verbraucherzentrale
Bundesverband

NEW GENOMIC TECHNIQUES – ASSESS RISKS AND USE LABELS

Statement from the Federation of German Consumer Organisations on the European Commission's proposal for a regulation on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 (COM/2023/411 final)

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Legal information

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The Federation of German Consumer Organisations (Verbraucherzentrale Bundesverband e.V.) is registered in the German Lobby Register and in the European Transparency Register. You can view the relevant entries here and here.

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I. SUMMARY

Consumers want freedom of choice and a high degree of safety when it comes to both traditional and new genomic techniques (NGTs). New genomic techniques, such as CRISPR/Cas, should also be subject to the precautionary principle. This entails thorough risk assessment and approval procedures, a comprehensive technology impact assessment, as well as obligatory labelling and traceability.

However, the European Commission's proposal on "plants obtained by certain new genomic techniques and their use for food and feed" fails to meet these requirements. According to the European Commission's plans, a lot of[1,2] plants and food produced using NGTs would, in the future, not be subject to **risk assessment** and **approval procedures**. Potential risks to humans and the environment would thus be ignored.

Furthermore, according to the European Commission's plans, the majority of foods obtained using NGTs such as CRISPR/Cas would no longer have to be labelled. While consumers can be sure that genetic engineering is not used to produce organic food, they will no longer know whether this is the case concerning conventional products. This represents a significant restriction on consumer's **freedom of choice**. In addition, the proposal includes **incentives** for the genetic engineering industry in the form of relaxed approval procedures and advisory services. Under certain circumstances, traceability will also no longer be required.

The Federation of German Consumer Organisations (Verbraucherzentrale Bundesverband – vzbv) calls for measures including the following:

- The continued use of **labelling** to ensure that consumers retain freedom of choice.
- **Risk assessments** for all plants and products produced using new and traditional genomic techniques. This should consider both intended and unintended effects on the organism and the resulting changes to people, animals, and the environment.
- Individual, evidence-based checks should be carried out to assess whether plants produced using new genomic techniques actually benefit society. A **technology impact assessment** should also consider alternatives and socio-economic consequences.
- A **transparent database** must enable seed traceability. Companies must be obliged to store the relevant documentation in the database.
- The **polluter pays principle** should be consistently applied and incorporated in a regulation that holds companies using genetic engineering techniques liable.

[1] Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection (BMUV): Federal Minister for the Environment Steffi Lemke on the EU Commission's plans concerning new genomic techniques, 2023: https://www.bmuv.de/meldung/bundesumweltministerin-steffi-lemke-zu-den-plaenen-der-eu-kommission-zur-neuen-gentechnik, 28/07/2023

[2] Repository, Parisi, C. and Rodriguez Cerezo, E.: Current and future market applications of new genomic techniques, 2021, https://publications.jrc.ec.europa.eu/repository/handle/JRC123830, 28/07/2023

- Sustainability arguments should not be offset against risks to humans and the environment. It is also essential to prevent labelling being used to facilitate **greenwashing** with respect to genetically modified plants and their products.[3]

II. RELEVANCE OF THE TOPIC TO CONSUMERS

Consumers are sceptical about the use of genetic engineering in agriculture and food production. This **scepticism** extends to new genomic techniques such as CRISPR/Cas. The German Federal Institute for Risk Assessment (BfR) conducted a focus group survey in 2017[4, 5] and held a consumer conference on NGTs in 2019.[6] The majority of consumers who took part opposed the agricultural use of NGTs for various reasons. Some felt the risks outweigh the potential benefits. Ethical considerations also played a role. The majority of participants were in favour of existing regulations on genetically modified organisms (GMOs), even after examining the issue in detail.

Surveys confirm that consumers want **freedom of choice** and a **high degree of safety** with respect to GMOs. A Forsa survey clearly shows that an overwhelming majority of consumers (92 per cent) want genetically modified food to be labelled, regardless of whether new methods or classical genetic engineering have been used.[7] In a survey carried out by the Munich Environmental Institute[8] in 2021, 84 percent of respondents believed genetically modified food should be labelled as such. 83 percent said that traditional and new genomic techniques should be subject to comprehensive risk analysis in line with existing regulations.

Consumers want to be able to recognise supermarket products that have been produced using NGTs. In 2008, to provide transparency beyond that assured by European law, the German Federal Government introduced the “Ohne Gentechnik” (“GMO-free”)

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[3] Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection (BMUV): Welche Forderungen hat das BMUV? [What does the BMUV call for?], 2023, https://www.bmuv.de/themen/naturschutz/gentechnik, 28/07/2023

[4] German Federal Institute for Risk Assessment (BfR): Durchführung von Fokusgruppen zur Wahrnehmung des Genome Editings (CRISPR/Cas9), Abschlussbericht [Focus group survey on the perception of genome editing, Final report], 2017, https://mobil.bfr.bund.de/cm/350/durchfuehrung-von-fokusgruppen-zur-wahrnehmung-des-genome-editings-crispr-cas9.pdf, 01/08/2023

[5] German Federal Institute for Risk Assessment (BfR): Verbrauchervotum, Ergebnis der BfR-Verbraucherkonferenz “Genome Editing im Bereich Ernährung und menschliche Gesundheit” [Consumer vote, results of the BfR Consumer Conference on “Genome Editing in the Field of Nutrition and Human Health]”, 2019, https://www.bfr.bund.de/cm/343/verbrauchervotum-genome-editing.pdf, 01/08/2023

[6] German Federal Institute for Risk Assessment (BfR): Conclusion of the BfR Consumer Conference on Genome Editing: Lots of potential, but clear rules required, 2019, https://www.bfr.bund.de/en/press_information/2019/35/conclusion_of_the_bfr_consumer_conference_on_genome_editing__lots_of_potential__but_clear_rules_required-242324.html, 01/08/2023

[7] Foodwatch: Neue Gentechnik Ergebnisse der forsa- Befragung, 25.09.2023, https://www.foodwatch.org/fileadmin/-DE/Themen/Gentechnik/2023-09-Umfrage_Forsa_Tabellen_Neue_Gentechnik.pdf, 25/09/2023

[8] Munich Environmental Institute: Neue Umfrage zeigt: Mehrheit der Deutschen will strikte Regeln für neue Gentechnik [New survey shows: majority of Germans want strict rules for new genomic techniques], 2021, https://meldungsarchiv.umweltinstitut.org/aktuelle-meldungen/meldungen/2021/gentechnik/umfrage-mehrheit-der-deutschen-will-strikte-regeln-fuer-neue-gentechnik.html?type=0%27, 24/07/2023

label.[9] The **market segment** for these products is growing continuously. Turnover for "Ohne Gentechnik" products in Germany rose by some 21 percent to almost 16 billion euros in 2022.[10] Turnover for organic farming products has also risen steadily in recent years, reaching 15 billion euros in 2022.[11]

Decades ago, traditional genetic engineering arrived on the scene with a promise to make **agriculture more sustainable**, to reduce hunger, and to produce especially healthy plants for humans. These promises have not been fulfilled – on the contrary. Genetic diversity decreased while pesticide use increased in countries that cultivate GMOs.[12] According to Misereor, genetic engineering did not lead to higher yields than farming that avoided such techniques. As NGTs are also a purely technological approach, they would only exacerbate sustainability deficits while failing to provide adequate solutions. Misalignments in the global food system would require, on the other hand, holistic approaches such as agroecology. Misereor argues that it is essential to practise agriculture in an ecologically compatible, sustainable, and diverse way. An ecologically adapted approach to agriculture must incorporate local farmers' knowledge and prevent dependencies.[13]

The majority of consumers also want food production to be compatible with climate and environmental protection.[14] A fundamental **reorganisation of agricultural and livestock practices**, geared towards high environmental and animal protection standards, is urgently needed in order to protect biodiversity and land, reduce the impact of climate on agriculture, and ensure healthy food. This requires variety and the strengthening of regionally adapted, resource-friendly agriculture, including better opportunities for regional value creation for farmers, instead of yet more dependence on a handful of seed companies with their patented seeds and the pesticides required for them.

For these reasons, the European Commissions' proposals are in opposition to consumer interests. vzbv thus advocates retaining the current laws on GMOs.

[9] Law to implement the regulations of the European Community or European Union in the field of genetic engineering and on the labelling of GMO-free food (EG-Gentechnik-Durchführungsgesetz – EGGenTDurchfG), 2004, http://www.gesetze-im-internet.de/eggentdurchfg/, 01/08/2023

[10] Verband Lebensmittel ohne Gentechnik (VLOG): Stable growth for "Ohne Gentechnik", 2023, https://www.ohnegentechnik.org/en/press/articles/stable-growth-for-ohne-gentechnik, 01/08/2023

[11] Statista: Umsatz mit Bio-Lebensmitteln in Deutschland bis 2022 [Turnover for organic food in Germany up to 2022], 2023, https://de.statista.com/statistik/daten/studie/4109/umfrage/bio-lebensmittel-umsatz-zeitreihe, 01/08/2023

[12] Jack A. Heinemann, Melanie Massaro, Dorien S. Coray, Sarah Zanon Agapito-Tenfen & Jiajun Dale Wen: Sustainability and innovation in staple crop production in the US Midwest, 2013, International Journal of Agricultural Sustainability, https://doi.org/10.1080/14735903.2013.806408, 15/08/2022

[13] Misereor: Diskussionsbeitrag – Neue Gentechnik in der Pflanzenzüchtung [Discussion paper – New genomic techniques in plant cultivation], 2021, https://www.misereor.de/fileadmin/publikationen/diskussionsbeitrag-neue-gentechnik-misereor_01.pdf, 15/08/2023

[14] Federal Ministry of Food and Agriculture (BMEL): Ernährungsreport [Food and nutrition report] 2022, 2022, https://www.bmel.de/DE/themen/ernaehrung/ernaehrungsreport2022.html, 15/08/2023

III. THE EUROPEAN COMMISSION'S PLANS IN A POLITICAL CONTEXT

The European Commission's proposal is linked to the Green Deal objectives, above all to the Farm to Fork and Biodiversity Strategies. However, the present Commission proposal will hinder rather than help achieve these objectives. It threatens European consumer and environmental protection principles.

Precautionary principle abandoned

The European Commission states that a general aim of the proposed regulation is to *"maintain a high level of protection for human and animal health and the environment in accordance with the precautionary principle"*.[15]

The precautionary principle, alongside the prevention and removal of the causes of pollution, and the polluter pays principle, is one of the cornerstones of European environmental policy.[16] It is firmly embedded as a legislative principle in Article 191 Paragraph 2 of the Treaty on the Functioning of the European Union (TFEU). The precautionary principle should, above all, come into play when there is uncertainty as to whether the protection level for human, animal, and environmental health may be compromised. It functions as a safety net for European consumers in cases where risk is difficult to assess and consequences are not clear. It allows authorities to take temporary precautionary measures where there is a lack of clear evidence regarding harm to consumers. It is distinct from the prevention principle, which seeks to prevent environmental harm when the effects are already known and indisputable.

New genomic techniques may lead to undesired genetic modifications and extreme forms or to new biological plant characteristics that are extremely unlikely in the case of conventional cultivation.[17,18] To date there has been no detailed risk analysis of NGTs that also systematically considers unintended changes. The same is true concerning interactions between genetically modified organisms that have been created using these new techniques.[19] Thus, many questions concerning risk assessment arise that

[15] European Commission Brussels, 5/7/2023 COM(2023) 411 final ANNEXES 1 to 3 Annexes to the Proposal for a Regulation of the European parliament and the council on plants obtained by certain new genomic techniques and their food and feed, 2023, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en, 24/07/2023

[16] European Parliamentary Research Service: The precautionary principle: Definitions, applications and governance. 2015, https://www.europarl.europa.eu/thinktank/es/document/EPRS_IDA(2015)573876, 15/08/2023

[17] Federation of German Consumer Organisations (vzbv): Vorsorgeprinzip muss auch für neue Gentechnik gelten, Gutachten: Neue Techniken zu Erbgutveränderungen von Pflanzen und Tieren könnten erhebliche Risiken haben [Precautionary principle must also apply to NGTs, Expert opinion: NGTs for plants and animals may involve considerable risks], 2022, https://www.vzbv.de/meldungen/vorsorgeprinzip-muss-auch-fuer-neue-gentechnik-gelten, 24/07/2023

[18] Christoph Then: Testbiotech New genomic techniques (NGTs): agriculture, food production and crucial regulatory issues, 2022, https://www.vzbv.de/meldungen/vorsorgeprinzip-muss-auch-fuer-neue-gentechnik-gelten, 24/07/2023

[19] Federation of German Consumer Organisations (vzbv): Vorsorgeprinzip muss auch für neue Gentechnik gelten, Gutachten: Neue Techniken zu Erbgutveränderungen von Pflanzen und Tieren könnten erhebliche Risiken haben, Zusammenfassung-Anforderungen an die Risikoanalyse [Precautionary principle must also apply to NGTs, Expert opinion: NGTs for plants and animals may involve considerable risks, Summary recommendations for risk analysis], 2022, https://www.vzbv.de/meldungen/vorsorgeprinzip-muss-auch-fuer-neue-gentechnik-gelten, 07/08/2023

still require expert clarification. The current proposal abandons the precautionary principle by excluding a large group of NGTs from obligatory risk assessment. A case-by-case analysis of NGTs and the resulting products is needed in order to make reliable statements about safety.[20]

No level playing field for economic operators

Another general aim stated by the European Commission is the effective functioning of the internal market for NGT plants and products, including "*a level playing field for economic operators*."[21]

European Union legislation on genetic engineering has encouraged more sustainable innovations and created new economic sectors. For example, turnover for products from organic farming, which also avoids genetically modified plants when it comes to animal feed, has risen continuously in recent years. The number of "Ohne Gentechnik" products produced and sold according to German law, which goes further than EU law, have also risen steadily.[22]

The present proposal favours only one side of the agriculture and food sector, namely production that uses genetic engineering, while it disadvantages organic farming. Conventional, organic farming can only exist in limited form under these conditions, as the effort required to prevent contamination from GMOs rises massively, leading to higher costs for consumers.

Transparency along the food supply chain abandoned

Transparency along the food supply chain, known as the Farm to Fork principle, has been maintained since the BSE crisis in the early 2000s and has become a key principle in achieving safe food production and processing.[23]

However, under the European Commission proposal, most plant products produced with certain genomic techniques will not be labelled in any way. Consumers will thus lose the right to choose products based on their production process. The Farm to Fork traceability principle is thus not being consistently applied here.

Failure to reduce pesticide use

The European Commission's plan to ease market access for genetically modified plants also undermines its own Farm to Fork Strategy, which seeks to reduce pesticide use by 50 percent by 2030 and reverse biodiversity loss in the EU.

The cultivation of genetically modified plants that are resistant to pesticides is rising worldwide. To date, the commercial distribution of plants is dominated by pesticide-resistant plants together with the large amounts of pesticides designed for them. The pro-

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[20] Environment Agency Austria: Fragen und Antworten zur neuen Gentechnik [Questions and answers on new genomic techniques], 2023, https://www.umweltbundesamt.at/gentechnik/faqs, 28/07/2023

[21] European Commission Brussels, 5/7/2023 COM(2023) 411 final to the Proposal for a Regulation of the European parliament and the council on plants obtained by certain new genomic techniques and their food and feed, 2023, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Rechtsvorschriften-fur-Pflanzen-die-mithilfe-bestimmter-neuer-genomischer-Verfahren-gewonnen-werden_de, 24/07/2023

[22] Ibid.

[23] The Farm to Fork principle which requires traceability along the supply chain and is fundamental to ensuring food safety is not to be confused with the Farm to Fork Strategy adapted in 2020 by the European Commission.

portion of genetically modified plants with tolerance to herbicides was already 43 percent in 2020. Genetically modified plants with combined traits, which are both resistant to various herbicides and develop defensive properties (poisonous protein, formed by the soil-dwelling bacterium Bacillus thuringiensis) against various harmful insects, made up 45 percent of commercially distributed plants. Insect-resistant plants made up 12 percent.[24]

The trend is particularly pronounced in the USA, where for many years cultivation has focused almost exclusively on genetically modified plants with resistance to the herbicide glyphosate. As a result, problems with resistant weeds have increased. Glyphosate often no longer functions as it should. Consequently, additional pesticides are used. This approach to weed control seems to be losing effectiveness.[25]

Research shows that the use of pesticides in pesticide-resistant plant cultivation has increased. According to the Federal Agency for Nature Conservation, there is often insufficient experience with NGT-based plants to reliably assess the actual risks to biodiversity. It is also possible that such plants require more fertiliser, pesticide, or water, with the associated impact on the environment.[26]

The widespread cultivation of genetically modified plants can, in fact, lead to agricultural problems. According to the German Environment Agency (UBA), the widespread and environmentally unrestricted use of pesticides poses a high risk to nature, groundwater, and biodiversity.[27] Plant cultivation over large areas, especially when monocultural, can further weaken the resilience of agricultural systems. Such practices are already leading to a collapse in herbicide resistance and necessitate the use of ever larger quantities of herbicides in cases where basic plant cultivation rules, such as the maintenance of soil health or crop rotation, are ignored.[28]

Free access to seeds is at risk

Patents are closely associated with both traditional and new genomic techniques. The seeds market is currently a global oligopoly. A handful of companies producing genetically modified seeds use patents to ensure their access to this market. These patents are granted both for the processes used to develop plants and for the developed plants themselves. This means that companies need only one patent that protects the process in order to also protect a variety of plants produced using this process. As the areas under cultivation grow, so too does dependence on this handful of companies. When it comes to product development, genetic engineering companies concentrate on just a

[24] Transgen: Anbau von Gentechnik-Pflanzen leicht rückläufig: 2019 weltweit 190,4 Millionen Hektar [Cultivation of genetically modified plants falls slightly: 190.4 million hectares worldwide in 2019], 2020, https://www.transgen.de/anbau/592.gentechnisch-veraenderte-pflanzen-anbauflaechen.html, 17/08/2023

[25] Transgen: Gentechnik-Pflanzen und resistente Unkräuter: Wenn Glyphosat nicht mehr wirkt, [Genetically engineered plants and resistant weeds: when glyphosate stops working] 2020, https://www.transgen.de/anbau/1429.resistente-superunkraeuter-gentechnik.html, 17/08/2023

[26] Federal Agency for Nature Conservation (BfN): Häufig gefragt: Gibt es konkrete Szenarien für Risiken, die von NGT-basierten Pflanzen für die Biodiversität ausgehen können? [Frequent question: are there specific scenarios for risks that NGT-based plants pose to biodiversity?], 2023, https://www.bfn.de/haeufig-gefragt-gentechnik, 01/08/2023

[27] German Environment Agency (UBA): Pflanzenschutzmittel in der Landwirtschaft [Pesticides in agriculture], 2023, https://www.umweltbundesamt.de/themen/landwirtschaft/umweltbelastungen-der-landwirtschaft/pflanzenschutzmittel-in-der-landwirtschaft, 15/08/2023

[28] Federal Agency for Nature Conservation (BfN): Häufig gefragt: Gibt es konkrete Szenarien für Risiken, die von NGT-basierten Pflanzen für die Biodiversität ausgehen können? [Frequent question: are there specific scenarios for risks that NGT-based plants pose to biodiversity?], 2023, https://www.bfn.de/haeufig-gefragt-gentechnik, 01/08/2023

few types and varieties of plants that function on the greatest possible number of markets and their conditions for plant cultivation. This promotes uniformity instead of diversity.

The use of patents means resources are no longer freely available, but only via licence fees. Organic farming, in contrast, follows an open-source model that enables free access to breeding material. Both organic and conventional breeders and companies can contribute to breeding progress under such conditions. The use of patents, on the other hand, prevents innovations that would enable resource-friendly agriculture adapted to local conditions.

IV. STRUCTURE OF THE PROPOSAL AND ITS COHERENCE WITH OTHER LEGAL REGULATIONS

The proposal creates two new categories for plant-based products produced using new genomic techniques and excludes one possible NGT method from European genetic engineering legislation as it has existed to date. It largely frees category 1 from the regulation concerning labelling and risk assessment. In addition, it also proposes numerous relaxations of rules, added incentives, and positive labelling options for plant products that will fundamentally continue to be classified as GMOs in the traditional sense (category 2).

1. CATEGORY 1 PLANTS

According to the European Commission, category 1 plants will be considered equivalent to conventional plants as long as they are subject to no more than 20 modified nucleotides (per gene site). However, NGT methods enable genetic modifications that go beyond those possible with traditional techniques, without necessitating the insertion of additional genes. The natural protective limits of what can be manipulated in a cell and what cannot, as defined by evolution to date, can thus be exceeded.

NGTs have already produced plants in which considerably fewer than 20 modified nucleotides (per gene site) have been required to create plants with characteristics that would not be expected from traditional plant cultivation. One example is the GABA tomato.[29] The tomato contains high levels of GABA (γ-aminobutryric acid), an amino acid believed to aid relaxation and help lower blood pressure. This benefit is used to market the tomatoes, which have been authorised in Japan. It is also known that the amino acid GABA in tomato plants can fulfil various functions. For example, it influences plant growth, resistance to pests and diseases, and various metabolic reactions. It can be assumed, based on GABA's multifunctional role, that it also influences plant metabolism in various ways. These changes may lead to **unintended health consequences** when the tomatoes are consumed. The plants may also show unexpected reactions to environmental stress factors. This may negatively impact the safety of the food.[30]

[29] Testbiotech: GABA tomatoes: Point mutations turning food into a sedative?, 2021, https://www.testbiotech.org/en/limits-to-biotech/crispr-tomatoes/basic_paper, 15/08/2023

[30] Nonaka et al: Efficiency increase of γ-aminobutryric acid (GABA) content in tomato fruits by targeted mutagenesis, 2017, https://www.nature.com/articles/s41598-017-06400-y, 16/08/2023

The decision to regard category 1 NGT plants as equivalent to conventional, commercially cultivated plants means plants that are significantly different biologically are accorded the same legal status. The proposal does not take these significant differences to conventional plants into consideration, as case-by-case risk assessment will no longer be required. Nor is any consideration given as to whether releasing these plants into the environment may cause harm. Once the plants have been introduced to the environment, they are no longer subject to any special monitoring. There is then also no possibility to remove them from the environment.

NGT category 1 plants will, in the future, only be subject to a **notification procedure** that determines whether the plants in question belong to category 1. Should this procedure determine that the novel plant influences the nutritional value of food or impacts metabolism, then **Regulation (EU) 2015/2283 on novel foods**[31] is to be applied. Checks will be made as to how harmful to health the product might be and whether it should be authorised for the market. The procedure will not look at environmental aspects. The regulation includes many vague terms, such as “significant changes in the composition or structure”. It thus remains unclear how the regulation will be applied in practice.

Category 1 plants make up the majority of NGTs. European Commission plans mean it will no longer be necessary to **label** these plants in the future. Thus consumers will no longer be able to tell whether the food in question has been genetically modified. Consumers, a majority of whom take a critical view of the use of NGTs, will thus lose **freedom of choice**. They can no longer freely decide whether they wish to consume certain products.

Additionally, seeds from NGT category 1 plants will be entered into a **public database**, the criteria for which are yet to be defined. However, for types that have undergone the notification procedure, it will be possible to redact DNA sequence information and breeding patterns and strategies in the planned database. This will make detection and traceability almost impossible. The proposed regulation does not necessitate documentation that would enable traceability.

VZBV CALLS FOR: CONSISTENT APPLICATION OF THE PRECAUTIONARY PRINCIPLE

vzbv opposes dividing plants into the proposed categories 1 and 2. Consumers want to be sure that their food is safe. **Risk assessment** should not only take place when there is already evidence of problems caused by a significant change in the composition or structure. Routine investigations into the health risks posed by all plants and products created using both new and traditional genomic techniques should be carried out. Similarly, environmental compatibility should be examined before products are released into nature. For consumers' freedom of choice, it is necessary that all GMO plants and products derived from them are recognisable as such and labelled as GMOs.

A **transparent database** must enable seed traceability. Companies must be obliged to store the relevant documentation in the database.

[31] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11/12/2015, p. 1), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R2283, 28/07/2023

2. CATEGORY 2 PLANTS

According to the proposal, NGT plants in which neither foreign DNA has been used (contain transgenes) nor are Category 1 plants are to be assigned to Category 2. The complexity of the changes in this category is determined only by the fact that more than 20 gene sites have been modified. One example is wheat with reduced gluten content.

For category 2 plants, the requirements for risk assessment and labelling will now only apply to a limited extent.

2.1 Less stringent risk assessment and documentation requirements

According to the proposal, future **risk assessment** for category 2 plants should only be based on the information provided by the company applying for authorisation for its products. In addition, it would only analyse intended modifications. Authorities will not take unexpected effects on the organism and the resulting impact on humans, animals, and the environment into account.

Furthermore, companies applying for approval will no longer be obliged to submit **documentation for traceability and detection purposes**, or such requirements will be relaxed, if the company demonstrates that it is technically impossible to do so. However "it cannot be done, because it is technically impossible" is not a valid argument. It is fundamentally possible to develop traceability and detection methods and it should be companies' responsibility to do so.[32]

Only 1.5 percent of research money spent on NGTs in the EU is invested in **safety research** and traceability and detection procedures. The rest is spent on product development and basic research.[33] The new regulation will further reduce the incentive to develop traceability and detection procedures. It is important to not only consider the potential benefits of NGTs, but also the associated risks and the need for traceability.

> **VZBV CALLS FOR: COMPREHENSIVE RISK ASSESSMENT AND TRACEABILITY FOR ALL NGT PLANTS**
>
> All plants and products created using traditional or new genomic techniques should undergo **comprehensive risk assessment** before reaching the market. This should consider both intended and unintended effects on the organism and the resulting changes to people, animals, and the environment.
>
> Research into developing **traceability and detection methods** should be ramped up. The gene-editing companies should be obliged to submit the relevant documentation. Assumptions about potentially positive characteristics should not provide the basis for exceptions.

[32] Agapito-Tenfen S.Z., Okoli A.S., Bernstein M.J., Wikmark OG., Myhr A.I.: Revisiting Risk Governance of GM Plants: The Need to Consider New and Emerging Gene-Editing Techniques, 2018, https://www.frontiersin.org/articles/10.3389/fpls.2018.01874/full, 18/08/2023

[33] Environment Agency Austria: Fragen und Antworten zur neuen Gentechnik [Questions and answers on new genomic techniques], 2023, https://www.umweltbundesamt.at/gentechnik/faqs, 28/07/2023

2.2 Incentives for companies

The proposed regulation sets out **incentives for an accelerated risk assessment procedure for applicants and better advisory services** to help developers complete the necessary documentation.[34] Article 22 of the regulation[35] defines when these incentives may be granted to category 2 NGT plants and products. Traits that might justify such incentives include higher yields, resistance and/or tolerance to, for example, fungi, or the possibility of more efficient use of resources such as water and nutrients, as well as, for example, a longer shelf life or improved nutritional value. The only trait that excludes application of the incentives mentioned in Article 22 is tolerance to herbicides.

These incentives aim to steer NGT development in a direction that makes the food supply chain more sustainable. However, in order to weigh up the various traits, it is necessary to first legally establish scientific criteria to substantiate the contributions that the traits of various plant and product types make to sustainability. This has not been the case to date.

Suppliers and researchers have often claimed that plants created using NGTs will contribute positively to sustainable agriculture and nutrition. However, as agriculture, food production, and nutrition are all highly complex systems, such claims are not tenable without thoroughly assessing the technological impact. A proper **technology impact assessment** must consider not only the risks and potential of individual applications, but also the interconnected ecological, socio-economic, and health effects, as well as examining possible alternatives.

Individual sustainability aspects must not provide a pretext to lower safety standards within the EU. This would undermine the precautionary principle, a core feature of European legislation.

VZBV OPPOSES ANY LOWERING OF SAFETY STANDARDS

Individual traits that may potentially improve a plant type must not serve as a pretext to lower safety and traceability standards. vzbv thus **opposes lowering safety standards** to incentivise individual technological solutions. NGTs represent hypothetical, individual solutions rather than solutions that take a holistic approach to the entire agricultural system. Improvements to plant cultivation that benefit the entire agricultural system are needed.

In addition, a **technology impact assessment** should also look at alternatives and socio-economic consequences.

[34] EU Commission, COM(2023) 411 final 2023/0226 (COD), Brussels, 5/7/2023, Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625, Proposal of the EU Commission, Brussels, 5/7/2023 COM(2023) 411 final 2023/0226 (COD), points 33 to 35, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en, 28/07/2023

[35] EU Commission, COM(2023) 411 final 2023/0226 (COD), Brussels, 5/7/2023, Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625, Proposal of the EU Commission, Brussels, 5/7/2023 COM(2023) 411 final 2023/0226 (COD), Art. 22, incentives for category 2 NGT plants and products that contain traits relevant to sustainability, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en, 28/07/2023

2.3 Advertising certain traits

An additional **voluntary labelling regarding the effects of the genetic modifications** is also possible. These traits can affect many product characteristics, such as flavour or a composition of contents that may interest the industry. Companies must suggest the form this information might take when applying for approval for NGT plants.

However, it is not yet clear which authorities will check whether these modified traits will actually have a positive impact and, if so, for whom. As standards and assessment criteria are lacking, authorities will have to decide on a case-by-case basis whether labels can be used to advertise these traits. Consumers will find it very difficult to know whether these product claims actually reflect the reality. This form of greenwashing could confuse consumers, who take a primarily critical view of genetically modified products, and lead to a conflict of interests.

VZBV CALLS FOR: NO GREENWASHING FOR NGT PRODUCTS

vzbv opposes the use of labels that promote the supposed benefits of genetically modified products and fears a market development similar to that seen regarding health statements in past decades. In the same way that promised health benefits did not necessarily lead to healthier products, vzbv is also concerned that this market segment will lead to highly promising advertising claims that are not actually reflected in the products.

3. USE OF NGTS IN ORGANIC FARMING PROHIBITED

The European Commission plans to prohibit the use of NGTs in organic farming based on the fact that "*the use of new genomic techniques is incompatible with the current concept of organic production in Regulation (EG) 2018/848 and consumers' perception of organic products.*"[36]

According to the European Commission plans, it is possible that only organic farming will continue to be GMO-free. Consumers will have to anticipate higher prices for such organic products in the future due to higher costs for protecting crops against contamination.

VZBV CALLS FOR: GMO-FREE PRODUCTION TO REMAIN POSSIBLE IN ORGANIC AS WELL AS CONVENTIONAL AGRICULTURE

[36] European Commission, COM(2023) 411 final 2023/0226 (COD), Brussels, 5/7/2023, Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625, Context of the proposal, Coherence with EU policy in other areas, p. 6, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en, 28/07/2023

4. LEEWAY FOR EU MEMBER STATES

The European Commission plans would remove the opt-out option for Member States[37]. Member States would thus not be allowed to prohibit or restrict the intentional introduction or use of NGTs if coexistence were to prove unrealisable, for example to due to small farming areas.

At the same time, the proposed regulation requires Member States to adopt measures to prevent the unintended existence of category 2 NGT plants in products that do not fall under EU Directive 2001/18 on the deliberate release of GMOs into the environment or EU Regulation 1829/2003 on genetically modified food and feed. The proposed regulation will have to answer questions about the future coexistence of GMO and GMO-free agriculture just as urgent as those concerning the labelling of GMO and GMO-free products. The Member States must themselves devise these regulations at the national level.

VZBV CALLS FOR: MEMBER STATES TO RETAIN THE OPT-OUT OPTION

5. USE OF THE POLLUTER PAYS PRINCIPLE AND LIABILITY FOR DAMAGE

Member States must also create regulations to ensure that those who cause damage are held responsible. In Germany the principle of joint and several liability, based on Paragraph 421 of the German Civil Code (Bürgerliches Gesetzbuch, BGB), has proved its worth. It is the only way to ensure that a company is compensated for damage caused by pollution linked to genetic engineering techniques. Pollution can lead to high costs when it comes to GMO-free agriculture. However, the Commission proposal leaves the question of liability open. It does not envision joint and several liability in the form in which it has existed in Germany to date.

VZBV CALLS FOR: INTRODUCING JOINT AND SEVERAL LIABILITY AND A LOCATION REGISTER FOR THE ENTIRE EU

Companies that use genomic techniques and pollute GMO-free agriculture must be held liable throughout Europe based on the **polluter pays principle**. Any such company would thus be held accountable for damage caused to neighbouring farmers. A **location register** is required for this purpose, so that neighbouring farmers know who to turn to in case of damage. Otherwise, evidence would be required and the aggrieved party would have to provide this evidence without knowing what was planted on neighbouring fields.

6. THE EUROPEAN COMMISSION'S EXTENSIVE RIGHT TO INTERVENE

The European Commission wants to be able to use delegated acts to adapt the criteria for category 1 NGTs (Annex I) as well as the criteria for labelling category 2 NGTs (Annex III). However, these are central political questions that should not be left exclusively in the hands of the European Commission. This would allow the Commission to change the rules of the regulation without approval from EU Member States or the European

[37] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory, https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=uriserv%3AOJ.L_.2015.068.01.0001.01.DEU&toc=OJ%3AL%3A2015%3A068%3AFULL, 03/08/2023

Parliament. Adjusting the provisions of this regulation in delegated acts should be restricted to technical questions.

> **VZBV CONSIDERS IT ESSENTIAL THAT ALL STAKEHOLDERS KNOW EXACTLY WHAT IS PLANNED WHEN THIS REGULATION ENTERS INTO FORCE**
>
> **vzbv opposes** delegated acts in this case, as they would take control away from parliaments. The issue at hand requires broad societal debate and transparent parliamentary procedures.