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Stakeholder questionnaire on new genomic techniques to contribute to a Commission study requested by the Council

Fields marked with * are mandatory.

Questionnaire on new genomic techniques to contribute to the study requested by the Council

Discussed and finalised in the Ad-hoc Stakeholder meeting on 10 February 2020

Background

The Council has requested [1] the Commission to submit, by 30 April 2021, "a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law" (*i.e.* Directive 2001/18/EC, Regulation (EC) 1829/2003, Regulation (EC) 1830/2003 and Directive 2009/41/EC).

To respond to this Council's request, the Commission is collecting contributions from the stakeholders through the questionnaire below. The study covers all new genomic techniques that have been developed after 2001.

Instructions

For the purpose of the study, the following definition for new genomic techniques (NGTs) is used: techniques that are capable of altering the genetic material of an organism and which have emerged or have been developed since 2001 [2].

Unless specified otherwise, the term "NGT-products" used in the questionnaire covers plants, animals, micro-organisms and derived food and feed products obtained by NGTs for agri-food, medicinal and industrial applications and for research.

Please substantiate your replies with explanations, data and source of information as well as with practical examples, whenever possible. If a reply to a specific question only applies to specific NGTs/organisms, please indicate this in the reply.

Please indicate which information should be treated as confidential in order to protect the commercial

interests of a natural or legal person. Personal data, if any, will be protected pursuant to Regulation (EU) 2018/1725 [3].

[1] Council Decision (EU) 2019/1904, OJ L 293 14.11.2019, p. 103-104, https://eur-lex.europa.eu/eli/dec/2019/1904/oj
[2] Examples of techniques include: 1) Genome editing techniques such as CRISPR, TALEN, Zinc-finger nucleases, mega nucleases techniques, prime editing etc. These techniques can lead to mutagenesis and some of them also to cisgenesis, intragenesis or transgenesis. 2) Mutagenesis techniques such as oligonucleotide directed mutagenesis (ODM). 3) Epigenetic techniques such RdDM. Conversely, techniques already in use prior to 2001, such as Agrobacterium mediated techniques or gene gun, are not considered NGTs.
[3] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295, 21.11.2018, p. 39–98

Guidelines

Please note that the survey accepts a maximum of 5000 characters (with spaces) per reply field. You might be able to type more than 5000 characters, but then the text will not be accepted when you submit the questionnaire. You will also receive a warning message in red colour below the affected field.

You have the option to upload supporting documentation in the end of each section. You can upload multiple files, up to the size of 1 MB. However, note that any uploaded document cannot substitute your replies, which must still be given in a complete manner within the reply fields allocated for each question.

You can share the link from the invitation email with another colleague if you want to split the filling-out process or contribute from different locations; however, remember that all contributions feed into the same single questionnaire.

You can save the draft questionnaire and edit it before the final submission.

You can find additional information and help here: https://ec.europa.eu/eusurvey/home/helpparticipants

Participants have until 15 May 2020 (close of business) to submit the questionnaire via EUsurvey.

QUESTIONNAIRE

Please provide the full name and acronym of the EU-level association that you are representing, as well as your Transparency Registry number (if you are registered)

If the name of the association is not in English, please provide an English translation in a parenthesis

Interessengemeinschaft für gentechnikfreie Saatgutarbeit – IG Saatgut (Association for GM-free breeding, seed production and seed saving)

Please mention the sectors of activity/fields of interest of your association

GM-free plant breeding (vegetables, cereals and fruit), organic plant breeding, seed growing and production, seed companies, maintenance breeding, seed saving

If applicable, please indicate which member associations (national or EU-level), or individual companies /other entities have contributed to this questionnaire

Apfel:gut e.V., Arche Noah, Bingenheimer Saatgut AG, Dreschflegel e.V., Forschung & Züchtung Dottenfelderhof, Getreidezüchtung Peter Kunz, Keyserlingk-Institut, Kultursaat e.V., ProSpecieRara, ReinSaat KG, Saat:gut e.V., Sativa Rheinau AG, Verein zur Erhaltung der Nutzpflanzenvielfalt e.V, Vitale Rassen, Plataforma Transgenicos Fora, Living Seeds Sementes Vivas SA, Semeillas Vivas SL, Lebende Samen – Living Seeds e.V., Red de Semillas "Resembrando e Intercambiando", Biaugerme, AEGILOPS.

If applicable, indicate if all the replies refer to a specific technique or a specific organism

Our replies focus on NGT-applications in agriculture.

A - Implementation and enforcement of the GMO legislation with regard to new genomic techniques (NGTs)

*** 1. Are your members developing, using, or planning to use NGTs/NGT-products?**

- ○ Yes
- ◉ No
- ○ Not applicable

* Please explain why not

For all our members and partners, developing, using or planning to use NGTs or NGT-products is totally inconceivable.

Our members and partners share a process-based view on breeding and farming: They work within the boundaries of living organic nature with respect for the integrity of living systems. Techniques that interfere directly at DNA level, e.g. NGTs, violate this integrity and are consequently rejected. At a socio-economic level, our members and partners reject patents on animals and plants and are concerned about the threat to GM-free farmers' and breeders' freedom of choice, as NGTs released into the environment can lead to contaminations. Instead, they promote the free access to genetic resources, participatory approaches to breeding and seed production, cooperation based on partnership between breeders, farmers, food producers and consumers and the preservation and development of biologic, plant genetic and socio-economic diversity. Our work aims at contributing to the self-determined production and use of seed and food (seed and food sovereignty). This is not compatible with the developments catalysed by the use of patents on NGTs and NGT-products. Recognising the complexity and integrity of both plants and eco-systems, we are concerned about the environmental and health risks inherent to the reductionist approach of genetic engineering and advocate the application of the precautionary principle. This is in line with the principles and values of the organic sector (IFOAM International 2017; Nujten et al. 2017).

The seed companies and breeders who are members of IG Saatgut work for the organic sector and comply with the worldwide standards of organic agriculture which do not allow for any genetically engineered (GE)

products, as laid down in Article 9 of Regulation (EC) 834/2007 or, respectively, of Art. 11 of Regulation (EC) 2018/848. Any contamination of their genetic and seed material with organisms developed on the basis of NGTs threatens their core activities.

As the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD) has concluded in 2008, we need to fundamentally change our cultivation and food production systems in order to meet the challenges of the 21st century, such as preserving our natural life-support systems, fighting the climate crisis and ensuring food security. This is only possible if we develop approaches to breeding and seed production which are oriented towards the provisioning of common goods, such as the maintenance and development of plant genetic and biological diversity and the building of resilient agro-ecosystems. Focusing on optimizing few food crops with the help of few capital-intensive technologies will not deliver appropriate solutions. Given the complex systemic character of the challenges, primarily technological and product-oriented innovations will not deliver. Even more so, if the business models of the patent- and license holders of the technologies damage socio-economic diversity and self-determination in breeding and seed production, as it is the case with NGTs. Instead, we need to create legal and economic frameworks which foster truly innovative, locally adapted, systemic approaches to breeding and agriculture which enhance and further develop genetic and biologic diversity as well as soil health, encourage diverse and self-determined approaches to seed and food production and guarantee the right of farmers and communities who sustain seeds to be able to sow their crops. This strengthens agro-ecosystems as a whole, creating resilient cultivation and food production systems (see Hilbeck/Oehen 2015; IPES-Food 2016).

Any deregulation of NGTs would massively impede, if not severely threaten alternative approaches and development paths, such as those implemented by our members and partners. In order to guarantee freedom of choice to produce and consume GE-free seed and food, the ruling of the European Court of Justice (Case C-528/16) has to be respected and implemented: The regulation of NGTs under current EU GMO legislation has to be maintained.

References:

IFOAM International 2017: Compatibility of Breeding Techniques in Organic Systems, Position Paper.

International Panel of Experts on Sustainable Food systems/IPES-Food 2016: From uniformity to diversity: a paradigm shift from industrial agriculture to diversified agroecological systems, http://www.ipes-food.org/images/Reports/UniformityToDiversity_FullReport.pdf

Hilbeck A., Oehen B., 2015 (editors): Feeding the people. The relevance of agroecology for nourishing the world and transforming the current global agri-food system, https://read.ifoam-eu.org/publication/feeding-the-people/agroecological-innovation/

Nujten, E., Messmer, M., Lammerts van Bueren, E.T 2017: Concepts and Strategies of Organic Plant Breeding in Light of Novel Breeding Techniques, in: Sustainability 2017, 9,18; doi:10.3390/su9010018.

* **2. Have your members taken or planned to take measures to protect themselves from unintentional use of NGT-products?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please provide details

As a stopgap and out of the their dilemma caused by the release of GMOs – facing the NGT-plants' inherent potential to contaminate other crops while being at the same time entirely committed to produce without GMOs and provide their customers with GMO-free material and products – organic breeders and seed companies amongst our members see themselves virtually forced to take measures in order to protect their programs and production from contamination by GMOs. For small breeding initiatives, farmers saving seeds on their farm, seed production for self-supply, seed savers and conservation initiatives such measures are too costly and not feasible.

But most importantly: First and foremost, in order to protect GM-free breeding and seed production from unintentional use of NGT-products, it is absolutely indispensable that the EU Commission, the EU Member States and their authorities ensure that the Directive 2001/18/EC is enforced for NGTs and NGT-products throughout the EU. Without such regulation, no effective protection is possible. The ruling of the European Court of Justice (C-528/16) must be respected.

For breeders and seed companies to be able to take protection measures, it is of also of utmost importance that the polluter pays principle is implemented, so that the costs for protection measures as well as the costs that arise when a contamination is detected are borne by those responsible for the threat of contamination, the developers of GMO products, and not by the breeders and seed producers that want to produce GM-free varieties and seed. Already today, GM-free breeders and seed producers bear the costs associated with damages occurring through GMO contaminations and with protection measures against contamination, e.g. for testing breeding material and seed lots of crops at risk of GMO contamination or checking areas around seed production on cultivation and field trials with cross-fertile GM species, as the polluter pays principle is not implemented. This is an already challenging situation. Under all currently discussed scenarios for deregulating NGT-products, these costs would dramatically increase and severely impact GM-free breeders and seed producers. In addition to that, they would be deprived of any effective means to protect against contamination.

* 2 bis. Have you encountered any challenges?

- (●) Yes
- ( ) No

* Please provide details

First and foremost, in order to protect GM-free breeding and seed production from unintentional use of NGT-products, it is absolutely indispensable that the EU Commission, the EU Member States and their authorities ensure that the Directive 2001/18/EC is enforced for NGTs and NGT- products throughout the EU. Without such regulation, no effective protection is possible. The ruling of the European Court of Justice (C-528/16) must be respected:

The EU Commission and EU Member States are in the duty to implement effective controls for agricultural goods imported from countries where NGT-products are released into the environment and marketed. The EU's zero tolerance policy for unauthorised NGT-products must be implemented.

For the protection of our sector from contamination with NGT-products, it is essential that the EU Commission and EU Member States foster research programs for the development of detection methods for NGT-applications. First of all, the developing companies should disclose full information about the modified genome sequences of their products and submit methods and reference materials for detection. GMOs

developed by NGTs are detectable with commonly used PCR-methods, provided prior information is available regarding the intended genomic changes (ENGL 2019). The identification of NGT-plants is also possible as genome-editing techniques open up entirely new possibilities to modify the plant genome. These can result in genetic modifications and new genetic combinations that are significantly different from those induced by classical mutagenesis breeding or natural mutations and can only be achieved by genome editing so far (Kawall 2019; Kannan 2018; Sanchez-Leon et al. 2018). In addition to that, it is evident that advances in detection technologies are needed for NGT-products. These advances are entirely possible, and it is a question of political will to enable them through fostering research. The European Network of GMO Laboratories (ENGL) has already discussed the issues surrounding detectability of NGT-products and concluded that further consideration is necessary. What is urgently needed, is the political will of EU policy-makers to develop suitable detection technologies. For instance, developments in different omics disciplines (e.g. genomics and metabolomics) and bio-informatics as well as the integration of their combined use are promising in order to identify NGT-products and to distinguish them from plants developed with classical mutagenesis techniques and natural mutations. It is essential that EU policy-makers foster research in this area. As a peer-reviewed paper concludes, “[t]he combination of multivariate statistics and high-resolution metabolomics are likely to prove instrumental as a means of discriminating gene-edited plants from their wild-type controls as well as from spontaneous mutants or early generations of physically or chemically induced mutants, which are likely to contain multiple mutations” (Fraser et al 2020).

In addition to that, for the identification of NGT-products, the establishment of a public international registry which includes NGT-products that are field trialed, cultivated and placed on the market globally, among them NGT-applications, is essential (see the proposal in Eckerstorfer et al. 2019). Transparency is a prerequisite for a free decision whether to use these products or not. Transparency is needed not only for NGTs, but for all breeding and selection methods applied on plants, and this should be ensured e.g. through a legal requirement for applicants to disclose the respective information when registering new varieties.

References:

European Network of GMO Laboratories (ENGL) (2019): Detection of food and feed plant products obtained by new mutagenesis techniques.

Kawall, K. (2019): New Possibilities on the Horizon: Genome Editing Makes the Whole Genome Accessible for Changes. Front. Plant Sci. 10:525. doi: 10.3389/fpls.2019.00525.

Kannan, B. et al. (2018): TALEN-mediated targeted mutagenesis of more than 100 COMT copies/alleles in highly polyploid sugarcane improves saccharification efficiency without compromising biomass yield. Plant Biotechnol J 16 (4), 856-866.

Sanchez-Leon, S. et al. (2018): Low-gluten, nontransgenic wheat engineered with CRISPR/Cas9. Plant Biotechnol J 16 (4), 902-910.

Fraser, P.D. et al. (2020): Metabolomics should be deployed in the identification and characterization of gene-edited crops. In: The Plant Journal 2020, https://doi.org/10.1111/tpj.14679

Eckerstorfer, M. F., Engelhard, M., Heissenberger, A., Simon, S., Teichmann, H. 2019: Plants Developed by New Genetic Engineering Techniques – Comparison of Existing Regulatory Frameworks in the EU and Non-EU Countries, Frontiers in Bioengineering and Biotechnology, February 2019, Volume 7, Article 26.

3. Are you aware of initiatives in your sector to develop, use, or of plans to use NGTs/NGT-products?

* ○ Yes
● No
○ Not applicable

*** 4. Do you know of any initiatives in your sector to guard against unintentional use of NGT-products?**

○ Yes
● No
○ Not applicable

* 4 bis. Are you aware of any challenges encountered?

● Yes
○ No

* Please provide details

In order to protect GM-free breeding, seed production and seed saving from unintentional use of NGT-products, it is, first and foremost, absolutely indispensable that the EU Commission, the EU Member States and their authorities ensure that the Directive 2001/18/EC is enforced for NGTs and NGT-products throughout the EU. The ruling of the European Court of Justice (C-528/16) must be respected:

The EU Commission and EU Member States are in the duty to implement effective controls for agricultural goods imported from countries where NGT-products are released into the environment and marketed. It is essential that they foster research programs for the development of detection methods for NGT-applications.

First of all, the developing companies should disclose full information about the modified genome sequences of their products and submit methods and reference materials for detection. GMOs developed by NGTs are detectable with commonly used PCR-methods, provided prior information is available regarding the intended genomic changes (ENGL 2019). The identification of NGT-plants is also possible as genome-editing techniques open up entirely new possibilities to modify the plant genome. These can result in genetic modifications and new genetic combinations that are significantly different from those induced by classical mutagenesis breeding or natural mutations and can only be achieved by genome editing so far (Kawall 2019; Kannan 2018; Sanchez-Leon et al. 2018). In addition to that, it is evident that advances in detection technologies are needed for NGT-products. These advances are entirely possible, and it is a question of political will to enable them through fostering research. The European Network of GMO Laboratories (ENGL) has already discussed the issues surrounding detectability of NGT-products and concluded that further consideration is necessary. For instance, developments in different omics disciplines (e.g. genomics and metabolomics) and bio-informatics as well as the integration of their combined use are promising in order to identify NGT-products and to distinguish them from plants developed with classical mutagenesis techniques and natural mutations. It is essential that EU policy-makers foster research in this area. As a peer-reviewed paper concludes, “[t]he combination of multivariate statistics and high-resolution metabolomics are likely to prove instrumental as a means of discriminating gene-edited plants from their wild-type controls as well as from spontaneous mutants or early generations of physically or chemically induced mutants, which are likely to contain multiple mutations” (Fraser et al 2020).

In addition to that, for the identification of NGT-products, the establishment of a public international registry which includes NGT-products that are field trialed, cultivated and placed on the market globally, among them NGT-applications, is essential (see Eckerstorfer et al. 2019). Transparency is a prerequisite for a free decision whether to use these products or not. Transparency is needed not only for NGTs, but for all breeding and selection methods applied on plants.

Our sector can have freedom of choice only if NGT-plants undergo an EU authorisation procedure, including the obligation to submit methods and reference materials for detection, and are subject to the labelling, traceability and monitoring requirements as laid down in EU GMO legislation. No other EU sectoral regulatory framework (e.g. for seeds, food and feed or pesticides) would provide us with appropriate protection measures against the unintentional use of NGT-products. Under all currently discussed scenarios for deregulating NGT-products, GM-free breeders and seed producers would be deprived of any effective means to protect against contamination.

References:
European Network of GMO Laboratories (ENGL) (2019): Detection of food and feed plant products obtained by new mutagenesis techniques.

Kawall, K. (2019): New Possibilities on the Horizon: Genome Editing Makes the Whole Genome Accessible for Changes. Front. Plant Sci. 10:525. doi: 10.3389/fpls.2019.00525.

Kannan, B. et al. (2018): TALEN-mediated targeted mutagenesis of more than 100 COMT copies/alleles in highly polyploid sugarcane improves saccharification efficiency without compromising biomass yield. Plant Biotechnol J 16 (4), 856-866.

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Eckerstorfer, M. F., Engelhard, M., Heissenberger, A., Simon, S., Teichmann, H. 2019: Plants Developed by New Genetic Engineering Techniques – Comparison of Existing Regulatory Frameworks in the EU and Non-EU Countries, Frontiers in Bioengineering and Biotechnology, February 2019, Volume 7, Article 26.

*** 5. Are your members taking specific measures to comply with the GMO legislation as regards organisms obtained by NGTs?**

Please also see question 8 specifically on labelling

- ○ Yes
- ◉ No
- ○ Not applicable

* Please explain why not

Our members and partners do not apply NGTs and do not work with NGT-products. Therefore, we do not have to comply with the rules applicable to those who bring NGT-products to the market.

Our members and partners working for the organic sector comply with the Organic Regulation and the standards of the organic sector which prohibit the use of GMOs.

* 5 bis. What challenges have you encountered?

Instead, in order to be able to continue to produce GM-free varieties and seed, we depend on the regulation of NGTs and NGT-products under current EU GMO regulation. Only on the basis of this regulation, the protection of our sector against contamination with NGT-products and the unintentional use of NGT-seed is possible. In order to protect us from contamination and unintentional use of NGT-products, it is absolutely indispensable that the EU Commission, the EU Member States and their authorities ensure that the Directive 2001/18/EC is enforced for NGTs and NGT-products throughout the EU. The ruling of the European Court of Justice (C-528/16) must be respected.

* **6. Has your organisation/your members been adequately supported by national and European authorities to conform to the legislation?**

- ○ Yes
- ◉ No
- ○ Not applicable

* What challenges have you encountered?

As our members do not use NGT-products, this is not directly applicable to us. However, there are areas in which support by European and national authorities is clearly needed:

It is essential that the EU Commission and EU Member States foster research programs for the development of detection methods for NGT-applications. First of all, the developing companies should disclose full information about the modified genome sequences of their products and submit methods and reference materials for detection. GMOs developed by NGTs are detectable with commonly used PCR-methods, provided prior information is available regarding the intended genomic changes (ENGL 2019). The identification of NGT-plants is also possible as genome-editing techniques open up entirely new possibilities to modify the plant genome. These can result in genetic modifications and new genetic combinations that are significantly different from those induced by classical mutagenesis breeding or natural mutations and can only be achieved by genome editing so far (Kawall 2019; Kannan 2018; Sanchez-Leon et al. 2018). In addition to that, it is evident that advances in detection technologies are needed for NGT-products. These advances are entirely possible, and it is a question of political will to enable them through fostering research. The European Network of GMO Laboratories (ENGL) has already discussed the issues surrounding detectability of NGT-products and concluded that further consideration is necessary. For instance, developments in different omics disciplines (e.g. genomics and metabolomics) and bio-informatics as well as the integration of their combined use are promising in order to identify NGT-products and to distinguish them from plants developed with classical mutagenesis techniques and natural mutations. It is essential that EU policy-makers foster research in this area. As a peer-reviewed paper concludes, “[t]he combination of multivariate statistics and high-resolution metabolomics are likely to prove instrumental as a means of discriminating gene-edited plants from their wild-type controls as well as from spontaneous mutants or early generations of physically or chemically induced mutants, which are likely to contain multiple mutations” (Fraser et al 2020).

Moreover, our sector struggles with the lack of transparency on NGT-plants released in third countries, as breeders exchange breeding material across countries and continents. The EU Commission and EU Member States should use their political weight and stand up for the establishment of a public international registry which includes all GMO plant varieties that are field trialed, cultivated and placed on the market globally, among them NGT-applications (see Eckerstorfer et al. 2019). For breeders and seed producers, such a registry would be an essential tool to identify varieties developed by NGTs. Transparency is a prerequisite for a free decision whether to use these products or not, and should also be in the interest of public authorities.

References:
European Network of GMO Laboratories (ENGL) (2019): Detection of food and feed plant products obtained by new mutagenesis techniques.

Kawall, K. (2019): New Possibilities on the Horizon: Genome Editing Makes the Whole Genome Accessible for Changes. Front. Plant Sci. 10:525. doi: 10.3389/fpls.2019.00525.

Kannan, B. et al. (2018): TALEN-mediated targeted mutagenesis of more than 100 COMT copies/alleles in highly polyploid sugarcane improves saccharification efficiency without compromising biomass yield. Plant Biotechnol J 16 (4), 856-866.

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Fraser, P.D. et al. (2020): Metabolomics should be deployed in the identification and characterization of gene-edited crops. In: The Plant Journal 2020, https://doi.org/10.1111/tpj.14679

Eckerstorfer, M. F., Engelhard, M., Heissenberger, A., Simon, S., Teichmann, H. 2019: Plants Developed by New Genetic Engineering Techniques – Comparison of Existing Regulatory Frameworks in the EU and Non-EU Countries, Frontiers in Bioengineering and Biotechnology, February 2019, Volume 7, Article 26.

* **7. Does your sector have experience or knowledge on traceability strategies, which could be used for tracing NGT-products?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please describe the traceability strategy, including details on the required financial, human resources and technical expertise

General labelling and traceability rules have been long-since implemented by the food and feed industries and considerable experience has already been gained with traceability strategies. Research on new, digital technologies is conducted which could further enhance the means to ensure traceability and transparency along the value chain. In the area of GMOs, Directive 1830/2003 provides an existing framework for the traceability of NGT-products. We do not identify a need for a basically new traceability strategy, but the need to implement a combination of labelling, documentation and other traceability mechanisms, supported by testing strategies to detect contamination and fraud.

According to Regulation (EC) 1830/2003 GMOs must be traceable through documentation systems also in the absence of detectable GM material in products; in this case, the labelling of final products relies on information transmission along the value chain. These rules are fully applicable for NGT-products; even if the technical tools might currently still lack to detect a specific product, regulation can “be based on a system of sworn statements, traceability etc.” (Duensing et al. 2018). A documentation-based approach is already successfully applied for oil products, such as oil from GM soy.

It is important to stress that it is possible to identify NGT-products. First, GMOs developed by NGTs are detectable with commonly used PCR-methods, provided prior information is available regarding the intended genomic changes (ENGL 2019). Hence, first of all, the developing companies should disclose full information about the modified genome sequences of their products. The identification of NGT-plants is also possible as

genome-editing techniques open up entirely new possibilities to modify the plant genome. These can result in genetic modifications and new genetic combinations that are significantly different from those induced by classical mutagenesis breeding or natural mutations and can only be achieved by genome editing so far (Kawall 2019; Kannan 2018; Sanchez-Leon et al. 2018). In addition to that, where advances in detection technologies are needed for NGT-products, these advances are possible, and it is a question of political will to enable them through fostering research. The European Network of GMO Laboratories (ENGL) has already discussed the issues surrounding detectability of NGT-products and concluded that further consideration is necessary. For instance, developments in different omics disciplines (e.g. genomics and metabolomics) and bio-informatics as well as the integration of their combined use are promising in order to identify NGT-products and to distinguish them from plants developed with classical mutagenesis techniques and natural mutations. It is essential that EU policy-makers foster research in this area. As a peer-reviewed paper concludes, “[t]he combination of multivariate statistics and high-resolution metabolomics are likely to prove instrumental as a means of discriminating gene-edited plants from their wild-type controls as well as from spontaneous mutants or early generations of physically or chemically induced mutants, which are likely to contain multiple mutations” (Fraser 2020). The ENGL-report discussed the collection of genomic data in pan-genome databases, which encompass all sequence variations in a species, to identify unique DNA alterations of genome editing (ENGL 2019).

Ensuring traceability for NGT-products is entirely possible, there needs to be political will to make it happen. Only with traceability, consumer’s and farmer’s choice, monitoring and regulatory oversight in the case of any adverse effects that appear post-commercialisation can be ensured. Traceability is also a minimum requirement for being able to assign causation and responsibility in the event of long-term effects.

References:

Duensing, N. et al. (2018): Novel Features and Considerations for ERA and Regulation of Crops Produced by Genome Editing.

European Network of GMO Laboratories (ENGL) (2019): Detection of food and feed plant products obtained by new mutagenesis techniques.

Kawall, K. (2019). New Possibilities on the Horizon: Genome Editing Makes the Whole Genome Accessible for Changes. Front. Plant Sci. 10:525. doi: 10.3389/fpls.2019.00525.

Kannan, B. et al. (2018) TALEN-mediated targeted mutagenesis of more than 100 COMT copies/alleles in highly polyploid sugarcane improves saccharification efficiency without compromising biomass yield. Plant Biotechnol J 16 (4), 856-866.

Sanchez-Leon, S. et al. (2018) Low-gluten, nontransgenic wheat engineered with CRISPR/Cas9. Plant Biotechnol J 16 (4), 902-910.

Fraser, P.D. et al. (2020) Metabolomics should be deployed in the identification and characterization of gene-edited crops. The Plant Journal.

* **8. Are your members taking specific measures for NGT-products to ensure the compliance with the labelling requirements of the GMO legislation?**

- ○ Yes
- ◉ No
- ○ Not applicable

* Please describe the measures and their effectiveness including details on the required financial, human resources and technical expertise

this is not applicable

* What best practices can you share?

This is not applicable

* Please explain why not

Our members and partners do not use NGT-products, so they do not have to label their seed in compliance with GMO legislation.

However, it is of utmost importance that the current EU GMO legislation and Directive 2001/18/EC are fully enforced to protect our sector from unintentional use of NGT-products. In this context, the enforcement of the labelling and traceability requirements as well as of the zero tolerance policy for unauthorised GMOs laid down in current EU GMO regulation is key. And there is an urgent and clear need for the European and national authorities to develop and apply detection methods which can be used to fully enforce Directive 2001/18/EC, including as regards to imports.

It is essential that the EU Commission and EU Member States foster research programs for the development of detection methods for NGT-applications. First of all, the developing companies should disclose full information about the modified genome sequences of their products and submit methods and reference materials for detection. GMOs developed by NGTs are detectable with commonly used PCR-methods, provided prior information is available regarding the intended genomic changes (ENGL 2019). The identification of NGT-plants is also possible as genome-editing techniques open up entirely new possibilities to modify the plant genome. These can result in genetic modifications and new genetic combinations that are significantly different from those induced by classical mutagenesis breeding or natural mutations and can only be achieved by genome editing so far (Kawall 2019; Kannan 2018; Sanchez-Leon et al. 2018). In addition to that, it is evident that advances in detection technologies are needed for NGT-products. These advances are entirely possible, and it is a question of political will to enable them through fostering research. The European Network of GMO Laboratories (ENGL) has already discussed the issues surrounding detectability of NGT-products and concluded that further consideration is necessary. For instance, developments in different omics disciplines (e.g. genomics and metabolomics) and bio-informatics as well as the integration of their combined use are promising in order to identify NGT-products and to distinguish them from plants developed with classical mutagenesis techniques and natural mutations. It is essential that EU policy-makers foster research in this area. As a peer-reviewed paper concludes, “[t]he combination of multivariate statistics and high-resolution metabolomics are likely to prove instrumental as a means of discriminating gene-edited plants from their wild-type controls as well as from spontaneous mutants or early generations of physically or chemically induced mutants, which are likely to contain multiple mutations” (Fraser et al 2020).

Our sector struggles with the lack of transparency on NGT-products released in third countries, as breeders exchange breeding material across countries and continents. The EU Commission and EU Member States should use their political weight and stand up for the establishment of a public international registry which includes all GMO plant varieties that are field trialed, cultivated and placed on the market globally, among them NGT-applications (see Eckerstorfer et al. 2019). For breeders and seed producers, such a registry would be an essential tool to identify varieties developed by NGTs. Transparency is a prerequisite for a free decision whether to use these products or not.

References:

European Network of GMO Laboratories (ENGL) (2019): Detection of food and feed plant products obtained by new mutagenesis techniques.

Kawall, K. (2019). New Possibilities on the Horizon: Genome Editing Makes the Whole Genome Accessible for Changes. Front. Plant Sci. 10:525. doi: 10.3389/fpls.2019.00525.

Kannan, B. et al. (2018) TALEN-mediated targeted mutagenesis of more than 100 COMT copies/alleles in highly polyploid sugarcane improves saccharification efficiency without compromising biomass yield. Plant Biotechnol J 16 (4), 856-866.

Sanchez-Leon, S. et al. (2018) Low-gluten, nontransgenic wheat engineered with CRISPR/Cas9. Plant Biotechnol J 16 (4), 902-910.

Fraser, P.D. et al. (2020) Metabolomics should be deployed in the identification and characterization of gene-edited crops. The Plant Journal.

* 8 bis. What challenges have you encountered?

Already today, GM-free breeders and seed producers bear the costs associated with damages occurring through GMO contaminations and with protection measures against contamination, e.g. for testing breeding material and seed lots of crops at risk of GMO contamination or checking areas around seed production on cultivation and field trials with cross-fertile GM species, as the polluter pays principle is not implemented. Under all currently discussed scenarios for deregulating NGT-products, these costs would dramatically increase and severely impact GM-free breeders and seed producers. In addition to that, they would be deprived of any effective means to protect against contamination.

References:
Input by the seed companies, breeders, seed producers, variety maintainers and seed savers associated in IG Saatgut.

IFOAM EU 2017: Socio-economic impacts of GMOs on European Agriculture, Chapter 4.1.: Seed production, 14-18.

* **9. Do you have other experience or knowledge that you can share on the application of the GMO legislation, including experimental releases (such as field trials or clinical trials), concerning NGTs/NGT-products ?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please describe for the:

- [x] Agri-food sector
- [ ] Industrial sector
- [ ] Medicinal sector

Agri-food sector

The political scientist Ulrich Hartung (Hartung 2020) describes the activities of the US company CIBUS to obtain a deregulatory status for its canola produced with the NGT oligonucleotide directed mutagenesis (ODM) in the EU. His research shows that the firm bypassed the EU level and that it lobbied competent authorities (CAs) in certain member states to gain support for the deregulation of NGTs. Cibus chose the CAs because their institutional "closedness" reduced the risk of the debate over the deregulation of NPBTs becoming public.

Regarding the German competent authority, the Federal Agency for Consumer Protection and Food Safety (BVL), Hartung writes: "In 2014, the German CA—the Federal Office for Consumer Protection and Food Safety (BVL)—received Cibus' request for field experiments by Perseus Consulting (Perseus), a consultancy that specializes in "biotechnology regulatory challenges" (Perseus, 2018). The BVL's response to this request provides enlightening insights for our argument regarding institutional closedness. The BVL wrote back that "the evaluation of your request by the BVL will not include any participation or active information of the public or involvement of other authorities. We will probably ask our national expert committee (ZKBS [Central Commission for Biological Safety]) for an opinion on the request." This statement indicates that the BVL was aware of how important it was for Cibus that the proceedings take place behind closed doors. Therefore, even the German CA's awareness that Perseus wanted the regulatory assessment to be dealt with away from other stakeholders and the public supports our above reasoning regarding institutional closedness. In fact, the BVL mandated the ZKBS to be the evaluation authority. This advisory body should now assess whether the modified canola falls into the scope of the German genetic engineering law, which reflects the GMO definition included in Directive 2001/18/EC. What is important here is that the ZKBS had already published a position paper on NPBTs in 2012. Therein, the experts concluded that most NPBT-modified products, including such produced by Cibus, should not be considered and regulated as GMOs (BVL, 2012). In fact, the committee, upon the BVL's mandate and in line with its previous opinion, classified Cibus' canola as non-GMO (ZKBS, 2015). Does this opinion represent a unpredictable, fortunate decision for Cibus or did its consultant, Perseus, know about how ZKBS would classify the crop?

Apparently, the latter holds true. In the request for the field trials sent to the CAs, Perseus, among many other things, refers to the ZKBS's 2012 regulatory opinion (Perseus, 2014). Most importantly, Perseus states therein that the ZKBS concluded that "organisms which have been generated using the ODM (Oligo Directed Mutagenesis) technique are not GMOs" (Perseus, 2014, p. 9). To make this clear: it is scientifically widely undisputed that the breeding technique employed by Cibus to modify the canola (rapid trait development system) represents one variant of ODM. Interestingly, Perseus, in its request for field trials, also refered to the regulatory opinions from two other CAs that received requests—the UK DEFRA and the Swedish Board of Agriculture, which had also concluded that the canola would not fall in the scope of their respective national GMO legislations (Perseus, 2014, p. 8). Hence, it can be concluded that Perseus was aware that the BVL would mandate the ZKBS to evaluate Cibus' canola. On this ground, the consultant apparently anticipated the BVL's regulatory opinion. Ultimately, in early 2015, Cibus received the response from the German CA Perseus had anticipated. In fact, the BVL stated that the canola would not be considered a GMO in Germany, wherefore it would be deregulated, which means that field trials with the crop could be conducted without regulatory oversight (BVL, 2015a)."

Reference:

Hartung, U. (2020): Inside Lobbying on the Regulation of New Plant Breeding Techniques in the European Union: Determinants of Venue Choices. Review of Policy Research, https://doi.org/10.1111/ropr.12366

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B - Information on research on NGTs/NGT-products

* **10. Are your members carrying out NGT-related research in your sector?**

- ○ Yes
- ◉ No
- ○ Not applicable

* Please explain why not

We reject the use of NGT in plant breeding, so we do not carry out application-related plant breeding research with NGTs, see answer to question no. 1.

* **11. Are you aware of other NGT-related research in your sector?**

- ○ Yes
- ◉ No
- ○ Not applicable

* **12. Has there been any immediate impact on NGT-related research in your sector following the Court of Justice of the EU ruling on mutagenesis?**

Court of Justice ruling: Case C-528/16 http://curia.europa.eu/juris/documents.jsf?num=C-528/16

- ○ Yes
- ◉ No
- ○ Not applicable

* Please explain why not

In the GM-free breeding and seed production sector, we do not carry out research related to NGTs.

Moreover, the ruling of the European Court of Justice (Case C-528/16) and the enforcement of Directive 2001/18/EC do not impede application-oriented NGT-related research. If the funding is secured, this kind of research can be carried out. There is hardly any other area of technology that has been funded in such a comprehensive and substantial manner as the technologies of genetic engineering. For decades, the EU and almost all its Member States have invested enormous sums of tax payers' money in promoting and researching genetic engineering in all its forms. In addition, this field of research enjoys wide financial and political support by the private sector.

Applying clear safety standards, monitoring and control mechanisms as laid down in EU GMO legislation on research related to NGTs is essential in order to prevent irreversible harm to eco-systems and human health in accordance with the precautionary principle.

Moreover, the application of the precautionary principle and enforcement of Directive 2001/18/EC for NGTs bears the potential to foster research and innovation in the area of alternative approaches to innovation in the agricultural sector, such as research into agro-ecological land use systems or decentralized plant breeding approaches developing locally-adapted plants that respect the complexity and integrity of eco-systems and further develop plant genetic and biologic diversity. The precautionary principle neither inhibits nor is hostile to innovation. While it does stress the potential for serious harm, it also demands a broadening of knowledge about opportunities and encourages alternative development paths, which may entail less potential harm but equal (or greater) potential benefits, to be considered at an early stage of product development (ECNH 2019; von Schomberg 2013). Without the enforcement of Directive the 2001/18/EC for NGTs, innovative approaches such as agro-ecological land use systems that are urgently needed to meet the threats to our food systems of the biodiversity and climate crisis, would be severely threatened.

References:
Federal Ethics Committee on Non-Human Biotechnology (ECNH) 2019: Does the precautionary principle need to be supplemented? Ethical considerations on the 'innovation principle'.

Von Schomberg, R., 2013, A vision of responsible innovation, in: Owen, R., Heintz, M. and Bessant, J. (eds), Responsible innovation, John Wiley, London.

*** 13. Could NGT-related research bring benefits/opportunities to your sector/field of interest?**

- ○ Yes
- ◉ No
- ○ Not applicable

* Please explain why not

The attention and resources given to research related to NGT-applications on plants for release in the environment or food must be re-directed into truly innovative, decentralized and participatory plant breeding approaches for the development of locally-adapted plants, respecting the complexity and integrity of both the plant and the eco-systems, and research into agro-ecological land use systems. These approaches enhance and further develop plant genetic and biologic diversity as well as soil health and are essential to be able to meet the challenges to our food systems associated with the biodiversity and climate crises (IPES-Food 2016; Bardgett 2017).

In order to meet the challenges to our food systems, it is essential to not define innovation narrowly as meaning technological, commercialized innovation only.

Innovation embraces (Hilbeck/Oehen 2015; Quist et al. 2013):

- Know-how innovation: the development of new management approaches and the introduction of both new and traditional knowledge related to methods and practices; for instance when farmers are enabled to link their own local knowledge to external expert and scientific knowledge for innovative management of soil fertility, crop genetic diversity, and natural resources. As the Standing Committee on Agricultural Research and Foresight Expert Group put it: Approaches that promise building blocks towards low-input high-output systems, integrate historical knowledge and agroecological principles that use nature's capacity and models nature's system flows, should receive the highest priority for funding (SCAR and FEG 2011: Sustainable Food Consumption and Production in a Resource-Constraint World. Brussels).
- Organisational innovation across the agro-food chain, such as more diverse systems of local crop production at farm and landscape scale, to create more diverse habitats for wild species/ecological communities and for the provision of ecosystem services, requiring institutional innovations to enable efficient marketing systems to handle diversified production;
- Social innovation: changing the behavior of groups in society, while maintaining or strengthening cooperation within farmers' networks, for example empowering primary producers vis-à-vis input suppliers and retailers, and altering the relationships between companies and the general public.

There is a clear and urgent need for more publicly funded, industry-independent research on the possible unexpected, unwanted effects of the genetic engineering of plants with NGTs, including long-term effects and considering interactions of the plant with the environment.

There is an urgent need that the Commission and Member States foster research for the development of detection methods for NGT-applications. GMOs developed by NGTs are detectable with commonly used PCR-methods, provided prior information is available regarding the intended genomic changes (ENGL 2019). In addition to that, it is evident that advances in detection technologies are needed. These advances are entirely possible, and it is a question of political will to enable them. The European Network of GMO Laboratories (ENGL) has already discussed the issues surrounding detectability of NGT-products and concluded that further consideration is necessary. For instance, developments in different omics disciplines (e.g. genomics and metabolomics) and bio-informatics as well as the integration of their combined use are promising in order to identify NGT-products and to distinguish them from plants developed with classical mutagenesis techniques and natural mutations (Fraser 2020).

References:

Hilbeck A., Oehen B., 2015 (editors): Feeding the people. The relevance of agroecology for nourishing the world and transforming the current global agri-food system, https://read.ifoam-eu.org/publication/feeding-the-people/agroecological-innovation/

European Network of GMO Laboratories (ENGL) (2019): Detection of food and feed plant products obtained by new mutagenesis techniques.

Fraser, P.D. et al. (2020) Metabolomics should be deployed in the identification and characterization of gene-edited crops. In: The Plant Journal 2020, https://doi.org/10.1111/tpj.14679

International Panel of Experts on Sustainable Food systems/IPES-Food 2016: From uniformity to diversity: a paradigm shift from industrial agriculture to diversified agroecological systems, http://www.ipes-food.org/images/Reports/UniformityToDiversity_FullReport.pdf

Bardgett, RD, Gibson, DJ 2017: Plant ecological solutions to global food security. J Ecol 105:859–864,

https://besjournals.onlinelibrary.wiley.com/doi/full/10.1111/1365-2745.12812

Quist, D. A., Heinemann, J. A., Myhr, A. I., Aslaksen, I., Funtowicz, S. 2013: Hungry for innovation: pathways from GM crops to agroecology. In: European Environment Agency/EEA 2013: Late lessons from early warnings: science, precaution, innovation. Luxembourg: Publications Office of the European Union, 2013, 458-485.

*** 14. Is NGT-related research facing challenges in your sector/field of interest?**

- ○ Yes
- ◉ No
- ○ Not applicable

* Please explain why not

The ruling of the European Court of Justice (Case C-528/16) and the enforcement of Directive 2001/18/EC do not impede application-oriented NGT-related research. If the funding is secured, this kind of research can be carried out. There is hardly any other area of technology that has been funded in such a comprehensive and substantial manner as the technologies of genetic engineering. For decades, the EU and almost all its Member States have invested enormous sums of tax payers' money in promoting and researching genetic engineering in all its forms. In addition, this field of research enjoys wide financial and political support by the private sector.

*** 15. Have you identified any NGT-related research needs/gaps?**

- ◉ Yes
- ○ No
- ○ Not applicable

* Please specify which needs/gaps, explain the reasoning and how these needs/gaps could be addressed

There is a clear and urgent need for more publicly funded, industry-independent research on the possible unexpected, unwanted effects of the genetic engineering of plants with NGTs, including long-term effects and considering interactions of the plant with the environment. It is essential that EU Commission and Member States provide comprehensive and substantial funding in this area. The companies developing products with NGTs should disclose full information about the modified genome sequences of their products and submit the plant materials needed to carry out the risk research.

There is an urgent and clear need for publicly funded research programs on detection methods for NGT-applications. It is essential that the EU Commission and EU Member States foster research programs for the development of detection methods for NGT-applications. First of all, the developing companies should disclose full information about the modified genome sequences of their products and submit methods and reference materials for detection. GMOs developed by NGTs are detectable with commonly used PCR-methods, provided prior information is available regarding the intended genomic changes (ENGL 2019). In addition to that, it is evident that advances in detection technologies are needed for NGT-products. These advances are entirely possible, and it is a question of political will to enable them through fostering research. The European Network of GMO Laboratories (ENGL) has already discussed the issues surrounding detectability of NGT-products and concluded that further consideration is necessary. For instance, developments in different omics disciplines (e.g. genomics and metabolomics) and bio-informatics as well as the integration of their combined use are promising in order to identify NGT-products and to distinguish them from plants developed with classical mutagenesis techniques and natural mutations. It is essential that EU policy-makers foster research in this area. As a peer-reviewed paper concludes, “[t]he combination of multivariate statistics and high-resolution metabolomics are likely to prove instrumental as a means of discriminating gene-edited plants from their wild-type controls as well as from spontaneous mutants or early generations of physically or chemically induced mutants, which are likely to contain multiple mutations.” (Fraser 2020). The ENGL-report discussed the collection of genomic data in pan-genome databases, which encompass all sequence variations in a species, to identify unique DNA alterations of genome editing (ENGL 2019).

References:

European Network of GMO Laboratories (ENGL) (2019): Detection of food and feed plant products obtained by new mutagenesis techniques.

Fraser, P.D. et al. (2020) Metabolomics should be deployed in the identification and characterization of gene-edited crops. The Plant Journal.

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C - Information on potential opportunities and benefits of NGTs/NGT-products

* **16. Could NGTs/NGT-products bring benefits/opportunities to your sector/field of interest?**

- ○ Yes
- ◉ No

* Please explain why not

All genetically engineered plants, including NGT-plants, due to their inherent potential to contaminate other crops, challenge the freedom of choice of GMO-free breeders, seed producers, farmers and food producers and consumers. Already now, seed producers and breeders need to take measures to prevent contamination, e.g. testing breeding material and seed lots of crops at risk of GMO contamination or checking on GMO cultivation and field trials with cross-fertile species around their fields. The costs associated with that and those arising when a contamination is discovered are borne by those who want to produce GM-free, as the polluter pays principle is not implemented. Under all currently discussed scenarios for deregulating NGTs and NGT-products, these costs would dramatically increase and GM-free breeders and seed producers would be deprived of effective means to protect against contamination. Freedom of choice for our sector can only be secured if the European Commission and EU Member States respect the ruling of the European Court of Justice (C-528/16) and enforce the Directive 2001/18/EC for NGTs and NGT-products.

The sector of GM-free breeding and seed production associated with IG Saatgut is committed to contribute to the development of solutions to the tackle the challenges to our food systems in the 21st century. This is only possible if we develop approaches to seed production that are oriented towards the provisioning of common goods, such as the maintenance and development of plant genetic and biological diversity and the building of resilient agro-ecosystems. Focusing on optimizing few specialised and highly uniform food crops with the help of few capital-intensive technologies as NGTs does not deliver appropriate solutions. Given the complex systemic character of the challenges, primarily technological and product-oriented innovations are not suitable. Even more so, if the business models of the patent- and license holders of the technologies damage socio-economic diversity and self-determination in breeding and seed production, as it is the case with NGTs.

It is highly questionable whether plant varieties with the promised traits such as stable high yields or robust stress-tolerance towards extreme weather can be developed with NGTs. These traits are the result of a complex interaction of many genes, the environment of the plants and other mechanisms, they are composed of many different cell components (Chen et al. 2002; Deinlein et al. 2014; Ramirez-Gonzalez et al. 2018). Plants react to drought, cold, or salt stress with the simultaneous modification of the expression of hundreds of genes. These reactions are adjusted in different parts of the plants to the respective levels of the stress condition. Furthermore, the knowledge from various life science disciplines demonstrates that living organisms are not the sum of their parts and not everything is ‘coded’ in DNA. To date, conventional breeding techniques have proven to be more successful in producing plants with complex traits (Gilbert 2014; Gilbert 2016). In the field of NGT applications in plants, currently approximately 90% of current CRISPR-applications on plants aim at switching off or eliminating genes. More complex applications, e.g. based on bringing DNA-templates into the cell or changing individual base pairs with one another, only function with less efficiency. Most likely for this reason, the current NGT-plant commercialization pipeline of companies is characterized by rather simple traits, e.g. modified starch or oil content, non-browning effects or herbicide-tolerance. Regardless of their relevance for sustainable agriculture, these traits could also be developed without any difficulty with conventional breeding methods.

References:

Chen W., Provart N.J., Glazebrook J., Katagiri F., Chang H.S., Eulgem T., Mauch F., Luan S., Zou G., Whitham S.A., Budworth P.R., Tao Y., Xie Z., Chen X., Lam S., Kreps J.A., Harper J.F., Si-Ammour A., Mauch-Mani B., Heinlein M., Kobayashi K., Hohn T., Dangl J.L., Wang X., Zhu T. 2002: Expression profile matrix of Arabidopsis transcription factor genes suggests their putative functions in response to environmental stresses. Plant Cell 14:559–574.

Deinlein U., Stephan A.B., Horie T., Luo W., Xu G., Schroeder J.I. 2014: Plant salt-tolerance mechanisms. Trends Plant Sci 19(6):371–379.

Ramirez-Gonzalez R.H., Borrill P., Lang D., Harrington S.A., Brinton J., Venturini L., Uauy C. 2018: The transcriptional landscape of polyploid wheat. Science. https://doi.org/10.1126/science.aar6089.

Gilbert, N. 2014: Cross-bred crops get fit faster. Genetic engineering lags behind conventional breeding in efforts to create drought-resistant maize. Nature 513:292.

Gilbert, N. 2016: Frugal Farming. Old-fashioned breeding techniques are bearing more fruit than genetic engineering in developing self-sufficient super plants, Nature. 533:308–310.

* **17. Could NGTs/NGT-products bring benefits/opportunities to society in general such as for the environment, human, animal and plant health, consumers, animal welfare, as well as social and economic benefits?**

- ○ Yes
- ◉ No

* Please explain why not

NGTs will not deliver solutions to the complex challenges to our food systems in the 21st century, see answer no. 16, and:

Proponents of NGTs suggest that we need NGTs to tackle the climate crisis with drought-resistant plants. However, there is no such thing as a single trait of drought tolerance. Rather, plants have many different ways to react to water deficiency. They can, e.g., root more deeply, more broadly, create finer roots, they can bring forth a stronger way layer or produce more hairs on their leaves, earlier close their stomas or change their circadian rhythm. Each of these characteristics alone does not make a drought-tolerant plant, though. Drought tolerance is always based on various combinations of traits.

Hence, while non-NGT breeding processes, such as selection sometimes under water stress and sometimes under optimal field conditions, have been effectively used since many years in order to enhance the drought tolerance in crops, this is a highly complex task. All properties that give rise to drought tolerance are deeply embedded in the organism of plants. Hence, the genetic improvement of drought tolerance is almost always associated with further fundamental changes in a plant. Simply equipping high-performance varieties with additional drought tolerance through NGTs while maintaining all other characteristics will not work.

Drought-tolerant plants must be able to react in different ways. For instance, if there was an excellent winter moisture prior to an extreme dry weather period, the capability of plants to grow deep roots is essential. However, if, before a dry weather period occurs, no moisture could accumulate in the soil, the ability to root deeply is of little use, but plants can increase their shallow rooting to fully exploit low precipitation levels. The combination of such different and possibly even conflicting traits in one single plant naturally has its limits. This is why a broad drought tolerance on the fields can be best achieved with diverse varieties, so-called heterogeneous populations or developable mixtures, in which different types prevail depending on weather conditions and types of water deficiency.

Breeding has always been based on variation and selection. NGTs, instead, are reinforcing an approach of inserting or silencing single traits located at specific loci as precisely as possible. This reductionist approach will not be successful in adapting crops that have been selected and bred over thousands of years to changing weather conditions.

Moreover, the challenges to our food systems cannot be tackled by breeding alone. We need to focus our resources and attention to a fundamental change in agricultural and horticultural systems, including a diversification of production systems and the regionalization of food production. We need to create political, legal and economic frameworks that foster truly innovative, locally adapted, systemic approaches to breeding and agriculture that enhance and further develop genetic and biologic diversity as well as soil health, and encourage diverse and self-determined approaches to seed and food production.

It is argued that NGT-plants would help reduce pesticide use. However, it is highly questionable whether plants with stable resistances against pests and diseases that contribute to reducing the pesticide use can be developed with NGTs. Experience shows that resistances in vegetable and fruit based on individual genes (so-called monogenetic resistances) are regularly neutralised after several years. Moreover, studies in the field of apple breeding found that the disease susceptibility of modern varieties is due to an extreme depletion of genetic diversity. In order to develop robust varieties, necessitating less pesticides, it is much more promising to invest in the development of plant genetic diversity and varieties on that basis, e.g. through conventional and organic breeding, than to insert single resistance genes into genetically depleted varieties by the means of NGTs (Bannier 2010). Given these facts, it is highly unlikely that NGT-varieties will contribute to a long-term, stable reduction in the use of pesticides, a goal of the Commission's Farm to Fork Strategy. All the more so, as several NGT-varieties that are in the commercialization pipeline are herbicide-tolerant. Scientific evidence demonstrates that the cultivation of herbicide-tolerant crops, designed for the application of herbicides, can lead to the emergence and spread of herbicide-tolerant weeds. This results in an increase in the application of herbicides, if the cultivation system is not fundamentally altered.

References:

Based on input by plant breeders associated with IG Saatgut.

Bannier, Hans-Joachim 2010: Moderne Apfelzüchtung: Genetische Verarmung und Tendenzen zur Inzucht. Erwerbs-Obstbau DOI 10.1007/s110341-010-0113-4.

* **18. Do you see particular opportunities for SMEs/small scale operators to access markets with their NGTs/NGT-products?**

- ○ Yes
- ◉ No

* Please explain why not

NGTs are patented as well as the plants developed on that basis. Hence, breeding companies that want to use a technique such as CRISPR to develop a plant and bring it to market need to negotiate with the owner (s) of the patent(s) to get the license to work with the patented “invention” and pay license fees.

For instance, in the field of CRISPR-Cas 9, agri-business corporations such as Bayer and Corteva (formerly DowDuPont) have concluded partly exclusive license treaties with the inventors of the technology in order to use their patents. Many of these patents are pending for authorization, some of them have already been granted. For specific applications, the corporations themselves apply for additional patents. In June 2018, Corteva was in leading position with about 50 international patent applications, followed by Bayer-Monsanto with about 30 applications (Testbiotech 2018). Particularly successful, Corteva brought together, in cooperation with the Broad Institute, 48 patents on basic applications of the CRISPR-Cas technology in one so-called patent pool. In order to use CRISPR-Cas-9 in breeding, companies need access to virtually all patents in this pool. In order to get access, they need to negotiate licenses with the administrator of the pool, which is Corteva. This gives the company the possibility to control competitors and further consolidate their market power (Gelinsky 2019; Then 2019).

Having to negotiate with large corporations puts small- and medium sized breeding companies in a difficult situation, and license fees are a financial burden. Moreover, patent claims related to CRISPR-Cas 9 are typically drafted very broadly. They therefore give the patent owners the power to create legal monopolies over a wide range of activities related to their invention, with rights reaching far beyond those applications of their invention which they originally anticipated (Mali 2020).

In addition to patents there are other obstacles that small- and medium-sized breeders are facing regarding the use of NGTs. In order to successfully apply NGTs in breeding, breeders need to have a significant amount of knowledge in molecular genetics and bioinformatics. Moreover, they need to have an appropriate laboratory equipment at their disposal. Small-sized breeders, however, often lack this expertise, nor do they dispose of the financial resources or laboratory equipment needed to work with molecular-genetic methods. A representative of the Dutch vegetable breeding company Rijk Zwaan stated: “We still know very little with respect to which genes and which mutations will have a positive effect on traits in the crops. For every crop effective gene editing methods have to be developed, and how to grow plants from the edited cells. For all these reasons conventional mutagenesis for vegetable seed breeding is still an acceptable alternative” (COGEM 2020).

References:
Testbiotech 2018: Hintergrund. Neue Gentechnikverfahren: zunehmende Monopolisierung von Landwirtschaft und Züchtung.
Gelinsky, Eva 2019: CRISPR für mittelständische Züchter? Mit Patentfamilien und -pools haben sich die Konzerne ihre Marktmacht bereits gesichert, Bauernstimme 09-2019, 18.

Then, Christoph 2019: Neue Gentechnikverfahren und Pflanzenzucht. Patente-Kartell für große Konzerne, in: Forum Umwelt und Entwicklung, Rundbrief 2/2019, 10-11.

Mali, Franc 2020: Is the Patent System the Way Forward with the CRISPR-Cas 9 Technology? Science & Technology Studies. Forthcoming..
COGEM 2020: Report of the International Symposium: Gene edited crops; global perspectives and regulation. October 2019, 4-5.

*** 19. Do you see benefits/opportunities from patenting or accessing patented NGTs/NGT-products?**

- ○ Yes
- ◉ No

* Please explain why not

Full and free access to and exchange of plant genetic diversity has been the cornerstone of plant breeding for generations.

Since the mid 1990s, agro-chemical and seed corporations have used the possibility to register patents in order to increase their market shares. Today, only few corporations dominate the global seed market. By the means of patents on NGTs and NGT-products, this development is continued and further fueled. Corporations already dominating the global seed market are able to further increase their market power – to the disadvantage of small- and medium sized breeding companies. This entails a further loss of socio-economic diversity and pluriformity in the breeding sector (Clapp 2018; OECD 2018).

Patents on NGT-material further impede the free access to and use of plant genetic material for breeding companies, as, with the possibility to patent plant material developed with NGTs, more patents are granted and, consequently, the patent situation, globally, becomes increasingly complex and unclear for breeders. Unintentional and unknowing use of patented material, which may occur in such a situation, can lead to patent infringement suits with possibly serious financial implications, difficult to bear especially for small-sized breeders (Howard 2015; Marco/Rausser 2008).

The patenting of seeds, plants, their harvest and products blocks access to genetic material, and so poses a fundamental risk not only to preserving plant genetic diversity and the traditional use of crop diversity in local communities, but also to future innovation in breeding. This can lead to a loss in diverse, locally adapted varieties and in plant genetic diversity which are vital to ensure that we are able to meet the challenges to our food system associated with the climate and biodiversity crises (Hendrickson et al. 2019; Solberg/Breian 2015).

References:
Clapp, J. 2018. Mega-Mergers on the Menu: Corporate Concentration and the Politics of Sustainability in the Global Food System. Global Environmental Politics 18: 12–33. https://doi.org/10.1162/glep_a_00454

Hendrickson, M., Howard, P.H. & Constance, D. 2019. Power, Food, and Agriculture: Implications for Farmers, Consumers, and Communities. In: Hansen, J., Gibson, J. & Alexander, S. (eds.). Defense of Farmers: The Future of Agriculture in the Shadow of Corporate Power. Lincoln: University of Nebraska Press. p. 13–62. https://doi.org/10.2307/j.ctvgs0crb.7

Howard, P.H. 2015. Intellectual Property and Consolidation in the Seed Industry. Crop Science 55: 2489–2495. https://doi.org/10.2135/cropsci2014.09.0669

Marco, A.C. & Rausser, G.C. 2008. The role of patent rights in mergers: Consolidation in plant biotechnology. American Journal of Agricultural Economics 90: 133–151. https://doi.org/10.1111/j.1467-8276.2007.01046.x

OECD 2018. Concentration in Seed Markets: Potential Effects and Policy Responses. Paris: OECD Publishing. https://doi.org/10.1787/9789264308367-en

Solberg, S.O. & Breian, L. 2015. Commercial cultivars and farmers' access to crop diversity: A case study from the Nordic region. Agricultural and Food Science 24:150–163. https://doi.org/10.23986/afsci.48629

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D - Information on potential challenges and concerns on NGTs/NGT-products

*** 20. Could NGTs/NGT-products raise challenges/concerns for your sector/field of interest?**

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

The challenges for our sector can only be kept at a bearable level if the ECJ ruling (C-528/16) and Directive 2001/18/EC are enforced for NGTs. This is essential for guaranteeing freedom of choice.

Already now, seed producers need to take measures to prevent contamination, e.g. testing breeding material and seed lots of crops at risk of GMO contamination or checking on GMO cultivation and field trials with cross-fertile species around their fields. The costs associated with that and those arising when a contamination is discovered are borne by those who want to produce GM-free, as the polluter pays principle is not implemented. This very challenging situation would further deteriorate if the current GMO laws were not enforced for NGTs:

Without GMO labelling and traceability, an implementation of zero tolerance for unauthorised GMOs in seed and any obligation for companies to provide methods and reference materials in order to detect new NGT-products, breeders would have no means to know if breeding material for which they cannot reconstruct the biography was developed, at any stage, using NGTs or interbreeding material produced on the basis of NGTs. Consequently, they would need to renounce from using external material with unknown biography in order to protect their breeding lines from contamination. This would severely limit their activities, as successful breeding is based on the exchange and diversity of genetic resources. Varieties received by other breeders often serve as comparison for assessing the performance of own lines in terms of quality, yield and plant health. And breeders interbreed external material with their own material in order to enlarge their gene pool.

But breeders could not afford to risk a contamination of their genetic resources, either. Such contamination could have devastating consequences. The contaminated lot or plants would need to be destroyed, which could mean that many years of breeding work (time and money) could be lost. In addition to that, the contamination might already have spread to other breeding lines, a variety as a whole or other breeding projects (due to exchanges with other breeders), possibly leading to the destruction of even wider parts of the gene pool, more seed lots, a whole variety and more breeding projects. Even though the precise potential financial costs are difficult to estimate and depend on specific scenarios, the contamination of a gene pool would imply the loss of long-term investment. Moreover, if not discovered at early stage, contamination could spread into seed production as well as farming supplied with the seed. This could cause cost for farmers and for the processing and trading industries along the value chain.

Under a deregulation scenario, releases and the cultivation of NGT-varieties were expected to significantly increase, given that these would be exempt of any GMO authorization procedure, safety checks and labelling, traceability and transparency requirements. Consequently, the risk that genetic resources and fields of non-GM breeders and seed producers would be contaminated with GMOs would intensify respectively, too. Activities as sharing machines with other holdings, storage, processing and transport

would be even more vulnerable to GMO contamination than currently.

Without transparency on cultivation areas, seed producers could not know whether NGT-plants were grown within a distance in which cross-pollination with their own plants was possible. If biotech companies were not obliged to provide detection methods for their GM constructs, breeders and seed producers, in the absence of these methods, could not even trace and contain possible contaminations. Contaminations could spread at increasingly large scale, without any means to control or track them, rendering, in the long run, non-GM seed production and plant breeding of the concerned cultivated species increasingly impossible.

Even if detection methods were provided, given the lack of labelling and traceability and the likely increase of GMO cultivation, under a deregulation scenario, organic breeders and small-sized seed producers and variety maintainers would not be able to appropriately protect against contamination. In some cases, the quantities of seed would simply be too small to conduct tests. Moreover, systematic testing would be too costly for small-sized companies and initiatives.

These developments would further exacerbate the structural change from decentralised breeding and seed growing towards concentration in a few capital-intensive large companies. Small-scale producers in local structures could, eventually, be forced to give up their production for the crops concerned. Increased contamination risks could hinder GM-free seed growing for concerned crops in entire regions.

References:
Input by IG Saatgut's breeders and seed producers

IFOAM EU 2017: Socio-economic impacts of GMOs on European Agriculture, Chapter 4.1.: Seed production, 14-18.

* Are these challenges/concerns specific to NGTs/NGT-products?

- (●) Yes
- ( ) No

* Please explain

The threat to the freedom of choice to breed GM-free varieties and produce GM-free seed is specifically caused by plant products and seed developed with genetic engineering methods:

GMOs are living organisms which are released into the environment and can reproduce, interbreed with plants of the same or closely related species, spread over large geographic distances and persist over long periods of time in the environment and agro-ecosystems. GMOs released into natural and agroecosystems can hardly be retrieved. On a regular basis, contaminations of seed and food with GMOs are detected, which have persisted, undiscovered, for many years and spread at large scale. For instance, in 2015, illegal GM-rapeseed (event OXY-235) sown on breeding fields in France, Germany, Hungary, Poland, Romania, Denmark and the Czech Republic had to be destroyed. Supposedly, field trials with GM rapeseed that had been conducted 20 years earlier in France were the source of the contamination. In 2018, the contamination of agricultural land with unauthorised GM-rapeseed (event: Gt-73) was discovered in France and Germany. Consequently, illegal rapeseed growing on more than 10.000 hectares of agricultural land had to be destroyed. Other examples for contaminations are illegal GMO-rapeseed plants detected along Swiss railways, or the detection of illegal GM petunia in many countries worldwide in 2017.

Hence, GM plants, due to their inherent potential to contaminate other crops, challenge the freedom of choice of GM-free breeders, seed producers, farmers and food producers and consumers. This challenge

can only be tackled as long as NGTs are regulated under GMO laws with requirements for safety checks, control mechanisms, traceability and labelling requirements. If new NGT-products were released into the environment without regulation under current GMO laws, freedom of choice for the whole food production chain and consumers was fundamentally threatened.

In order to secure freedom of choice, it is essential to respect the ruling of the European Court of Justice (C-528/16) and enforce the Directive 2001/18/EC for NGTs and NGT-products.

* **21. Could NGTs/NGT-products raise challenges/concerns for society in general such as for the environment, human, animal and plant health, consumers, animal welfare, as well as social and economic challenges?**

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

NGTs are powerful, extremely new technologies with no history of safe use. Just like first generation GE techniques, NGTs can give rise to unexpected and unpredictable effects in the resultant GMOs, even if any inserted genes are subsequently removed prior to commercialization. Even intended molecular changes can result in unexpected effects, due to the incomplete understanding of the (often multiple) role(s) of the gene sequences or gene product(s) in regulatory or metabolic processes. Recent research has found that genome editing can result in numerous unexpected, unpredictable and undesirable outcomes, off-target or even at the intended gene editing site and regardless of the precision of the initial edit.

In addition to that, genome editing techniques, including Site-Directed Nucleases 1 (SDN-1), open up entirely new possibilities to modify the plant genome. They can be applied rapidly and repeatedly to the same genes or alter many genes simultaneously or serially one after the other. Even in cases where each a change is individually small, the totality of changes applied could produce organisms that are substantially different from the non-GM original. The techniques can also target areas of the genome that are normally highly resistant to mutation. Hence, NGTs can give rise to a broader spectrum of new genetic combinations and novel traits compared to the traits introduced with classical genetic engineering. With genome-editing techniques, entirely new genetic combinations can be produced (Kawall 2019; Kannan 2018; Sanchez-Leon 2018).

The scientific facts on NGTs, whose products are consumed as food and are living organisms released into the environment, are clear indications of potential serious and irreversible harm. They clearly demonstrate that all NGTs must be regulated at least as stringently as it is currently required under EU GMO legislation, including SDN-1-applications and applications where no foreign genes are inserted or any inserted genes are subsequently removed prior to commercialization, in accordance with the precautionary principle.

NGT-plants, due to their inherent potential to contaminate other crops, challenge the freedom of choice of GM-free breeders, seed producers, farmers and consumers. This challenge can only be tackled as long as NGTs are regulated under GMO laws with safety checks, control mechanisms, traceability and labelling requirements. If new NGT-products were released into the environment without regulation under GMO laws, freedom of choice for breeders and the whole food production chain as well as consumers was fundamentally threatened.

The political attention and financial resources given to the development of NGT-applications are diverting much needed resources and attention from truly innovative, decentralized and participatory plant breeding approaches for the development of locally-adapted plants and from research into agro-ecological land use

systems. These approaches that enhance and further develop plant genetic and biologic diversity as well as soil health are essential to ensure that we are able to meet the challenges to our food systems associated with the biodiversity and climate crises (IPES-Food 2016; Hilbeck/Oehen 2015) – while NGTs will not deliver on tackling these challenges. Focusing on optimizing few food crops with the help of few capital-intensive technologies such as NGTs does not deliver appropriate solutions. Given the complex systemic character of the challenges, primarily technological and product-oriented innovations are not suitable. Even more so, if the business models of the patent- and license holders of the technologies damage socio-economic diversity and self-determination in breeding and seed production, as it is the case with NGTs. It is high time that EU policy-makers wake up, stop diverting their attention and resources to NGTs and focus on the political action needed to foster real solutions to our global problems. Deregulating NGTs out of GMO legislation would fundamentally threaten these solutions.

References:

Kawall, K. 2019: New Possibilities on the Horizon: Genome Editing Makes the Whole Genome Accessible for Changes. Front. Plant Sci. 10:525. doi: 10.3389/fpls.2019.00525.

Kannan, B. et al. 2018: TALEN-mediated targeted mutagenesis of more than 100 COMT copies/alleles in highly polyploid sugarcane improves saccharification efficiency without compromising biomass yield. Plant Biotechnol J 16 (4), 856-866.

Sanchez-Leon, S. et al. 2018: Low-gluten, nontransgenic wheat engineered with CRISPR/Cas9. Plant Biotechnol J 16 (4), 902-910.

International Panel of Experts on Sustainable Food systems/IPES-Food 2016: From uniformity to diversity: a paradigm shift from industrial agriculture to diversified agroecological systems.

Hilbeck A., Oehen B., 2015 (editors): Feeding the people. The relevance of agroecology for nourishing the world and transforming the current global agri-food system.

* Under which conditions do you consider this would be the case?

The described challenges can only be tackled if the ruling of the European Court of Justice (C-528/16) is respected and the Directive 2001/18/EC is enforced for NGTs and NGT-products.

Without NGT-regulation under GMO laws, public and environmental safety would be left to the assumptions and choices of those who alter the genetics of living organisms, without any impartial risk assessment to protect public health and the environment. This would remove any series of checks and balances to stop potentially dangerous products from being released into our environment and food chain. Without an also process-based regulation, the mechanisms, by which unintended and off-target gene function disruption effects can take place when applying NGTs, would not be considered any more, placing an unacceptable risk onto public health and the environment. Possible long-term effects could not be controlled.

Without the regulation of NGTs under current EU GMO legislation, truly innovative, locally-adapted and agro-ecological approaches to breeding, agriculture and food systems (see (IPES-Food 2016; Hilbeck/Oehen 2015) would be fundamentally threatened, as well as the freedom of choice of breeders, seed producers, farmers, food producers and consumers to produce and consume without GMOs. Without any labelling of NGTs and NGT-products, regulatory oversight would not be possible in the case of any adverse effects that appear post-commercialisation. Traceability and labelling are also minimum requirements for being able to assign causation and responsibility in the event of long-term effects.

The negative impacts of the patentability of NGTs and NGT-products and of the business models of the patent- and license holders of the technologies would not be less pronounced if NGTs were deregulated. Also without any regulation under GMO laws, patents on NGTs and NGT-products would catalyse further the concentration processes at the seed market, with the negative consequences described in answer 23. However, if NGTs were not regulated under GMO legislation, it can be expected that these products would gain much larger market shares than with such a regulation and that the market penetration by patented products would be exacerbated, resulting in an increase of the negative impacts described.

References:
International Panel of Experts on Sustainable Food systems/IPES-Food 2016: From uniformity to diversity: a paradigm shift from industrial agriculture to diversified agroecological systems, http://www.ipes-food.org/images/Reports/UniformityToDiversity_FullReport.pdf

Hilbeck A., Oehen B., 2015 (editors): Feeding the people. The relevance of agroecology for nourishing the world and transforming the current global agri-food system, https://read.ifoam-eu.org/publication/feeding-the-people/agroecological-innovation/

* Are these challenges/concerns specific to NGTs/products obtained by NGTs?

- (●) Yes
- ( ) No

* Please explain

NGTs are extremely new, powerful technologies with no history of safe use. There is no guarantee that the use of these techniques will result in predictable outcomes, or that any resulting products will be safe, while they bear the potential to cause serious harm for human beings and the environment. The described safety concerns are firstly inherently linked to entirely the new possibilities that NGT offer to modify the plant genome. Secondly, the safety concerns are associated with the process of genetically engineering plants with NGTs, which, just like first generation GE techniques, can give rise to unexpected and unpredictable effects in the resultant GMOs, even if any inserted genes are subsequently removed prior to commercialization and regardless of the precision of any initial edit (for references see: ENSSER 2019; ENSSER 2017; Cotter et al. 2020).

Also the described threat to freedom of choice to breed GM-free varieties and produce GM-free seed is specifically caused by plant products and seed developed with NGTs: GMOs are living organisms that are released into the environment and can reproduce, interbreed with plants of the same or closely related species, spread over large geographic distances and persist over long periods of time in the environment and agro-ecosystems. GMOs released into natural and agroecosystems can hardly be retrieved. On a regular basis, contaminations of seed and food with GMOs are detected, which have persisted, undiscovered, for many years and spread at large scale. Hence, NGT-plants, due to their inherent potential to contaminate other crops, challenge the freedom of choice of GM-free breeders, seed producers, farmers and food producers and consumers. This challenge can only be tackled as long as NGTs are regulated under GMO laws with requirements for safety checks, control mechanisms, traceability and labelling requirements. If new NGT-products were released into the environment without regulation under current GMO laws, freedom of choice for the whole food production chain and consumers was fundamentally threatened. In order to secure freedom of choice, it is essential to respect the ruling of the European Court of Justice (C-528/16) and enforce the Directive 2001/18/EC for NGTs and NGT-products.

NGTs cannot be considered and assessed separately from the socio-economic framework and the business models they are part of. NGTs and NGT-products are patentable and are patented, resulting in the consequences described in our answers to questions no. 22 and 23.

The opportunity cost of channelling financial resources and political attention into NGT-application related research and development and the deregulation of NGTs – resources and attention which are lacking for truly innovation approaches that could ensure that we are able to meet the challenges to our food systems – is clearly linked to NGTs and NGT-products. There is hardly any other area of technology that has been funded in such a comprehensive and substantial manner as the technologies of genetic engineering. For decades, the EU and almost all its Member States have invested enormous sums of tax payers' money in promoting and researching genetic engineering in all its forms. In addition, this field of research enjoys wide financial and political support by the private sector.

For references, see:
Cotter, J., Kawall, K., Then, Chr. 2020: New Genetic Engineering Technologies. Report of the results from the RAGES project 2016-2019.

ENSSER 2017: ENSSER Statement on New Genetic Modification Techniques, https://ensser.org /publications/ngmt-statement/

ENSSER 2019: New genetic modification techniques and their products pose risks that need to be assessed, ENSSER Statement, 7 November 2019, https://ensser.org/publications/2019-publications/ensser-statement-new-genetic-modification-techniques-and-their-products-pose-risks-that-need-to-be-assessed/

* **22. Do you see particular challenges for SMEs/small scale operators to access markets with their NGTs /NGT-products?**

- (●) Yes
- ( ) No

* Please explain and provide concrete examples and data

NGTs are patented as well as the plants developed on that basis. Hence, breeding companies which want to use a technique such as CRISPR to develop a plant and bring it to market need to negotiate with the owner (s) of the patent(s) to get the license to work with the patented "invention" and pay license fees.

For instance, in the field of CRISPR-Cas 9, agri-business corporations such as Bayer and Corteva (formerly DowDuPont) have concluded partly exclusive license treaties with the inventors of the technology in order to use their patents. Many of these patents are pending for authorization, some of them have already been granted. For specific applications, the corporations themselves apply for additional patents. In June 2018, Corteva was in leading position with about 50 international patent applications, followed by Bayer-Monsanto with about 30 applications (Testbiotech 2018). Particularly successful, Corteva brought together, in cooperation with the Broad Institute, 48 patents on basic applications of the CRISPR-Cas technology in one so-called patent pool. In order to use CRISPR-Cas-9 in breeding, companies need access to virtually all patents in this pool. In order to get access, they need to negotiate licenses with the administrator of the pool, which is Corteva. This gives the company the possibility to control competitors and further consolidate their market power (Gelinsky 2019; Then 2019).

Having to negotiate with large corporations puts small- and medium sized breeding companies in a difficult situation, and license fees are a financial burden. Moreover, patent claims related to CRISPR-Cas 9 are

typically drafted very broadly. They therefore give the patent owners the power to create legal monopolies over a wide range of activities related to their invention, with rights reaching far beyond those applications of their invention which they originally anticipated (Mali 2020).

In addition to patents there are other obstacles that small- and medium-sized breeders are facing regarding the use of NGTs. In order to successfully apply NGTs in breeding, breeders need to have a significant amount of knowledge in molecular genetics and bioinformatics. Moreover, they need to have an appropriate laboratory equipment at their disposal. Small-sized breeders, however, often lack this expertise, nor do they dispose of the financial resources or laboratory equipment needed to work with molecular-genetic methods. A representative of the Dutch vegetable breeding company Rijk Zwaan stated: “We still know very little with respect to which genes and which mutations will have a positive effect on traits in the crops. For every crop effective gene editing methods have to be developed, and how to grow plants from the edited cells. For all these reasons conventional mutagenesis for vegetable seed breeding is still an acceptable alternative” (COGEM 2020).

References:
Testbiotech 2018: Hintergrund. Neue Gentechnikverfahren: zunehmende Monopolisierung von Landwirtschaft und Züchtung.
Gelinsky, Eva 2019: CRISPR für mittelständische Züchter? Mit Patentfamilien und -pools haben sich die Konzerne ihre Marktmacht bereits gesichert, Bauernstimme 09-2019, 18.

Then, Christoph 2019: Neue Gentechnikverfahren und Pflanzenzucht. Patente-Kartell für große Konzerne, in: Forum Umwelt und Entwicklung, Rundbrief 2/2019, 10-11.

Mali, Franc 2020: Is the Patent System the Way Forward with the CRISPR-Cas 9 Technology? Science & Technology Studies. Forthcoming..
COGEM 2020: Report of the International Symposium: Gene edited crops; global perspectives and regulation. October 2019, 4-5.

*** 23. Do you see challenges/concerns from patenting or accessing patented NGTs/NGT-products?**

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

Full and free access to and exchange of plant genetic diversity has been the cornerstone of plant breeding for generations.

Since the mid 1990s, agro-chemical and seed corporations have used the possibility to register patents on genetically engineered crops in order to increase their market shares. Today, only few corporations dominate the global seed market (Howard 2015). By the means of patents on NGTs and NGT-products, this development is continued and further fueled. Corporations already dominating the global seed market are able to further increase their market power – to the disadvantage of small- and medium sized breeding companies. This entails a further loss of socio-economic diversity and pluriformity in the breeding sector (Clapp 2018).

Patents on new GM plant material further impede the free access to and use of plant genetic material for breeding companies, as, with the possibility to patent plant material developed with NGTs, more patents are granted and, consequently, the patent situation, globally, becomes increasingly complex and unclear for breeders. Unintentional and unknowing use of patented material, which may occur in such a situation, can

lead to patent infringement suits with possibly serious financial implications, difficult to bear especially for small-sized breeders.

The patenting of seeds, plants, their harvest and products blocks access to genetic material, and so poses a fundamental risk not only to preserving plant genetic diversity and the traditional use of crop diversity in local communities, but also to future innovation in breeding. This can lead to a loss in diverse, locally adapted varieties and in plant genetic diversity which are vital to ensure that we are able to meet the challenges to our food system associated with the climate and biodiversity crises (Hendrickson et al. 2019, OECD 2018).

References:
Clapp, J. 2018. Mega-Mergers on the Menu: Corporate Concentration and the Politics of Sustainability in the Global Food System. Global Environmental Politics 18: 12–33. https://doi.org/10.1162/glep_a_00454

Hendrickson, M., Howard, P.H. & Constance, D. 2019. Power, Food, and Agriculture: Implications for Farmers, Consumers, and Communities. In: Hansen, J., Gibson, J. & Alexander, S. (eds.). Defense of Farmers: The Future of Agriculture in the Shadow of Corporate Power. Lincoln: University of Nebraska Press. p. 13–62. https://doi.org/10.2307/j.ctvgs0crb.7

Howard, P.H. 2015. Intellectual Property and Consolidation in the Seed Industry. Crop Science 55: 2489–2495. https://doi.org/10.2135/cropsci2014.09.0669

OECD 2018. Concentration in Seed Markets: Potential Effects and Policy Responses. Paris: OECD Publishing. https://doi.org/10.1787/9789264308367-en

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E - Safety of NGTs/NGT-products

*** 24. What is your view on the safety of NGTs/NGT-products? Please substantiate your reply**

NGTs are powerful and extremely new technologies with no history of safe use. There is no guarantee that the use of these techniques will result in predictable outcomes, or that any resulting products will be safe.

In brief, the fundamental concern as regards GMOs and the direct modification of genetic material in general is that it can unintentionally interfere with the gene expression of an organism or interfere with complex biochemical pathways within an organism, which can give rise to unintended or altered proteins or altered secondary metabolites, for instance. Hence, the biological and biochemical characteristics of an organism might be changed in a way that impacts human and animal health and/or the environment. In addition, the novel trait conferred by the genetic engineering can also have consequences for agricultural systems, the environment and often for food and animal feed safety.

Most, if not all, of these principal concerns apply to NGTs as well. Just like first generation GE techniques, they can give rise to unexpected and unpredictable effects in the resultant GMOs, even if any inserted genes are subsequently removed prior to commercialization. Even intended molecular changes can result in unexpected effects, due to the incomplete understanding of the (often multiple) role(s) of the gene

sequences or gene product(s) in regulatory or metabolic processes (Baltimore et al. 2015). And, a fact that is often forgotten in the debate: In order to introduce the construct of CRISPR-Cas, the most noticed NGT-technique, in the form of DNA into a plant cell, classical GE techniques are used, such as transfer by an agrobacterium or so-called 'shotgun'-methods. In this regard, CRISPR-Cas involves the very same risks as classical genetic engineering.

Recent research has found that genome editing can result in numerous unexpected, unpredictable and undesirable outcomes, even at the intended gene editing site. This includes large deletions and complex re-arrangements of DNA (Kosicki et al. 2019), and the creation of new proteins (Tuladhar et al. 2019). These unpredictable and undesirable genetic mutations result after the gene editing tool has completed its task and occur regardless of the precision of the initial edit. The recent discovery that cattle that had been gene-edited to be hornless unexpectedly contained antibiotic resistance genes from bacteria illustrates why all NGT-plants should be regulated under current GMO legislation. The company which genetically engineered the cattle claimed "we have all the scientific data that proves that there are no off-target effects" (Berman 2019). Furthermore, applying NGTs, off-target, unintended changes in the genome do occur at DNA, RNA and protein levels which can lead to unintended alterations of the biochemistry of an organism. Off-target effects can lead to unexpected toxins or allergens, or altered or compromised nutritional value. The radical nature of the changes that can be introduced with NGTs could result in unexpectedly high levels of such toxins. Peer-reviewed research also demonstrates that genome editing techniques including Site-Directed Nucleases 1 (SDN-1), open up entirely new possibilities to modify the plant genome. They can be applied rapidly and repeatedly to the same genes or alter many genes simultaneously or serially one after the other. Even in cases where each a change is individually small, the totality of changes applied could produce an organism that is substantially different from the non-GM original. The techniques can also target areas of the genome that are normally highly resistant to mutation. Hence, NGTs can give rise to a broad spectrum of new genetic combinations which can only be achieved with genome editing so far (Kawall 2019) and novel traits (Agapito-Tenfen et al. 2019; Eckerstorfer et al. 2019). As the scientist Wayne Parrott, Institute of Plant Breeding and Genomics of the University of Georgia puts it: "With gene editing we are now able to change genes we have never had access to before" (COGEM 2020: Report of the International Symposium: Gene edited crops; global perspectives and regulation. October 2019, p. 10).

The scientific facts demonstrate that all NGTs should be regulated at least as stringently as it is currently required under EU GMO legislation.

For references see:
ENSSER 2019: New Genetic Modification Techniques and Their Products pose Risks that need to be assessed, https://ensser.org/publications/2019-publications/ensser-statement-new-genetic-modification-techniques-and-their-products-pose-risks-that-need-to-be-assessed/

Cotter, J., Kawall, K., Then, Christoph 2020: New Genetic Engineering Technologies. Report of the results from the RAGES project 2016-2019.

COGEM 2020: Report of the International Symposium: Gene edited crops; global perspectives and regulation. October 2019, p. 10.

*** 25. Do you have specific safety considerations on NGTs/NGT-products?**

- (●) Yes
- ( ) No

* Please explain

The scientific facts on NGTs are clear indications of potential serious and irreversible harm. In spite of scientific uncertainty involved, action must urgently be taken to prevent such harm. This is precisely what constitutes the precautionary principle, a fundamental principle of EU legislation. The precautionary principle was not borne out of risk aversion, but out of a history of “late lessons from early warnings”. GMOs are organisms that are living systems with the ability to self-replicate and spread their modified genes, far and wide.

The precautionary principle does not require an impossible proof of safety prior to regulatory acceptance, but instead requires scientifically independent, searching and sustained examination of the questions of harm of NGT-products, with the injunction to intervene even where scientific proof of harm is incomplete, if there are reasonable scientific grounds to suppose potential harm from the processes involved. This requires that the processes themselves are subject to regulatory assessment and not only their products.

Public and environmental safety cannot be left to the expectations and assumptions of those who alter the genetics of living organisms and to their choice of whatever potential hazard to look for. Instead, we need impartial regulators and the comprehensive risk assessment laid down in current EU GMO legislation to protect public health and the environment. Regulation does not prevent responsible industries from bringing forward safe products that are sought by the public. However, it is essential to provide a series of checks and balances to stop potentially dangerous products from being released into our environment and our food chain (ENSSER 2019).

The scientific facts demonstrate that all NGTs should be regulated at least as stringently as it is currently required under EU GMO legislation, including SDN-1-applications and applications where no foreign genes are inserted or any inserted genes are subsequently removed prior to commercialization.

It is essential that EU GMO regulation, applied on NGTs, remains process-based, in addition to product-based considerations. Unlike product-based regulation-only regulation, process-based regulation and risk assessment is capable of considering the mechanisms by which unintended and off-target gene function disruption effects can take place. Hence, process-based regulation is appropriate for NGTs, given their inherent potential to produce unintended and off-target effects throughout the process. Attempts to argue that process-based regulation was superfluous place an unacceptable risk onto public health and the environment. Furthermore, as NGT crops are released into the environment, risk assessment should consider interactions of the plant with the environment and possible long-term effects (ENSSER 2017).

While current EU GMO legislation is fit for purpose to regulate NGTs and NGT-products, the current EU risk assessment guidance would need to be expanded in order to assess the additional unintended effects that genome editing can cause. Also, the risk assessment would need to consider a broader range of traits conferred by NGTs, for some of which there may be a lack of experience (Cotter el al. 2020). Furthermore, with NGTs, it is possible to develop more rapidly a larger number of GMOs than it is possible with classical GE methods, and to release them into the environment. The resulting amplified potential for damaging consequences should be considered and may require stricter regulatory standards than for classical GE (ENSSER 2017).

It is essential to continue to regulate NGTs under GMO legislation. Other sectoral EU regulations which apply to all agricultural and food products fail to provide for a breadth and standard of risk assessment comparable with the requirements according to the respective biosafety frameworks (Eckerstorfer et al. 2019).

References:
Eckerstorfer, M. F., Dolezel, M., Heissenberger, A., Miklau, M., Reichenbecher, W., Steinbrecher, R. A., & Wassmann, F. 2019: An EU Perspective on Biosafety Considerations for Plants Developed by Genome

Editing and Other New Genetic Modification Techniques (nGMs). Front Bioeng Biotechnol, 7, 31. doi:10.3389/fbioe.2019.00031.
Cotter, J., Kawall, K., Then, Chr. 2020: New Genetic Engineering Technologies. Report of the results from the RAGES project 2016-2019.

ENSSER 2017: ENSSER Statement on New Genetic Modification Techniques, https://ensser.org/publications/ngmt-statement/

ENSSER 2019: New genetic modification techniques and their products pose risks that need to be assessed, ENSSER Statement, 7 November 2019, https://ensser.org/publications/2019-publications/ensser-statement-new-genetic-modification-techniques-and-their-products-pose-risks-that-need-to-be-assessed/

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F - Ethical aspects of NGTs/NGT-products

*** 26. What is your view on ethical aspects related to NGTs/NGT-products? Please substantiate your reply**

Due to the application of NGTs in complex environmental systems in which the occurrence of serious damage is typically uncertain, the precautionary principle must be applied. The Federal Committee on Non-Human Biotechnology (ECNH, see ECNH 2018, 2019b) sets out in detail why it is highly relevant to go beyond the concept of precaution as laid down in environmental law and to examine the ethical significance and the ethical justification of precautionary measures in the environmental field. Precaution is a morally significant action-guiding principle in the regulation of new biotechnologies.

Other ethical aspects include considerations on risk ethics, responsibility in research and questions of nutrition and self-determination (ECNH 2016).

In this context, food is a key aspect of our lives, one which determines our understanding of ourselves and forms a major aspect of our identity, and is therefore seen as morally relevant. One essential expression of a person’s self-determination is freedom of choice, which is considered as a right of consumers for protection by the State from being forced to consume GM products. As a result of this right, we insist that also NGT-products should be labelled so as to provide information about their contents and production methods, giving consumers the freedom to choose to avoid these products.

The discussion about self-determination and food also includes other stakeholders, especially food producers. Seed producers, breeders and farmers must have the right to freely choose seeds, breeding methods and farming techniques. However, the production of seeds and the production and cultivation of crops are a prerequisite for ensuring individual self-determination with regard to food. To secure this right in the long term, the very foundation of food production must be protected: biodiversity in general and agrobiodiversity in particular, as well as arable land and sufficient water to cultivate crops.

The public authorities must ensure that the biodiversity and agricultural biodiversity necessary for food production are protected in the long-term. As new biotechnologies like NGTs and their products, particularly

if not regulated under current EU GMO regulations, threaten diversified GM-free seed production and hence agricultural biodiversity, the state is morally obliged to take all necessary measures to preserve the foundations of diverse and sustainable food production (ECNH 2016, 25f).

There is a close connection between the need to preserve and foster agrobiodiversity and research into plant breeding. If, due to the further development of NGTs, the type of research pursued by the private sector seems to be leading to a narrowing of the scope of the research objectives and, consequently, in the longer term to a reduction in agrobiodiversity, public funding of plant breeding research must strike a balance and ensure greater diversification in the research sector. Furthermore, developments in intellectual property and its impacts on research and objectives in plant breeding should be carefully monitored. If the developments in the field of NGTs have impacts on agrobiodiversity and the respect for self-determination that cannot be justified, intellectual property rights in plant breeding should be restricted. Relating to responsible research and NGTs, proper risk research needs to be conducted. Access to plant material must be guaranteed so that results can be assessed by independent third parties. Access to unpublished studies and studies with negative research results need to be ensured (ECNH 2016, 30)

The organic sector, according to its principle of health, works within the boundaries of living organic nature with respect for the integrity of life and the integrated whole. Techniques that interfere directly at DNA level, e.g. NGTs, violate this integrity and are consequently not allowed.

Moreover, there is a moral duty to care for and protect the natural life-support systems as basis for the life of future generations. In 2010, the German Federal Constitutional Court declared in its ruling on the German Genetic Engineering Act: "In view of the fact that the state of scientific knowledge regarding the long-term consequences of the use of genetic engineering has not yet been finally clarified, the legislator has a special duty of care in which it must observe the mandate contained in Article 20a of the Constitutional Law to protect the natural foundations of life for future generations, too."

References:

ECNH/Federal Ethics Committee on Non-Human Biotechnology 2016: New Plant Breeding Techniques. Ethical Considerations. https://www.ekah.admin.ch/inhalte/ekah-dateien/dokumentation/publikationen/EKAH_New_Plant_Breeding_Techniques_2016.pdf

For more references, see answer no. 27.

*** 27. Do you have specific ethical considerations on NGTs/NGT-products?**

- (●) Yes
- ( ) No

* Please explain

NGTs enable human beings to deeply intervene into living organisms and systems and to manipulate nature to a new, unprecedented extent. Furthermore, if released into the environment, NGT-products can have irreversible consequences for the whole ecosystem. It is undeniable that these are deeply ethical issues.

Due to the application of NGTs in complex environmental systems in which the occurrence of serious damage is typically uncertain, the precautionary principle must be applied. The Federal Committee on Non-Human Biotechnology (see ECNH 2018, 2019b) sets out in detail why it is highly relevant to go beyond the concept of precaution as laid down in environmental law and to examine the ethical significance and the ethical justification of precautionary measures in the environmental field. Therefore precaution is a morally

significant action-guiding principle in the regulation of new biotechnologies.

A precautionary situation is one in which harm could occur, but where there is only limited knowledge about the probability of the occurrence of this possible harm. The precautionary principle is a response to such situations of uncertainty. The ethical idea of precaution justifies an obligation to take measures to prevent possible serious harm or, if harm does occur, to limit it to an extent not exceeding a permissible degree.

Precautionary measures serve to shape the situation, e.g. with regard to new technologies, as to minimise the probability of serious harm occurring while enabling the collection of the necessary data to acquire the knowledge needed to assess the level of the risk. As long as we are in the area of precaution, it is not a matter of 'weighing up' or 'balancing' risks and opportunities, but of identifying the unknown probabilities of potential serious harm. Only once these risks are known, they can be evaluated.

The precautionary principle neither inhibits nor is hostile to innovation. While it does stress the potential for serious harm, it also demands a broadening of knowledge about opportunities and encourages alternative development paths, which may entail less potential harm but equal (or greater) potential benefits, to be considered at an early stage of product development.

In addition to that, we are highly concerned about the potentially devastating consequences of the use of NGT-products in both gene drives and biological warfare.

References:

ECNH/Federal Ethics Committee on Non-Human Biotechnology 2018: Precaution in the environmental field. https://www.ekah.admin.ch/inhalte/ekah-dateien/dokumentation/veranstaltungen/Veranstaltung_7._Mai_2018/EKAH_Broschu__re_Vorsorge_Umweltbereich_e__18_Web_V2.pdf

ECNH/Federal Ethics Committee on Non-Human Biotechnology 2019a: Gene Drives. Ethical Considerations on the use of Gene Drives in the Environment. https://www.ekah.admin.ch/inhalte/ekah-dateien/dokumentation/publikationen/EKAH_Bericht_Gene_Drives_EN_V2.pdf

ECNH/Federal Ethics Committee on Non-Human Biotechnology 2019b: Does the precautionary principle needs to be supplemented? Ethical Considerations on the "innovation principle". https://www.ekah.admin.ch/inhalte/ekah-dateien/dokumentation/publikationen/EKAH_Innovationsbericht_EN_V.pdf

Willemsen, A., Rippe, K. P. 2018: The Idea of Precaution: Ethical Requirements for the Regulation of New Biotechnologies in the Environmental Field. In: Frontiers in Plant Science, December 2018 | Volume 9 | Article 1868 doi: 10.3389/fpls.2018.01868

Wynne, B. 2019: Ethical Questions Raised by Gene-editing GM Technologies – and by their Modes of Governance. Presentation at European Commission's Ethics Expert Group Roundtable on Gene-Editing on 16 October 2019. https://ensser.org/from-our-members/ethical-questions-raised-by-gene-editing-gm-technologies-and-by-their-modes-of-governance/

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G - Consumers' right for information/freedom of choice

*** 28. What is your view on the labelling of NGT-products? Please substantiate your reply**

Food is a key aspect of our lives that contributes to the understanding of ourselves and forms a major aspect of our identity. It is therefore seen as morally relevant. One expression of a person's self-determination in this key area of life is freedom of choice which is considered as a right of consumers for protection from being forced to consume genetically engineered products. Based on this right, NGT-products should be traced and labelled in accordance with current EU GMO legislation in order to give consumers the right to avoid these products and to ensure access for them to GM-free products. Nobody should be compelled to consume GM products, and the State has the duty to protect consumers from this compulsion (ECNH 2003).
Labelling of NGTs is and should continue to be required as per the current regulatory framework for GMOs: No distinction should be made between the labelling of "old" GMOs and NGTs. A single label must ensure simple, clear information for consumers. The requirement to label NGT-products as GMOs does not prevent them from being marketed.

NGT-labelling as GMOs is essential to ensure legal certainty and freedom of choice for breeders, seed producers, farmers, food producers, food traders and retailers as well as consumers. Any loss of freedom of choice for consumers would seriously undermine the trust of European citizens in the EU, EU institutions and EU law-making. NGT-labelling is also essential to enable transparency, traceability, post-marketing monitoring and product recalls in case a product placed on the market is subsequently found to be harmful.

For the GM-free breeding and seed production sector, the labelling of NGT-products is fundamentally important. Without such NGT-labelling, we would run risk to unknowingly and unintentionally produce GM seed and varieties which could then spread, untracked and uncontrolled, on the European market. We strongly oppose any change of the current EU GMO legislation, including its labelling requirements, as all currently discussed deregulation scenarios would fundamentally threaten the existence of our GM-free sector. For the organic sector, any deregulation and lack of labelling of NGTs as GMOs would have devastating consequences as it would make it impossible for this whole sector to produce according to its standards including a prohibition of GMOs. The organic sector could not produce any more in accordance with its own values and rules. Again, if this is caused by European policy-making, this would seriously undermine the trust of European citizens in the EU institutions. The ruling of the European Court of Justice (C-528/16) must be respected.

Only those companies developing NGT-products and bringing them to market would benefit if GMO labelling was ended for NGT-products. The needs, values and interests of the majority of consumers and whole economic sectors that want to produce GM-free would be disregarded. Given the lack of societal benefits generated by NGTs, this is unjustifiable. Moreover, this is incompatible with the declared objective of the EU' s Farm to Fork Strategy to "help consumers choose healthy and sustainable diets […] and […] explore new ways to give consumers better information, on details such as where the food comes from, its nutritional value, and its environmental footprint." (https://ec.europa.eu/food/farm2fork_en)

Opinion polls and surveys demonstrate that there is significant resistance amongst citizens towards genetically modified food, both produced with classical genetic engineering and with NGTs. For instance, in Austria, market research "Positions to Genetical Engineering" carried out in Oct. 2019 (n = 1.002) by marketagent.com demonstrated that Austrian consumers want to see a strict regulation of NGT & NGT-products, in the same intensity as implemented for classical GMOs (84,1%), would not buy food produced with NGTs (69,3%) and explicitly called upon the Austrian government to enforce within the EU that NGTs are subject to the same controlling mechanisms as existing GMOs (94%). In Germany, several surveys

show that consumers do not want GMOs in their food, neither classical GMOs nor NGT-products. In a focus group interview conducted by the Federal Institute for Risk Assessment (BfR) in October 2017 on the risk perception of genome editing, the respondents classified NGT-processes as genetic engineering, opposed their use in the food sector and argued in favour of strict regulation and labelling. The BfR consumer conference on genome editing in September 2019 came to similar conclusions.

Supporting document:

ECNH/Federal Ethics Committee on Non-Human Biotechnology 2003: Gene Technology for Food. Ethical considerations for the marketing of genetically modified foodstuffs and animal feed. https://www.ekah.admin.ch/inhalte/ekah-dateien/dokumentation/publikationen/e-Broschure-Gentechnik-Essen-2003.pdf

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H - Final question

*** 29. Do you have other comments you would like to make?**

- (●) Yes
- ( ) No

Please provide your comments here

All NGTs must remain regulated under current EU GMO legislation, as ruled by the ECJ. NGTs are extremely new and powerful technologies. Due to the uncertainty und knowledge gaps associated with NGTs and their potential to cause serious harm for human beings and the environment, the precautionary principle must be applied. This principle is not 'hostile to innovation'. Precautionary measures can act as a spur to innovation in the quest for alternative, less risky development paths, while also addressing legitimate safety concerns.

The scientific facts demonstrate that all NGTs should be regulated at least as stringently as it is currently required under EU GMO legislation, including SDN-1-applications and applications where no foreign genes are inserted or where any inserted genes are subsequently removed prior to commercialization. We need impartial regulators and the comprehensive risk assessment laid down in EU GMO legislation to protect public health and the environment. Regulation does not prevent responsible industries from bringing forward safe products that are sought by the public. However, it is essential to provide a series of checks and balances to stop potentially dangerous products from being released into our environment and food chain.

Current EU GMO legislation, combined with an expansion of the risk assessment guidance to assess the additional unintended effects that genome editing can cause, is fit for the purpose of regulating NGTs. Other sectoral EU regulations for agricultural and food products fail to provide for the breadth and standard of risk assessment needed to evaluate the potential risks associated with NGTs. It is essential that EU GMO regulation, applied on NGTs, remains process-based, in addition to product-based considerations, given the

inherent potential of NGTs to produce unintended and off-target effects throughout the process.

The authorisation, labelling, traceability and monitoring requirements laid down in the EU GMO legislation must be fully applied on NGTs in order to ensure freedom of choice of seed producers, farmers, food producers and consumers, and to create legal certainty. Importantly, the regulation of NGTs and NGT-products under current GMO legislation does not constitute any ban on NGTs or NGT-products, but protects an essential free space for those who want to produce GM-free seed, plants and food. Under such regulation, research on NGTs and NGT-products can be carried out, and new NGT-products can be brought to market.

We expect the Commission, as part of the Council-commissioned study, to assess equally into both "opportunities/benefits" and "challenges/concerns" linked to the deployment of NGTs. Focusing on potentials only is not what the Council has mandated the Commission to do.
NGTs will not deliver on tackling the challenges to our food systems in the 21st century such as the climate and biodiversity crisis. Instead, we need approaches to breeding and seed production that are oriented towards the provisioning of common goods, such as the maintenance and development of plant genetic and biological diversity and the building of resilient agro-ecosystems. Focusing on optimizing few food crops with the help of few capital-intensive technologies such as NGTs does not deliver appropriate solutions. Given the complex systemic character of the challenges, primarily technological and product-oriented innovations are not suitable. Even more so, if the business models of the patent- and license holders of the technologies damage socio-economic diversity and self-determination in breeding and seed production, as it is the case with NGTs.

Instead, we need to create legal and economic frameworks which foster truly innovative, locally adapted, systemic approaches to breeding and agriculture which enhance and further develop genetic and biologic diversity as well as soil health, encourage diverse and self-determined approaches to seed and food production, and guarantee the right of farmers and communities who sustain seeds to be able to sow their crops. This strengthens agro-ecosystems as a whole, creating resilient cultivation and food production systems.

Any deregulation of NGTs would massively impede, if not severely threaten these alternative approaches and development paths that are urgently needed to meet our challenges and to achieve the aims of the European Green Deal to protect, conserve and enhance the EU’s natural capital as well as the Farm to Fork strategy’s declared goal to make European food the global standard for sustainability. Only with the regulation of NGTs under current EU GMO legislation, these much needed approaches have a protected space in which they can develop. For instance, deregulating NGTs would fundamentally threaten the further development of organic plant breeding which is incompatible with the objective of the new Organic Regulation (EU) 2018/848 to foster the development of organic plant breeding activities.

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