particular in the plant breeding sector, research, and beyond. Those questions concern, inter alia, how to ensure compliance with Directive 2001/18/EC when products obtained by means of new mutagenesis techniques cannot be distinguished, using current methods, from products resulting from natural mutation, and how to ensure, in such a situation, equal treatment between imported products and products produced within the Union. The Council considers that a study is necessary to clarify the situation.

In the study, the Commission intends to provide a state-of-play on the implementation and enforcement of the GMO legislation, as regards NGTs, based inter alia on contributions from targeted consultations of Member States and stakeholders. The study should also give information on the status and use of NGTs in plants, animals and micro-organisms for agri-food, industrial and pharmaceutical applications. For the study, NGTs are defined as techniques capable of changing the genetic material of an organism and that have emerged or have been developed **since 2001**, when the existing GMO legislation was adopted.

The European Food Safety Authority (EFSA) will prepare an overview on the risk assessment of plants developed through new genomic techniques, and the Commission's Joint Research Centre will offer an overview of current and future scientific and technological developments in new genomic techniques, as well as of new products that are, or are expected to be, marketed.

The study will also take into account the past and ongoing work of the European Union Reference Laboratory and the European Network of GMO Laboratories, on the detection of products obtained by certain NGTs. In addition, the study will take the opinion on gene editing that is being developed by the European Group on Ethics in Science and New Technologies (EGE) into account.

In this context, the Commission carried out targeted consultations with Member States and EU-level stakeholders. Consulted stakeholders had until 15 May 2020 to reply. The participating stakeholders

are active not only in the agri-food chain, but also in a variety of fields, e.g. pharmaceuticals, cosmetics, academia/research, as well as environmental protection, and also include organic business operators and breeders. The Commission is currently analysing the responses it received from stakeholders.

In its Farm to Fork Strategy of May 2020, the Commission reminds that it is 'carrying out a study which will look at the potential of new genomic techniques to improve sustainability along the food supply chain', and says that 'new innovative techniques, including biotechnology and the development of bio-based products, may play a role in increasing sustainability, provided they are safe for consumers and the environment while bringing benefits for society as a whole'. According to the Commission, they can also 'accelerate the process of reducing dependency on pesticides'.

The German Science Academies Leopoldina and the German Research Foundation (DFG) organised an international conference on genome-edited organisms (GEOs) in October 2020 and published a summary statement calling for amendment of the EU GMO legislation in the short-term to accelerate the deployment of gene-editing technologies and facilitate field trials; and adopting a completely new legal framework in the long-term. GEOs should be exempt from GMO legislation, if they do not contain foreign genetic information, or contain a combination of genetic material which could have occurred naturally, or through traditional breeding methods. According to the statement, more than 100 potentially marketable genome-edited crops are currently known worldwide: these include soybeans with healthier fatty acids, gluten-reduced wheat, potato tubers with a longer shelf life, bacteria-resistant rice, fungus-resistant varieties of grapes, wheat and cocoa, and drought-tolerant varieties of corn, wheat, and soybeans. The statement deplores that European genetic engineering legislation hinders the research and development of these kinds of improved crops to support climate-adapted and sustainable agriculture.

Environmental NGOs, in their turn, dismissed the statement and argued that several recent publications show that the technical potentials and the risks of new genetic engineering techniques are far more complex than presented in the Leopoldina and DFG statement. Several NGOs sent an open letter in September 2020 to Commissioner for Health and Food Safety, Stella Kyriakides, expressing 'concern that she may consider a separate, light-touch regulatory regime' for genetically modified organisms (GMOs) derived from genome editing.

In September 2020, a study was published in a scientific journal, reporting the development of a new detection method for the first genome-edited crop commercialised (in North America), a rapeseed conferring herbicide tolerance. The study was welcomed by some researchers and stakeholders as an important step towards effective controls, while others claim that the study demonstrates nothing new, and that the problem of whether detection is able to prove whether the mutation was naturally derived or a consequence of gene editing remains. The German Federal Office for Consumer Protection and Food Safety (BVL) already concluded that, while the test could identify a known point mutation in a plant's genome, it could not identify whether or not that mutation was induced by genome-editing. In addition, the BVL says that, based on the information available, the mutation in this case was not caused by a genome editing technique. The European Commission has indicated that it is in the process of analysing the study, and the European Union Reference Laboratory for GM Food and Feed (EURL GMFF) is to make a scientific assessment of the detection method.

FURTHER READING

Bioökonomierat, Genome editing: Europe needs new genetic engineering legislation, August 2018.
Eckerstorfer M. et al., 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.
European Academies Science Advisory Council, The regulation of genome-edited plants in the European Union, March 2020.
New techniques in biotechnology, European Commission website.

Shukla-Jones A., Friedrichs S. and Winickoff D., Gene editing in an international context: Scientific, economic and social issues across sectors, OECD Science, Technology and Industry Working Papers, No 2018/04, March 2018.

Synthetic biology and biodiversity, Science for Environment Policy, Directorate-General Environment, European Commission, September 2016.

The State of the World's Biodiversity for Food and Agriculture, Food and Agriculture Organization of the United Nations (FAO), 2019.

Van Woensel L., Kritikos M. with Van Steereghem J., What if CRISPR became a standard breeding technique? EPRS, European Parliament, April 2020.

ENDNOTES

1 Directive 90/220/EEC on the deliberate release of GMOs into the environment and Directive 90/219/EEC on the contained use of genetically modified micro-organisms.

2 Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, and Directive 2009/41/EC on the contained use of genetically modified micro-organisms. Regulation (EC) No 1829/2003, concerning genetically modified food and feed, was added in 2003.

3 The working group considered the following eight new breeding techniques: oligonucleotide directed mutagenesis (ODM); zinc finger nuclease (ZFN) technology (ZFN-1, ZFN-2 and ZFN-3); cisgenesis and intragenesis; grafting; agro-infiltration; RNA-dependent DNA methylation (RdDM); reverse breeding; and synthetic genomics.

4 Cisgenesis is the genetic modification of a recipient organism with a gene (cisgene) from the same species or a closely related (crossable) species.

5 Intragenesis is the genetic modification of a recipient organism that involves the insertion of the reorganised, full or partial coding region of a gene from another gene (intragene) of the same species or a crossable species.

6 Scientific opinion on the safety assessment of plants developed by cisgenesis and intragenesis (February 2012), and on the safety assessment of Zinc Finger Nuclease 3 (October 2012).

7 Transgenesis means the transfer of an exogenous gene (derived from another unrelated species) from one organism to another. Conventional genetically modified organisms are usually produced in this way.

8 Many different types of nuclease have been developed that can be directed to the exact place where a DNA break is to be introduced. Different results are obtained depending on the method used to repair the DNA breaks: insertions or deletions of nucleotides, gene inversions or translocations, changes in the nucleotide sequence.

9 Commonly used genetic engineering breeding methods used to leave easily detectable traces of genetic material from the bacteria or viruses (used as gene shuttles) in the genome of the plant.

10 Traceability and labelling are of paramount importance to the organic sector, as GMOs are not to be used in organic production.

11 DNA from plant pests, such as viruses or bacteria, were used in traditional GM-plants.

12 Premarket voluntary plant biotechnology consultation programme. A recent example of participation in the programme is, according to the FDA, a new high-oleic soybean, the first genome-edited plant to complete the voluntary premarket consultation programme.

13 As for 'traditional' GM food in the US, a new regulation, the National Bioengineered Food Disclosure Standard, will make it mandatory from 1 January 2022 for companies to disclose information about foods offered for retail sale that are genetically modified (the term often used in the US is 'bioengineered'). The Agricultural Marketing Service (AMS) in the US keeps a list of bioengineered foods that are currently in legal production somewhere in the world.

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