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New Genetic Engineering

A basis for the upcoming political debate

Anita Greiter, Andreas Heissenberger

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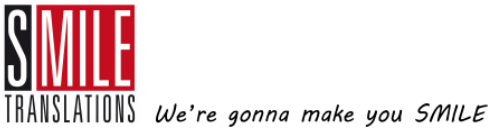

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FOREWORD

The "new genetic engineering" also known as “genome editing” or "new genomic techniques" opens up many new possibilities to intervene in the genetic material of organisms, plants, animals or humans. New genetic engineering comprise a wide range of methods, of which the best known is CRISPR/Cas. The modifying potential is significantly bigger than with previous methods due to the many application possibilities: from small point mutations in the cell to several traits brought in simultaneously and altering complex characteristics or entire metabolic pathways.

In July 2018, the Court of Justice of the European Union (CJEU) defined that products manufactured by new mutagenesis techniques are genetically modified organisms (GMOs), and therefore are subject to EU genetic engineering legislation. This consequently means that these GM products need to undergo comprehensive risk assessment before they are approved for the market, and they need to be labelled as GMO products. The CJEU explains this decision by stating that the new GMOs could be associated with the same risks as conventionally produced GMOs. This decision is welcomed by the Vienna Chamber of Labour (Arbeiterkammer Wien, *AK Wien*) and environmental and consumer protection organisations.

The industry and parts of the scientific world are unhappy about this decision and want to see an erosion of the EU’s genetic engineering legislation. They want the new genetic engineering to be put on an equal footing with conventional breeding, and therefore they are not calling it new genetic engineering but rather new breeding methods. They want to avoid a detailed investigation of the risk to human health and the environment and labelling.

But are products made by these new genetic engineering really without any risk for human health and the environment, and therefore safe? What does this mean for consumers when there are no legal regulations for products genetically modified by new methods, and if they get to the market without risk assessment and labelling? What impact would this have on GMO-free products and organic food production?

The outcome of a study assigned to the Environment Agency Austria by the AK Wien is straightforward: without clearly defined regulations and clear labelling, products made with new genetic engineering will get into food, even into organic food, unnoticed. Therefore, consumers would no longer be sure that their food does not contain any genetic engineering, and both GMO-free as well as organic food production would be at risk.

For many years, GMO-free status has been an indispensable aspect for many consumers when grocery shopping. In the Chamber of Labour’s opinion, this is why products made by means of new genetic engineering must clearly be defined as GMO products and must comply with the precautionary principle through a risk assessment prior to market approval.

Iris Strutzmann (AK Wien) and Heinz Schöffel (AK Wien)

Vienna, September 2020

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1 INTRODUCTION

In the past, conventional genetic engineering (transgenesis) was the method for genetically modifying plants and animals. This “old genetic engineering” has been expanded by a number of technologies in recent years. The “new genetic engineering” comprises a wide range of biomolecular methods for which there is however no uniform definition. Depending on the context, different terms are used, as well: the term “new genetic engineering”, as well as “new biotechnological breeding techniques”, “genome editing”, “new mutagenesis techniques” or “new genomic techniques” are used.

The new genetic engineering has increasingly been made a subject of discussion in the public media, among other topics regarding the CRISPR/Cas technique or in connection with the decision of the Court of Justice of the European Union in 2018. This judgement in the legal case C-528/16 clearly states that products obtained by new mutagenesis techniques are genetically modified organisms (GMOS) and fall under the currently valid genetic engineering legislation (Court of Justice of the European Union 2018).

Since the judgement has been published, it has been heavily discussed by all stakeholder groups. Environment and consumer protection organisations as well as organic and GMO-free producers welcomed the decision. The open letter of *ARGE Gentechnik-frei* and *Verband Lebensmittel Ohne Gentechnik* to the European Commission is one example showing this approval, which was also signed by many food and feed producers as well as retail companies (*ARGE Gentechnik-frei & Verband Lebensmittel Ohne Gentechnik* 2018). In the course of the appointment of the new EU Commission, *ARGE Gentechnik-frei* vehemently spoke out against a deregulation of new genetic engineering and in favour of a rapid implementation of the judgement in their press release from July 2019, among other aspects regarding detection methods and import controls (*ARGE Gentechnik-frei* 2019). Many German associations also turned to the German Federal Minister of Agriculture regarding a rapid implementation of the judgement (*Arbeitsgemeinschaft bäuerliche Landwirtschaft* 2019). The scientific world also supports the judgement (Gelinsky & Hilbeck 2018).

Others were critical of the judgement of the Court of Justice of the European Union. In April 2019, for instance, an open letter signed by many European associations of companies who support a change of the European genetic engineering legislation was published. Genome-edited products containing changes which also could have been obtained with conventional breeding methods should not fall under the genetic engineering legislation (EuropaBio 2019). In July 2019, the Max-Planck-Gesellschaft (Max Planck Society) published an open letter from some scientists in the course of the appointment of the new EU Commission. In this letter, the scientists support among other things the opinion that GMOs created by genome editing, which show only small changes in the genome, should be taken out of the current genetic engineering regulation. Furthermore, the legal basis of GMOs should be reviewed according to scientific progress in the field of biotechnology (MPG 2019, *Max-Planck-Gesellschaft*).

On a political level, in March 2019 the then EU Commissioner Andriukaitis recommended a new legal framework for the new genetic engineering (Euractive 2019). The Netherlands (which has already published a proposal for the amendment of the genetic engineering legislation in September 2017;

see Government of the Netherlands (2017)), put the judgement and its consequences on the agenda of the Agricultural Council on 14 May 2019. They asked for a harmonised approach regarding the implementation of the genetic engineering legislation with respect to new mutagenesis techniques and other new breeding techniques. Additionally, the Netherlands asked the European Commission to review the genetic engineering legislation. Both requests were supported by many member states (Council of the European Union 2019).

Subsequently, on 8 November 2019 the Council of Ministers published a decision in which the European Commission is requested to present an investigation of the legal status of novel genomic techniques, and if necessary, a proposal for legal regulation by 30 April 2021 (Council of the European Union 2019).

The discussion about new genetic engineering has thus not ended yet. On the one hand, a continuation of the process at the EU level as a consequence of the aforementioned study is to be expected. On the other hand, it can be assumed that additional new genetic engineering for changing genetic material will be developed in future. The “European Green Deal” published by the European Commission in December 2019, refers to new technologies and scientific knowledge from which all stakeholders of the food value-added chain will profit. Moreover, the EU must develop “innovative ways” to protect harvests against pests and diseases. This needs to take into account the potential of “new innovative techniques” (European Commission 2019). This reference is explained in more detail by the European Commission in its Farm to Fork Strategy. New innovative techniques including biotechnology are attributed a possible role in sustainable production as long as they are safe for the consumer and the environment (European Commission 2020).

As a follow up of the first study on genetic engineering carried out on behalf of the AK Wien and published in the series “*Informationen zur Umweltpolitik”* (Information on environmental policies, Greiter & Heissenberger 2018), the goal of this report is to prepare the basis for a political debate in the context of the current discussion as a consequence of the judgement.

New genetic modifying techniques can be applied not only in plant but also in animal breeding. Farm animals should, for instance, be modified in such a way that they produce more meat or milk with altered ingredients. Polled cattle or virus-resistant pigs are the focus of development (Kawall et al. 2020). The present report focuses on applications in plant breeding as a reflection of the current debate. For ease of readability, the term GMO will be used for both entire plants and products which contain genetically modified plants or were produced from them.

2 BACKGROUND

This chapter gives first a technical overview of the new genetic engineering which comprise not only the new possibilities of modifying genetic material but also the status of knowledge on possible risks. It will also explain which legal provisions regarding new genetic engineering are currently effective in the EU, with a focus on aspects that are of particular interest to the consumer.

2.1 Technical aspects

2.1.1 Methods of new genetic engineering

As mentioned above, some biomolecular methods can be counted among new genetic engineering. These include, for instance, genome editing techniques (Genome Editing), which intervene in the genome in different ways and use special artificially-produced enzymes called site-directed nucleases such as CRISPR/Cas nucleases, zinc finger nucleases (ZFNs) or the TALE nuclease system (TALEN). Another genome editing technique is oligonucleotide-directed mutagenesis (ODM). Additional new methods include cisgenesis, intragenesis and transgrafting (High Level Group of Scientific Advisors 2017).

The first study on new genetic engineering published in the series *Informationen zur Umweltpolitik* (Information on environmental policies) contains descriptions of these techniques, as well as product examples (Greiter & Heissenberger 2018). Some aspects are mentioned in the following; regarding detailed information we refer to the aforementioned report.

Genome editing techniques allow various modifications in the genome (see chapter 2.1.2), which go beyond both the possibilities of the old genetic engineering, as well as conventional breeding. This may include the insertion of genes as in the old genetic engineering, however, single base pairs may also be modified. Furthermore, genome editing pursues the goal of producing alterations at pre-determined sites (with the old genetic engineering techniques, you could not pre-determine at which site in the genome the new gene should be inserted). Another genome editing technique is known as the genetic scissors. In the US and Canada, for instance, the herbicide-resistant SU canola 5715 by Cibus is marketed under the Falco™ brand[1].

New genes can be inserted in plants by cisgenesis and intragenesis. The same methods are applied for inserting genetic material into the cell as in the old technique (transgenesis). The difference is that no foreign genes are inserted but genetic material from the same or a related crossable breed (instead of bacterial genes, for instance, genes from a wild apple are inserted into an apple). These techniques were, for instance, applied for producing Innate™ potatoes approved in the US and Canada. This potato produced by Simplot is grown and sold under the brand White Russet™. It shows reduced bruising and fewer black spots when transported and stored[2].

[1] https://www.falcoseed.com/

[2] http://whiterusset.com/

Transgrafting is a combination of grafting used in the refinement of fruits and wine or roses and genetic engineering: Two GMOs, or one GMO and one non-modified plant are joined which then grow together into one plant. One frequently discussed point regarding new genetic engineering, in particular regarding the techniques of genome editing, is the use of recombinant nucleic acids (artificial, recomposed DNA or RNA). As described above, you need specific enzymes (nuclease complex) for modifications in the genome by means of genome editing, which can be produced in two ways. First, these can be produced in the cell you want to alter by recombinant DNA. However, after successful modification in the genetic material they must be removed by means of breeding. In the second option, newer techniques make external insertion of nuclease complexes in the cell possible. Therefore, genome editing techniques do not always and not necessarily integrate recombinant nucleic acids into the genome (which was the case in old genetic engineering). However, they may be applied in product development (Eckerstorfer et al. 2019). ODM also inserts artificial oligonucleotides into the cell, which should be degraded by cell metabolism after producing the desired mutation.

2.1.2 Range of modifications

CRISPR/Cas nucleases are bacteria-based, artificially produced nuclease complexes which can be used to modify the genetic material of an organism in a targeted way. An artificially produced Guide-RNA, composed of approximately 20 nucleotides matching the target sequence in the organism to be modified, directs the system to the correct site in the genome. There, the Cas protein causes a double-strand break. Many Cas nucleases are used, the most renowned one is Cas9 endonuclease.

The range of modifications which is fundamentally possible with the new genetic engineering comprises on the one hand new possibilities to modify genetic material; on the other, and this is a consequence of the aforementioned aspect, the production of new traits in plants and animals. Since these are new technological possibilities, scientists are continuously working on the improvement of the techniques in order to obtain the various objectives and to take basic application methods from research status to product development. Uncertainties and possible unexpected effects are described in chapter 2.1.3.

With the new genetic engineering, very different modifications of genetic material can be produced. The current discussion mainly focuses on those techniques which modify genetic material by the means of site-directed nucleases. They include CRISPR/Cas, among others. In this type of genetic modification of genetic material (genome editing), one component of the nuclease complex recognises the site of the genome which should be modified. A second component cuts through the DNA at this site and produces a double-strand break. This is then closed again, making use of the cell's natural repair mechanisms. This process causes modifications in the genome.

This type of genome modification allows for three classes (SDN1-SDN3, SDN= site-directed nucleases) of alterations:

- SDN1: aims at modifying the genome at a determined site. By making use of the cell's natural repair mechanism, the break in the DNA is closed, which might cause coincidental point mutations. For example, nucleotides can be inserted or removed.
- SDN2: also aims at modifying the genetic material at a determined site, however, the mutation is targeted and not coincidental. This is accomplished by additionally inserting a DNA molecule as a template into the cell. This template largely equals the target sequence, however, it contains deviations where the mutation should be inserted. SDN2 may correct existing mutations and produce new ones.
- SDN3: also inserts a DNA molecule as a template for the cell's natural repair mechanism. However, larger mutations are produced, and entire genes can be inserted.

New genetic engineering additionally allow for very complex modifications in the genetic material, e.g. by simultaneously changing different DNA sites or serial insertion of different mutations (multiplexing). For example, whole gene families (groups of similar or very similar genes) and metabolic processes can be modified (Kawall 2019). This allows for inserting the required mutation in all gene copies at the same time in plant species showing several chromosome sets (e.g. wheat).

Additionally, the new genetic engineering, in particular the methods of genome editing, make alterations in genetic material beyond natural mutations (e.g. modification of all existing copies of a gene at the same time) possible. Furthermore, genome sites can be modified which until now were very difficult to access due to natural limitations. There are, for instance, sites in genetic material which are particularly well protected against mutation by the cell's own natural repair mechanisms (Kawall 2019, Kawall et al. 2020).

To summarise, the new genetic engineering basically make a number of totally different modifications in genetic material possible:

- Coincidental and determined alterations at targeted sites in the genome
- Point mutations (changes of single base pairs, e.g. removal, insertion or replacement) and insertion of longer DNA sequences up to insertion of single or multiple genes
- Insertion of genes from related, crossable species as well as foreign genes from non-related species
- In addition to the insertion of new genes, the deactivation of existing genes (knock-out mutations)
- By means of two adjacent double-strand breaks, the DNA sequences between the two can be removed
- Simultaneous alteration of multiple genes
- Alterations can be produced in the entire genome

New genetic engineering make it possible to produce traits in an agriculturally used plant which are already present in related wild species (e.g. wild apple). However, new traits can also be inserted which have been previously unknown to the respective species. Special proteins are often produced not only by one but several genes. By the means of new genetically modifying techniques altering a number of wheat genes at the same time, wheat with a lower gluten level could be produced, for example (Eckerstorfer et al 2019). Up to now, this trait could not be obtained in wheat through conventional breeding. As Gelinsky & Hilbeck (2018) stated, complex traits such as drought tolerance or salt tolerance require complex alterations in the genome since many genes and different parts of the plant are involved in the adjustment processes of a plant.

New genetic engineering are also used in animal breeding. Kawall et al. (2020) list a number of applications where traits in farm animals have been altered by means of SDN-1, SDN-2 and SDN-3. The respective patents for, e.g. cattle and swine with increased muscle growth and for cattle without horns have been filed. Another application is inhibiting farm animals from reaching maturity to prolong the fattening period.

A special application of new genetic engineering are gene drives. By site-targeted nucleases, the genome is modified in such a way that the required mutation is passed on to all descendants and therefore is spread quickly through a population. When producing gene drive organisms, not only is the required mutation produced but also the nuclease complexes for producing the mutation is inserted. The objective is for example reducing or eliminating mosquito populations transmitting malaria.

The special qualities of the new genomic techniques lie on the one hand in the new possibilities to alter genetic material. The aforementioned modifications go beyond the old genetic engineering and

conventional breeding. On the other, these possibilities (e.g. by targeted modification of all present gene copies in a plant) come with the potential for new traits being in the interest of breeding (e.g. disease resistance, drought or salt tolerance). Additionally, the methods of new genetic engineering can be used for a broad range of species.

New genetic engineering are subject to different legal regulations worldwide, and there is no global database for those products available outside the EU. This is why it is difficult to get a comprehensive and updated overview of successful applications of new genomic techniques. An initiative by the Dutch university Wageningen and the German Federal Office for Consumer Protection and Food Safety (*Deutsches Bundesamt für Verbraucherschutz und Lebensmittelsicherheit*) is trying to set up such a database (www.euginius.eu).

2.1.3 Unpredictable effects and uncertainties

Innate to the discussion of new genetic engineering are questions of the safety of application. The following fields are important and will be explained in detail below:

- Experience with new genetic engineering
- Precision of alteration and unintentional modifications
- Knowledge of inserted alterations in genetic material and their consequences
- Knowledge of and experience with the newly inserted trait and its interaction with the environment

The methods of the new genetic engineering are relatively new, as the name already indicates. For example, CRISPR/Cas is a technique which has been used in the laboratory only since 2012. Experience with unintentional or unexpected effects of the new genetic engineering and scientific investigations regarding the risks are therefore limited. Currently, there are only a few market-ready products available which were produced with new genetic engineering. This is why long-term experience regarding food and feed safety or experience with possible environmental effects are non-existent.

Even if the alterations of genomes generated by new genetic engineering, in particular with the methods of genome editing, can in principle be produced in a more targeted way, unintended modifications are possible and also partly known (see examples in Agapito-Tenfen et al. 2018, Eckerstorfer et al. 2019, Gelinsky & Hilbeck 2018 or Kawall et al. 2020, among others, on unintended alterations with the application of the CRISPR/Cas method). They are described in the following:

Unintended alterations can occur both through the applied technical method, inserting the nuclease complex into the plant cell (e.g. by the means of a bacterium) and through the method itself (e.g. CRISPR/Cas). Additionally, adverse effects can be caused by the generated new trait in the plant.

These adverse alterations can occur both in the target sequence (on-target) and at other sites of the genome (off-target), e.g. unintended removal, rearrangement or insertion of DNA. These unintended alterations can have an effect, for instance the loss of a gene function, the modification of gene expression or the alteration of protein functions. Negative effects can be the consequence of very small alterations, as we see in the example of sickle cell anaemia in humans. Gelinsky & Hilbeck (2018) therefore recommend the examination of even small alterations in the genome for adverse negative effects.

Even if the alteration of the genome was successful, adverse effects can occur. Since genes often have not only one but several functions, for instance, deactivating a gene or modifying its functions can cause a change in other metabolic pathways (Agapito-Tenfen et al. 2018, Kawall 2020). These effects, however, may occur only under certain environmental conditions. Gelinsky & Hilbeck (2018)

as well as Kawall et al. 2020 note that precise alterations are not necessarily to be equated with safety. Knowledge on gene functions, the impact of environmental conditions or epigenetic regulations currently was still limited. They come to the conclusion that unexpected and unpredictable alterations will occur and their impact should be investigated.

There are also knowledge gaps and lack of experience where new traits are generated in crops which have not existed in these species so far. There is no practical experience regarding safe use of new combinations consisting of crop and inserted trait, since they have not been in use for very long (see chapter 2.2 and the reasons given there for the judgement on new mutagenesis techniques). Such plants with new traits would be subject to regulation in countries such as Canada, for example, since "novelty" is the decisive factor for an assessment.

In summary it may be stated that:

- Due to the novelty of the techniques, long-term experience on safety is lacking
- In newly generated traits there is no experience regarding interaction between altered plant and the environment
- Unintended alterations in the genome are possible and have already been proven
- Unintended alterations in modified organisms could occur (e.g. under changed environmental conditions)

These open questions and uncertainties are met by the EU with a case-specific environmental risk assessment which is part of the authorisation procedure, as well as monitoring after authorisation (see chapter 2.2.1).

2.2 Current legal rules

In the EU, GMOs or genetically modified products (e.g. food and feedstuff) may only be imported, marketed or cultivated if they have previously received the relevant authorisation. The respective legal framework is defined on a European level.

GMOs may only be authorised if they neither harm human health nor the environment. Furthermore, farmers and consumers may decide freely which products they cultivate or buy. Within the EU, a labelling and control system has been established in order to guarantee this freedom of choice. Additionally, there are provisions to possibly avoid contamination of products.

The basis for all of these regulations is Directive 2001/18/EC. Among other things, it defines what GMOs are. Additionally, it contains a (not exhaustive) list of techniques which can be used to produce GMOs. At the time when this directive was created, it was additionally defined that the provisions contained in the directive shall not apply to those organisms which were altered by the means of techniques which at that point in time were used in a "conventional way" and "had been considered safe for a long time" (known as the "history of safe use"). This wording referred to mutagenesis techniques using ionising radiation or genome altering chemicals to produce alterations in the genome of plants.

With the judgement of the Court of the European Union on 25 July 2018, it was determined that "new" mutagenesis methods which had not been developed in 2001 are subject to the provisions of Directive 2001/18/EC (Court of the European Union 2018, case C-528/16). The reason for the judgement by the Court was that, among other things, GMOs produced by new mutagenesis methods and GMOs produced by the means of old genomic methods (transgenesis) could be connected to comparable risks. Additionally, altering the genome by the means of new mutagenesis techniques can achieve the

same effect as altering the genome by inserting a foreign gene. Furthermore, with the new mutagenesis methods, new products can be produced faster and in bigger dimensions than with the old mutagenesis methods. In the judgement, the Court also states that Directive 2001/18/EC serves the implementation of the precautionary principle with the corresponding goal to prevent negative effects on human health and the environment. In accordance with this objective, new mutagenesis techniques are to be regulated (Court of the European Union 2018). As a consequence of the judgement, the provisions of the European genetic engineering legislation (Directive 2001/18/EC and referring laws) account for both the old genetic engineering and for the new genetic engineering methods. New genetic engineering are therefore not forbidden; however, they are subject to corresponding legislation.

In the following selected key provisions of current legal regulations for producers and consumers are described. These include specifications to guarantee the protection of human health and the environment, provisions to guarantee the consumers' freedom of choice and the possibility to restrict and prohibit cultivation.

2.2.1 Protection of human health and the environment

As stated above, the goal of Directive 2001/18/EC is the protection of human health and the environment. This objective of the genetic engineering legislation is based on the precautionary principle which is of central priority in the EU. It takes effect regarding the application of GMOs and in the entire environmental policy of the European Union, and is stipulated in the Treaty on the Functioning of the European Union (Art. 191, TFEU).

According to EU genetic engineering legislation, the protection of human health and the environment is to be guaranteed by a number of provisions, e.g. by the environmental risk assessment which needs to be presented for the individual case in the course of an authorisation procedure and by monitoring provisions for authorised GMOs. Furthermore, measures can be taken for already authorised GMOs whenever new information on negative effects is published.

In the course of the authorisation procedure the applicant must present information on the GMO, e.g. on the altered plant, on the genetic modification and the procedures applied for producing it, as well as on the trait(s) inserted into the plant. In the course of the specific risk assessment for the respective GMO it is to be assessed whether, and if so, which, risks exist for human health and the environment. As a result, the direct effects, i.e. caused by the GMO itself and the indirect effects, e.g. interaction with other organisms must be taken into account. Additionally, risks which could occur immediately are to be assessed, as well as risks which become obvious later. This risk assessment comprises, for instance, information on possible allergen and toxic effects of the GMO, on its invasiveness into natural habitats, effects on non-target organisms or the effects of interaction of the GMO with target organisms such as resistance developments. The data presented are to be reviewed by the European Food Safety Authority (EFSA) and presented to the Competent Authorities of the member state for an opinion.

After successful authorisation, the marketing authorisation holder must additionally adhere to a monitoring plan and report on this monitoring to the Competent Authority of the member state and the European Commission on a regular basis. The objective of this monitoring is firstly the review of the conclusions of the environmental risk assessment; secondly, it should be monitored if effects of the GMO which were not considered in the risk assessment occur.

Whenever new information on authorised GMOs which suggests negative effects on human health or the environment becomes known, the requirements of the authorisation may be adjusted. Furthermore, member states can temporarily restrict or prohibit the application or the distribution of a GMO

and its products in their territories within the framework of the safeguard clause, if information is presented which gives legitimate reason to assume that human health or the environment are in danger.

According to Directive 2001/18/EC, EU member states must ensure traceability and labelling of GMOs. Traceability on the entire production and distribution chain is important in order to be able to, for instance, withdraw products which have proven to be harmful to health or the environment (R (EC) No. 1830/2003 defines the details).

2.2.2 Freedom of choice

The European genetic engineering legislation contains provisions regarding labelling of GMOs, as well as controls of these provisions in order to guarantee freedom of choice for producers and consumers. Additionally, there are recommendations for co-existence measures to prevent contamination of GMO-free products. Detection and controls are of the utmost importance, first of all for GMO-free production lines, in particular for organic farming which must be GMO-free according to the EU regulation on organic production (R (EC) No. 834/2007, Art. 9 and R (EU) 2018/848, Art. 11).

GMOs and products containing GMOs must be labelled with the words: “This product contains genetically modified organisms”. This provision applies from a proportion of 0.9% of an ingredient in food or feed as long as these traces are random and technically unavoidable. Compliance with this labelling is controlled by the member states (e.g. by random sample tests). The Competent Authorities have access to the necessary information in a central register. It comprises, e.g. detection methods, which must be made available by the applicant for every authorised GMO (and are subsequently reviewed by state-owned, accredited laboratories) according to R (EC) No. 1829/2003. If available, this register also contains information on GMOs not authorised in the EU. This information is particularly important for import controls to guarantee that no GMOs without authorisation get into the EU market. Respective methods must be made available and/or developed in order to ensure functioning controls, therefore financial means for research on detection methods for genome-edited products are demanded in the current discussion (also see chapter 1).

As mentioned above, member states can take measures against contamination of GMO-free products. This is important in order to keep conventionally or organically cultivated fields free from GMOs, among other reasons. These co-existence measures should make it possible for GMO cultivation, conventional cultivation and organic cultivation to co-exist. This is the basis for making freedom of choice possible for producers and consumers, regarding GMO-free products, for example. Respective recommendations for developing such measures have been worked out by the European Commission (European Commission 2010).

2.2.3 Restriction and prohibition of cultivation

Current genetic engineering legislation allows the member states to issue restrictions or prohibitions of cultivation of GMOs authorised by the EU. In 2015 the opt-out directive came into force (Directive (EU) 2015/412). This directive enables the member states of the European Union to:

- request the applicant, even in the course of the authorisation procedure, to exclude the respective member state from the application for authorisation, or
- restrict or prohibit the cultivation of an authorised GMO under certain circumstances.

If a member states wants to issue a restriction or prohibition of cultivation, it must give a reason, e.g. with reference to incompatibility of the cultivation of the GMO with environmental or agricultural objectives, the socio-economic impact of the GMO or the prohibition of the GMO insertion in particular, e.g.

GMO-free products. It would also be possible to give a reason which refers to cultural traditions. The restriction or prohibition must be in accordance with EU legislation and proportionate.

Austria requested from the applicants of all GMOs which are currently in an authorisation procedure for cultivation to exclude Austria from the respective applications. These requests were approved[3].

[3] https://ec.europa.eu/food/plant/gmo/authorisation/cultivation/geographical_scope_en#at

3 POSSIBLE CHANGES IN GENETIC ENGINEERING LEGISLATION AND THEIR CONSEQUENCES

The following chapter describes different scenarios of future regulations of new genetic engineering and possible consequences thereof. They are primarily based on the proposals brought up by the different stakeholders in the current discussion.

Possible changes in the genetic engineering legislation do not necessarily need to stay restricted to new mutagenesis techniques. The current discussion was, however, triggered by the judgement of the Court of the European Union on these techniques, but one needs to bear in mind that the study to be undertaken by the European Commission (see chapter 1) comprises “new genomic techniques” and therefore has a broader approach.

The following developments are possible on a European level:

- retention of the current legal provisions for the old and the new genetic engineering
- complete deregulation of new genetic engineering
- a new legislation for new genetic engineering
- a simplified authorisation procedure for new genetic engineering
- deregulation, a new legislation or simplified authorisation procedure for certain techniques or applications

3.1 Possible developments

3.1.1 Comprehensive regulation

Comprehensive regulation for new genetic engineering would mean that all products of the new genetic engineering would fall under the current provisions of EU legislation. According to the core items of the judgement on the new mutagenesis techniques (see chapter 2.2, among others objectives of Directive 2001/18/EC and precautionary principle) it would be possible to regulate all methods of new genetic engineering and the ones which will be developed in future.

In this case, it needs to be considered that the judgement of the Court of the European Union only refers to new mutagenesis techniques and does not comprise new genetic engineering in their entirety. As is the case with other genetic engineering or future developments, it could be unclear whether they are included in Directive 2001/18/EC. This is the outcome of a working group of experts at the EU level which focussed on different methods of new genetic engineering and their being included in Directive 2001/18/EC (New Techniques Working Group 2012). The assessment of these experts does

not present a valid legal interpretation; however, it shows that the assessment was not always unanimous. Therefore, the outcome of the aforementioned study by the European Commission on new genomic techniques, which should be published in 2021, is in this respect of particular importance.

A comprehensive regulation would mean that all products made by new genetic engineering must undergo the same authorisation procedure as is done with products produced by old genetic engineering. According to the precautionary principle, the products may consequently only be authorised after a complete risk assessment and when no negative effects on human health or the environment are to be expected. Furthermore, the applicant must deliver a detection method, one of the basic requirements for traceability and control of GM products and GMO-free products.

3.1.2 Deregulation

A complete deregulation of the new genetic engineering would mean that products manufactured by the means of such methods are excluded from the provisions of the European genetic engineering legislation. A deregulation of individual application areas would basically also be possible regarding legal rights, for example SDN1 mutations or selected techniques such as CRISPR/Cas. Another possibility would be a deregulation of plants with traits which had already been created by conventional breeding and have been in use for a long time. For these, the “history of safe use” would come into effect, i.e. the long-standing and safe application of plants with certain traits.

Currently there are no precise and detailed proposals for the design and legal implementation of such a deregulation of individual techniques or application areas on the table. In the discussion, however, two ideas have been identified (see chapter 1):

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

As described in chapter 2.1.2, a wide range of alterations in the genome can be produced by new genetic engineering. Additionally, sites can be altered which are difficult to modify by means of conventional methods or can't be done at all. A deregulation of individual techniques based on a comparison with conventional breeding methods would not do justice to this fact.

When only individual application areas should be deregulated, the extent thereof would need to be defined very precisely in order to prevent any obscurities and to guarantee legal certainty. The discussion of the New Techniques Working Group (2012) showed that even among experts some terms of the current Directive 2001/18/EC can be interpreted in different ways (e.g. beginning at which number of modifications do you need to use the term recombinant nucleic acid).

For instance, should only GMOs with small modifications according to the aforementioned example be deregulated, then the following questions, among others, will arise:

- Where will the line be drawn for "small" alterations? Should only products with point mutations be deregulated, or also those with a larger number of modified base pairs?
- Would multiplex approaches be comprised when they generate, for instance, a point mutation but on many different genes?
- Should “small” modification only refer to modifications in the genome, or as well to the impact of the genetic modification on the plant’s traits (e.g. in the case of producing a totally new trait in a plant with a small alteration which has previously not been known for this species)?

- What role does a specific method play which was used for generating a "small" modification? Does the use of recombinant DNA need to be excluded?

Regarding the second of the aforementioned ideas, the following questions, among others, need to be raised:

- How should mutations by new genetic engineering methods and mutations which were produced naturally or by conventional breeding methods be compared? Should deregulation be enforced when it is possible theoretically (but is not known in practice) or should deregulation only be considered in such cases where a variant with exactly the same modification is already known and applied?
- How should the situation be handled when a newly inserted trait has not been known in the respective cultivated plant so far (e.g. wheat with reduced gluten content or wheat with mildew resistance)?

The aforementioned examples show that deregulation must legally be formulated very precisely or decided case by case by the Competent Authorities based on a number of criteria.

Deregulation, however, would definitively mean as a consequence that neither risks for human health nor for the environment would be assessed. Furthermore, the developers would not need to make detection methods available. Detection and control of such deregulated products would not be possible and in the case of a deregulation, would legally not be necessary any more. This also means that products with the GMO-free label and organic products would no longer be GMO-free in the current sense. Deregulated products could, in a legal sense, be used in organic farming, for example. It would be necessary in this case of voluntary restriction to GMO-free products that farmers receive adequate information, e.g. via a database in which seeds, feed and the respective new genetic engineering used are evident.

3.1.3 Simplified authorisation procedure

Although the desire to have a simplified authorisation procedure is repeatedly stated in the discussion on new genetic engineering, there are no detailed proposals yet. Some scientists and companies, however, regularly criticise the time taken and expense of the processes. A simplified authorisation procedure could therefore mean that fewer data need to be presented for certain GMOs than the current legal provisions and EFSA guidelines for environmental risk assessment (EFSA 2010) have determined. In line with the considerations described above (see chapter 3.1.2), a simplified authorisation procedure for the entirety of genetic engineering or selected techniques or application areas could be proposed.

Kawall et al. 2020 could imagine facilitating the procedure in the case 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.

In general, Directive 2001/18/EC provides for the possibility to deviate from the defined application procedure for GMOs. The European Commission, for example, can propose deviating criteria or information which must be presented by the applicant in the authorisation procedure. This information can be valid for “certain GMO types”, however, this term is not defined in any more detail. Conceivable would be, e.g. provisions only for GMOs with certain traits such as drought-tolerant GMOs. According

to the objectives of the Directive, a high level of safety regarding human health and the environment needs, however, to be ensured nevertheless.

Which consequences a simplified authorisation procedure would have depends on its actual design. As long as the provisions for detection methods are not eased, at the least detection and control of the authorised GMOs as well as freedom of choice for consumers would be ensured. Member states could also apply the opt-out regulation for such products. Possible impacts on health and the environment are the result of the provisions of the risk assessment which are eased or removed.

3.1.4 Legislation for new genetic engineering

Besides regulation and deregulation of new genetic engineering, or a simplified authorisation procedure, working out a legal basis for new genomic techniques on an EU level would also be conceivable. As described above, it could be considered that such a new legislation only comprises individual techniques or application areas. However, no proposals have been presented thus far.

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 to organic and GMO-free agriculture. If new genetic engineering were 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 legislation only for certain methods or applications. Additionally, it would make sense to have provisions regarding how to deal with genetic engineering which will possibly be developed in future.

3.2 Consequences for the protection of the environment and health

As described in chapter 2.2.1, the objective of a risk assessment is the protection of the environment and health. Therefore, negative impacts should be eliminated and examined in the course of monitoring after successful authorisation. A risk assessment not adequately carried out due to legal changes could have respective consequences. Without adequate risk assessment prior to the authorisation of a product, it would not be possible to eliminate negative effects on human health and the environment.

Considerations on risk assessment of products manufactured by the means of new genetic engineering were undertaken by, for instance, Eckerstorfer et al. (2019) and Kawall et al. (2020). According to the aforementioned aspects, the focus is not only on intended and unintended modifications in the genome and their desired or undesired consequences, but also the impact of the modified traits in a plant regarding its interaction with the environment.

Eckerstorfer et al (2019) raised two main questions regarding risk assessment:

- Do unintended alterations in the genome exist and do they lead to negative effects on health and the environment?
- Does the intentional use of the GMO cause negative effects which are related to the new traits of the GMO?

The issues identified by Eckerstorfer et al. (2019) regarding risk assessment comprise case-specific provisions on the newly inserted trait, on unintended effects of the genetic modification and on the currently existing experience with comparable products and country-specific protection goals. Further elements are an analysis of unintended existing transgenic elements in the end product and whether

the genome shows unintended alterations (e.g. off-target alterations). Based on case-specific risk scenarios for the respective GMO, the phenotypical characterisation should test different parameters which are not covered by other existing legal provisions (e.g. authorisation of varieties).

Kawall et al (2020) describe the elements to be taken into account in a risk assessment and the described possible consequences between modified plants and the environment for a number of examples, for instance plants with altered ingredients (oil, protein, vitamins, etc.) or plants with increased fitness (drought tolerance, pest and disease resistance, etc.). Modified ingredients could, for instance, not only have an impact on wild animals eating the plants, but also need to be tested for feed and food production in order to eliminate negative effects. Furthermore, Kawall et al (2020) list a number of criteria for risk assessment (e.g. complete sequencing of the genome, testing of the plant under different stress conditions, assessment of impacts on the microbiome in the human and animal digestion systems).

Considerations on risk assessment of new genetic engineering were also undertaken by Agapito-Tenfen et al. (2018). They prescribe among others how new instruments such as bioinformatics or new DNA sequencing technologies can support risk assessment. They recommend collecting information on both unexpected alterations in the target sequence (on-target alterations), as well as unintended alterations at different sites in the genome (off-target alterations). This complies with the requests of Kawall et al. (2020), who recommend an expansion of molecular characterisation in the course of risk assessment in order to identify unintended alterations in the genome.

3.3 Consequences for freedom of choice

Consequences of deregulating new genetic engineering 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 (Marketagent.com 2019) shows that for 53.8% of the people interviewed, GMO-free production is important and for another 31.4% it is somewhat important. These numbers are even higher than for organic farming products (these are in total an important aspect for 67.5% of the people interviewed when shopping for groceries).

If a legislation was to be worked out only for new genetic engineering, legislative proposals shall be analysed among other things regarding their impact on these two product groups. Key issues in particular regarding control and traceability or connections between different directives and regulations are described in the following.

3.3.1 GMO-free label

In addition to a mandatory labelling of GMO products, there are some voluntary labellings of GMO-free products in Austria and some other countries. They are based on the respective regulations on the national level. Due to national responsibility, the regulations are not homogenous. The umbrella organisation *Euro GMO-free*, which is in the founding process, aims to work on such a harmonisation in Europe, among other things.

In Austria, the control label "*Ohne Gentechnik hergestellt*" (produced GMO-free) by ARGE Gentechnik-frei based on the Austrian food book "*Richtlinie zur Definition der 'Gentechnikfreien Produktion' von Lebensmitteln und deren Kennzeichnung*" (Guidelines for the definition of 'GMO-free production' of food and its labelling) is awarded to respective products. Its equivalent in Germany "*Ohne Gentechnik*" (no genetic engineering) label is awarded by *Verband Lebensmittel ohne Gentechnik* (VLOG) (Association for food without genetic engineering). GMO-free products are checked on a regular basis, in Austria by accredited external inspection authorities. In Austria more than 3,500 food products have

been awarded this label, ranging from bread and bakery products to ready-made meals to sweets and frozen products.

In the past, the different labelling systems of GMO-free products in Europe have already been investigated. An appropriate report commissioned by the European Commission also had the objective to examine core elements for a harmonised approach within the EU (European Commission 2013). The authors of this report expected that the use of GMO-free labels would increase. In Austria, for instance, 100% of eggs and milk produced domestically are GMO-free. Chickens and turkeys are exclusively fed GMO-free in Austria. The study also showed that there is a market in the EU for GMO-free products, which is the result of adequate demand by consumers (European Commission 2013).

Even if labelling of GMO-free products is not regulated on an EU level, the control, for instance regarding contamination, is closely linked to EU provisions for genetic engineering. It is based on information and detection methods made available by the applicants contained in the respective registers. Without adequate regulation of new genetic engineering, it would not be possible to identify genetically modified products for the control of GMO-free products. If control of GMO-free products cannot be guaranteed any more, this would be the end of the respective product labelling and of GMO-free production.

The study of the European Commission also broaches the issue of how difficult it is for consumers to interpret the labels correctly. This circumstance would become important if some products manufactured by means of new genetic engineering would be excluded from the scope of application of the Directive. It remains to be seen how it will be communicated to the consumer that in this case, "produced GMO-free" means in reality that selected genetic engineering are excluded. The aforementioned study also shows that the market for GMO-free products would be in danger if there was incorrect labelling. This could have a negative impact on the trust consumers have in the market (European Commission 2013) and could lead to a collapse of demand for GMO-free products.

3.3.2 Organic farming

Currently, no GMOs are to be used in the European Union in organic farming (R (EC) No. 834/2007, Art. 9). The new EU organic farming regulation, which will come into force as of 1 January 2021 (R(EU) 2018/848, Art. 11), contains this ban as well.

Both regulations refer to GMOs according to Directive 2001/18/EC. If this Directive is changed regarding covering new genetic engineering or if the new genetic engineering are going to have their own legislation, this will then have a direct impact on organic farming. If there continues to be demand for a ban on old and new genetic engineering in organic farming, the Directive (EU) 2018/848 must be adjusted appropriately. However, it remains unclear how a GMO-free status will then be implemented in practice, because basic issues like traceability, control or co-existence are currently regulated by the genetic engineering legislation. GMO-free production of food and organic farming are closely connected. Since higher standards are to be applied in organic farming, consumers are willing to pay more for these products. Erosion or loss of the provisions for GMO-free production would be a significant trend reversal and would have massive consequences, as mentioned above.

Currently, both old and new genetic engineering are seen as non-compatible with organic farming principles. IFOAM, the umbrella organisation of organic farming, for instance, has published a relevant position paper. IFOAM EU presented its position paper on new genetic engineering in 2015, emphasising the importance and the necessity of traceability, labelling, risk assessment and precautionary principle. This is why new genetic engineering shall fall under EU genetic engineering legislation. This is the only way that freedom of choice of breeders, farmers and consumers can remain unchanged.

Image and reputation of organic farming products were to be maintained, which in the case of contamination would have negative impacts (IFOAM EU Group 2015). These principles are also reflected in IFOAM International's position paper on compatibility of different breeding systems with organic farming. New (including synthetic biology) as well as old genetic engineering are seen as non-compatible with organic farming, since breeding techniques intervening directly with DNA are rejected. Accordingly, this is why it is irrelevant if the modifications could theoretically have been developed naturally, because the process causing the modification is the only relevant aspect. In this respect, the paper also refers to the high expectations of the consumer to be met (IFOAM Organics International 2017).

On a political level, organic farming also plays a role. The current Austrian and German governments, for instance, are recommending an expansion of organic farming in their legislative programmes and coalition contracts (Federal government 2018, Federal government 2020). The European Commission has also set the goal in its European Green Deal to increase the area of organic farming in Europe (European Commission 2019). Deregulating new genetic engineering would counteract these objectives. The share of organically farmed land in the total agriculturally utilised space is 24%[4] in Austria (most current numbers from 2018).

[4] https://ec.europa.eu/eurostat/web/products-datasets/-/SDG_02_40

4 CONCLUSIONS

New genetic engineering comprise many methods and application possibilities. Additionally, it can be presumed that existing techniques will be developed and new methods will be applied.

The new genetic engineering, in particular the methods of genome editing, can generate a broad range of modifications in genetic material. The current public discussion, however, often emphasises the possibilities for generating small alterations and at the same time, refers to the allegedly comparable possibilities of conventional breeding. What is overlooked is the fact that applications of new genetic engineering make far more complex alterations possible, and that the possibilities of conventional breeding are limited (and that, for example, not all parts of the genome can be altered).

A new regulation based on the applied technique would therefore not take into account that one single method (e.g. CRISPR/Cas) can generate small and big alterations. Since many small mutations (multiplexing) also make complex alterations in a plant possible, and since these are going to become increasingly important in future, new legal provisions should be well considered for these applications. Furthermore, it should not be disregarded that impacts do not correlate with the size of the alteration, and with new genetic engineering, alterations in the genome are possible which go beyond conventional possibilities.

The legal framework for genetic engineering currently in force in the EU is based on the precautionary principle. Risks for human health and the environment are assessed appropriately early, i.e. before the marketing of a product. This legal system does not constitute a ban, but makes it possible to proactively react to developments and collect experience and data for products and applications. This is especially significant for those applications for which there is only limited data on biosafety, and for which there is no experience regarding “long-term and safe” application. This is not only true for experience with the applied techniques, but also for the newly generated traits in the plants, some of which could not be previously produced. A risk assessment guarantees the review of unintended alterations in the genome and their effects. Additionally, effects on human and animal health as well as on the environment are reviewed.

In conclusion, it can be said that both regarding regulation and risk assessment the following issues are of importance and should be taken into account:

- The desired genetic modification and possible unintended alterations in the genome
- The generated trait, which could be completely new to the respective plant or animal species
- Unintended effects on health and the environment, both due to the new organism and its application
- Uncertainties and a lack of experience: This can be related to the applied technique (e.g. CRISPR/Cas), the specifically generated alteration in the genetic material or the newly generated organism with its new traits

The control systems established within the EU also make it possible to react to unexpected negative effects and to, for example, withdraw products from the market if necessary. Additionally, the control and labelling systems make it possible for the consumers to freely choose between conventionally and GMO-free manufactured products. Changes in the legislation for genetic engineering should therefore be well considered. In this case it is of pivotal importance to formulate these changes precisely, to avoid ambiguities and therefore to guarantee legal security for everybody affected.

The request to deregulate new genetic engineering is based on the alleged comparability of new genetic engineering with conventional breeding. The examples used in this report show that this is not always the case. Detailed proposals for a simplified authorisation procedure are currently not on the table, and the same is true for scientific reasons. Only a few considerations have been made in this respect. The range of alteration possibilities and the possibility for new traits, however, require a case-by-case assessment.

Different stakeholder groups have different opinions, of course. This is why it is the task of politics to take macrosocial decisions and take into account the impact on different population groups, because benefits for one group could cause disadvantages for another. Additionally, not only the current most-used applications of new genetic engineering should be taken into account, but also future developments (e.g. new techniques, complex alterations in the genome), and actual experience.

On the one hand, the Farm to Fork strategy of the European Commission will be decisive in future, in particular regarding applications of biotechnology. On the other hand, and related to the strategy, the outcome of the European Commission study on new genomic techniques will be of significance. A very important question in this respect will be if the Commission will propose new legal regulations as a result of the study. Currently it is not to be foreseeable how such a proposal could be designed.

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