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POLICY BRIEF

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Genome Editing – How to protect the interests of consumers

Key points

- The ruling of the ECJ on genome editing is a strong signal concerning the rights to information of consumers in Europe. It means that there will be a clear and mandatory labelling of these products as genetically engineered. Consumers will be able to decide whether they want genetic engineering in their food or not.
- In order to ensure the "right to safety" and the "right to choose", products with genome editing need to undergo a comprehensive risk assessment and clear labelling of genetically modified organisms (GMO) is needed before approval on the EU market. This is why current GMO legislation must not be deregulated in any way.
- Consumers must be able to rely on the fact that organic products and products labelled as GMO-free do not come into contact with genetic engineering during the entire production process.

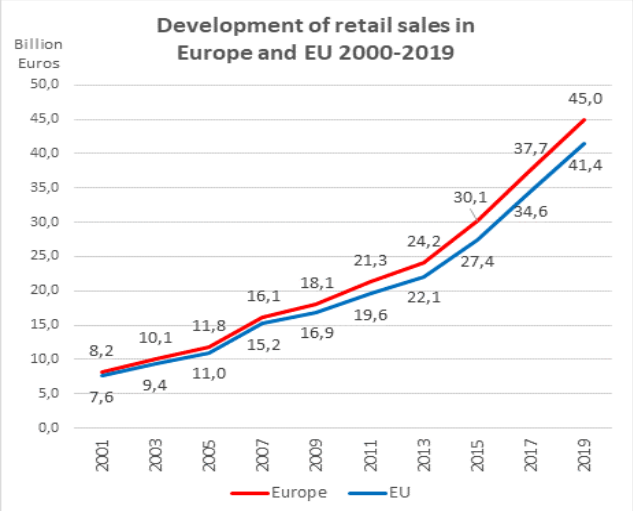
Background

Food placed on the EU-market has to be safe and adequately labelled to enable free and informed food choices. For many years, GMO-free status has been indispensable for consumers when buying food. When you ask consumers what their definition of sustainable food is, it is a synonym for environmentally friendly, GMO- and pesticide-free, and local, with some specificities across countries as BEUC found out in a recent study. We can also observe that more and more consumers are interested in organic food and GMO-free food. Already in ten countries there are GMO-free food seals, and their sales are rising. Looking at a market research poll in Austria, about 84% of consumers want genome editing to be labelled.

Genome editing (GE) also known as new genomic techniques (NGTs) or new genetic engineering opens up many possibilities to intervene in the genetic material of organisms, plants, animals or humans. GE techniques allow various modification of the genome, which go beyond the possibilities offered by the old genetic engineering, as well as conventional breeding. It comprises a wide range of methods the best known of which is CRISPR/Cas. In July 2018, the EU Court of Justice ruled (C-528/16) that products from new GE techniques such as CRISPR/Cas are to be considered genetically modified organisms and fall under the currently valid genetic engineering legislation. This means that such products need to undergo comprehensive risk assessment and be clearly labelled before being approved for the EU market. Since the judgement was published, the regulation of GE has been widely discussed. By the end of April 2021 the Commission will present a study of the legal status on novel genomic techniques, and if necessary, a proposal for legal regulation.

What possibilities are offered by GE?

New GE basically make a number of totally different modifications in genetic material possible, for instance, to produce traits which are already present in wild species (e.g., apples) in agriculturally used plants, which have previously been unknown to the respective species, can also be inserted. Special proteins are often produced not only by one but several genes. By the means of GE techniques i.e., altering a number of wheat genes at the same time, wheat with less gluten or cattle without horns (at the moment under research) could be produced. New GE are also used in animal breeding. Kawall et al. (2020) list a number of applications where traits in farm animals have been altered. The respective patents for cattle without horns and swine with increased muscle growth have been filed. Another application is inhibiting farm animals from reaching maturity to prolong the fattening period.



Source: FIBL and IFOAM, 2021

Organic and GMO-free production in Europe

Throughout Europe the demand for organic products has been on the rise continuously for years. The COVID-19 pandemic shows, that consumers are getting even more sensitive about food. This can be confirmed by current figures on purchases of organic food in Austria. The share of purchases of organic food is rising continuously and already constitutes 10% of all sold food. The highest levels have been reached with organic milk (22%) and organic eggs (21%). An Austrian household already spends spends 190 euros per year on organic food. One of the targets set by the Commission´s Green Deal is for organic farming to reach 25 percent by 2030 and it is supported not only by consumer organisations.

Apart from organic farming, the market for GMO-free products is growing as well. Companies organized in the German "Verband Lebensmittel ohne Gentechnik" (VLOG) association generated sales of 8.8 billion euros in 2019 with more than 14,000 products. Member companies of the Austrian "Arge Gentechnikfrei" generated an estimated annual turnover of around 1.5 billion euros with over 3,800 products. All milk, eggs, poultry and turkey production in Austria has been converted to „GM-free production".

Whats about the safety of GE products

These methods of the genome editing are relatively new, e.g., CRISPR/Cas has been used in the laboratory only since 2012. Experience with unintentional or unexpected effects of these new genetic engineering and scientific investigations regarding the risks is therefore limited. As Greiter, Heissenberger pointed out in their study, long-term experience regarding food and feed safety or experience with possible environmental effects or risks is also non-existent. Researchers have found out that unintended alterations can occur in the target sequence ("on-target-effect") as well as in other parts of the genome ("off-target-effect"). Negative effects can be the consequence of very small alterations. It is likely that as the use of genome editing develops new risks will be uncovered. This shows that a precautionary approach to the use of these techniques and a case-by-case assessment is necessary to guarantee the safety of food, animals and the environment. Therefore, researchers recommend the examination of even small alterations in the genome for adverse negative effects. There are also knowledge gaps and a lack of experience where new traits, which have not existed in these species so far, are generated in crops.

Main findings

For the discussion on genome editing, the Austrian Environmental Agency worked out different scenarios of future regulations of new genetic engineering and possible consequences thereof which could be possible on a European level:

A **comprehensive regulation** for new genetic engineering would mean that all products with genome editing would fall under the current EU legislation, as foreseen with the decision of the EU Court of Justice in 2018. For consumers, this means an EU market authorization with complete risk assessment, traceability, and freedom of choice due to GMO labelling.

Another idea is a **simplified authorisation procedure**, but there are no detailed proposals on the table yet. It could mean that fewer data need to be presented for certain GMOs than the EFSA guidelines for risk assessment have determined. Kawall et al. 2020 could imagine facilitating the procedure when a product manufactured by means of genome editing is identical with a conventionally produced product which has already been marketed. This, however, would need to be detected with adequate methods (e.g., with sequencing the entire genome). In such a case, a certain amount of basic information would need to be presented in order to demonstrate, for instance, the similarity of the GMO with the conventionally produced organism.

A **legislation for new genetic engineering** is another possible option. It could be considered that such legislation only comprises individual techniques or application areas.

Possible consequences of a legislation only for certain methods or applications would be the result of those aspects which deviate from the current legal provisions. This has an effect, among other things, on the relation with organic and GMO-free agriculture. If new genetic engineering was to continuously be excluded from these production methods, the appropriate legal

basis (among others, EU organic farming regulation) needs to be adjusted. Furthermore, in this case the legislation for new genetic engineering needs to contain provisions making an implementation of a GMO-free status possible (e.g., the development of detection methods). Having a clear scope and legal definitions for preventing obscurities would again be key for a given legislation only for certain methods or applications. From a consumer´s point of few, clear labelling would be essential.

A **complete deregulation** of genome editing would mean that all products manufactured by the means of such methods are excluded from European genetic engineering legislation. Industry and science often bring two ideas into the discussion

- Deregulation of GMOs which show only small alterations of the genome
- Deregulation of products which could be produced not only by genome editing but also naturally or by conventional breeding methods

As a wide range of alterations in the genome is possible with these new techniques, a comparison with conventional breeding methods would not justify this fact. Other questions arise, like: How should mutations by new genetic engineering methods and mutations which were produced naturally or by conventional breeding methods be compared?

Deregulation, however, would as a consequence definitively mean that neither risks for human health nor for the environment would be assessed and no detection method would be available. This means that products with organic label and GMO-free seal would no longer be GMO-free in the current sense.

Deregulation: Consequences for freedom of choice for consumers, environment protection and health

Consequences of deregulating genome editing can mainly be expected for those consumers who prefer GMO-free and organic farming products. In Austria, this is a significant proportion. A market research survey carried out in October 2019 shows that for nearly 86% of the people interviewed, GMO-free production is an important aspect. These numbers are even higher than for organic farming products (67.5%). GMO-free production and organic farming are closely connected. Consumers are willing to pay more for these products as higher standards are to be applied in organic farming. Erosion or loss of provision for GMO-free production would have a negative impact on the trust of consumers in these products.

Without adequate risk assessment prior to the authorisation of a product, it would not be possible to avoid negative effects on human health and the environment. Also, interactions with the environment could not be observed. New genetic engineering organisms would be released into the environment without the possibility of traceability.

For consumers and the organic and GMO-free sector deregulation of genome editing would mean the following:

- No mandatory risk assessment for environment and health
- No possibility for Member States to temporarily restrict or prohibit the use of the product in case of a risk to human health or the environment a risk to human health or the environment
- No obligatory labelling of products to inform consumers and farmers
- No obligatory coexistence measures to prevent contamination of GMO-free products
- GE products that are not covered by genetic engineering law could be used in organic farming. According to the EU Organic Regulation only GMOs as defined in the Directive are prohibited in organic farming.
- The possibility for national restrictions and bans on cultivation (national self-determination, opt-out), which only came into force in 2015, can´t be applied
- If the member states regulate products produced with genome editing techniques themselves, this can lead to very different regulations in the EU. Control measures, such as border controls, are to be expected as a consequence.

Currently, both old and new genetic engineering are seen as non-compatible with organic farming principles. IFAOM, the umbrella organisation of organic farming, has published a relevant position paper in 2015.The GMO-free organisations in Germany and Austria did so as well. A deregulation scenario would have economic consequences for the organic and GMO-free producers who would have to take additional measures to ensure GM-free production. This could cause a raise of prices for consumers.

Conclusio of the scenarios from a consumers prospective

The EU genetic engineering legislation is based on the precautionary principle. Risks for human and health and the environment are assessed before placing products on the EU market. This does not mean that there is a ban of GM-products but it allows the review of unintended alterations in the genome and possible effects at an early stage. This is why genome editing should fall under EU genetic engineering legislation. This is the only way that freedom of choice for consumers, farmers and breeders can remain unchanged.

Demands

Consumer confidence in food in general and GM-free products in particular must not be undermined in any way. Possibly, in the event of deregulation, due to a lack of detectability of products with genome editing, it would no longer be able to offer GMO-free products. An EU-wide approval procedure that includes reliably functioning traceability procedures as well as systems for detection and a clear labelling of GE products is absolutely necessary for consumers in order to keep their "right to choose" and "right to safety". Consumers must not run the risk of buying untested and unlabelled GMOs. The following is needed:

- Freedom of choice is important to consumers, especially in the case of genetically modified foods. For many years, GMO-free status has been an indispensable aspect for consumers when buying food. Labelling of genetically modified products is therefore an important information for consumers in order to enable them to make a self-determined choice when buying their food.
- For consumers it is important that unforeseen consequences are properly monitored. Therefore it is necessary that products obtained from GE are required to undergo a comprehensive risk assessment which looks at the risks to human health, the environment and animal welfare before them being placed on the market. Compliance with the precautionary principle must be ensured for GE.
- Deregulation of the EU GMO Legislation for products with GE would allow to provide untested and invisible food and feed on the European market. Consumers will no longer know whether they are purchasing GMO-free products or not. Consumers trust in GMO-free production of organic farming and GMO-free production. This trust may not be undermined by any deregulation of genome editing.
- There is an urgent need for more research for the detectability and possible health and environmental effects of GE. The Commission should ensure and support this research.
- Deregulation of GE products would undermine the Green Deal's goals for sustainable agriculture. Expanding organic agriculture and at the same time putting GE crops on the field and on the market without environmental and health assessment do not fit together.
- The current EU GMO legislation in force is established and well proved. According to the ECJ ruling of July 2018 it should be retained and must not be deregulated in any way.
- A global transparency register, which covers new genetically modified organisms in particular would be necessary to ensure that no GE products enter the EU market without approval.

Literature

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