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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

ARGE Gentechnik-frei (Arbeitsgemeinschaft für Gentechnik-frei erzeugte Lebensmittel / Platform for GMO-free Food Production), VLOG (Verband Lebensmittel ohne Gentechnik - Association Food without Genetic Engineering)

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

agri-food sector: non GMO industry (agriculture, food, feed, consumers)

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

Verein Donau Soja / Donau Soja Association

- IKC Institut za kontrolo in certifikacijo UM
- Sennereiverband Südtirol / Federazione Latterie Alto Adige
- Hofer KG (Austria)
- SPAR Österreichische Warenhandels GmbH
- REWE International AG
- Fixkraft Futtermittel GmbH
- Obersteirische Molkerei eGen
- Wech Geflügel GmbH
- BIO AUSTRIA – Verein zur Förderung des Biologischen Landbaus
- Arbeiterkammer Wien
- Umweltbundesamt GmbH / Environment Agency Austria
- Prüf Nach! Werner Lampert Beratungs GmbH
- German regional non-GMO brand meat program
- Members of the German feed and poultry industry

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

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

Members from all sectors of food and feed production and agriculture fully and consciously refrain from NGTs and NGT-products. Using NGT-products would contradict their objectives, commitment and business model.
The Austrian association ARGE Gentechnik-frei, the German association VLOG, Donau Soja and the Slovenian IKC Institut za kontrolo in certifikacijo UM follow a strict non-GMO policy. All relevant European non-GMO production standards (including all standards for organic production) and policy papers show a clear rejection of the use of old GMOs as well as “new GMOs” on all levels of the value chain.
Members throughout all countries and levels of production have clearly stated that they see NGTs/NGT-

products as a threat to the non-GMO sector – which is a strongly growing economic factor all over Europe. NGT-products are regulated according to EU GMO law. If they would enter the EU market this would require complex segregation systems; our members have to keep them continually out of their value chains. Due to the absence of a polluter-pays principle in the EU they would induce significant costs onto the non-GMO sector (monitoring, analyse, segregation). The more NGT products entering the EU market, the more complex and costly the segregation measures have to be.
Non-regulated NGT-products could cause huge potential losses to the non-GMO sector, with the potential of destroying it completely. The non-GMO claim is based on high trust by consumers; numerous market research supporting this. Consumers in many member states clearly state that they don't want GMOs in their food chain (see attachment). With a softening of EU GMO legislation, food and feed produced with NGTs could come onto the market untested and invisible to manufacturers, marketers and consumers. It would become extremely expensive if not impossible for the non-GMO industry to keep NGT-products out of the production chain. Any such measures would severely discriminate the non-GMO industry on the European market.
Our members fully meet consumer demand for non-GMO products. Since GMOs have been introduced to the EU markets in 1996, a substantial amount of European consumers have explicitly and repeatedly claimed that they do not want to have them anywhere in their food chain; many European supermarkets do not want to sell food products containing GMOs (old and new). Consequently, there are hardly any GMO products on European supermarket shelves. Instead, we witness a rapidly growing range of products labelled as "non-GMO" that already has turned into a strong and successful business segment.
The non-GMO claim is important to close the labelling gap in EU GMO legislation. Currently, only genetically modified feed is subject to GMO labelling, but not the food products made with it. Substantial amounts of GMOs (soya, rape, maize) are being imported for feed production. The non-GMO label excludes GMOs along the full production chain, so of course also in feed and seed.
Non-GMO production has turned into a highly acknowledged and well established quality standard in many European countries: At present in Austria, France, Germany, Luxemburg, Slovenia, Italy, Hungary, Poland and Bosnia-Herzegowina laws or industry agreements allow non-GMO labelling on a voluntary basis. In Belgium and Serbia efforts are underway to introduce a non-GMO labelling system.
ARGE Gentechnik-frei, founded in 1997, represents more than 190 companies and is facilitating, promoting and supporting GMO-free production in Austria (food, feed and agricultural products). It awards the quality label „Ohne Gentechnik hergestellt"(produced without GMOs). Its member companies achieve an annual turnover of around 1.5 billion euros, with more than 3,800 products. In Austria, the entire milk and egg production (since 2010) and all poultry (since 2012) are "non-GMO". 95 % of Austrian retailers pro-actively support non-GMO products and are ARGE members.
VLOG, founded in 2010, represents 750 companies, food manufacturers and retailers as well as the upstream and downstream areas of food production. It grants licences for the state-owned seal "Ohne GenTechnik" (without genetic engineering) for food produced accordingly and the seal "VLOG geprüft" (verified by VLOG) for animal feed. In 2019 the member companies of VLOG have generated sales of 8,8 billion euros with more than 14,500 labelled non-GMO products, standing for consumer spendings of 11,3 billion euros. In Germany, 60 percent of milk, 60 percent of poultry meat and 70 percent of eggs are produced "non-GMO".

For further information on organisations that contributed to the questionnaire see attachment.

* **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

Our members follow strict legal requirements so that products can carry the non-GMO label. They will continue to do so in the future. Our members see it as their utmost obligation to be able to guarantee the validity and trustworthiness of their non-GMO quality claim to their customers and business partners at any given time and throughout the whole value chain. Any unintentional use of NGT-products would significantly undermine confidence in non-GMO products and could cause product recalls, economic losses and very complex liability litigation. Complex and expensive protection measures against NGT-products are seen as a severe discrimination of the non-GMO industry on the European market.
We have informed our members and contract partners about the European Court of Justice ruling and its potential implications for the non-GMO feed and food sector.
VLOG member DVT (German Association for Animal Nutrition) and the German Raiffeisen Association have recommended that feed companies draw their suppliers' attention to the legal situation after the ECJ ruling by means of a clause in the terms of delivery and thus legally secure themselves against unintentional use of NGT-products.
ARGE Gentechnik-frei and VLOG and two laboratories (VLOG members) are supporting or working on the development of detection methods for a specific NGT-product.
As long as NGT-products enter the EU markets only from third countries and none of them has an EU authorization, we want to clearly stress that it is not the task of economic operators to protect themselves from unintentional use of NGT-products in order to implement existing EU GMO law. In this matter, economic operators have to be able to rely on the political (and technical!) support by member states and the European Commission.
On behalf of our members we have repeatedly addressed the key demands of the non-GMO sector to the responsible political bodies at EU and national level:

- Appeal for the regulation of new techniques of genetic engineering by the EU.

Addressees: EU President Mr. Jean-Claude Juncker, EU Commissioner Mr. Vytenis Andriukaitis, 10th of July 2018 (attached).

- Open Letter: Judgment of the European Court of Justice on new genetic engineering proceedings: Ensuring the protection of GMO-free production,

Addressees: EU President Mr. Jean-Claude Juncker, EU Commissioner Mr. Vytenis Andriukaitis, November 2018. (http://www.ohnegentechnik.org/fileadmin/ohne-gentechnik/dokumente /English_Open_Letter_EU_Commission_28102018_final.pdf)

- Meeting with members of biotech unit of DG SANTE on the 13th of June 2019 (ARGE, VLOG).

- VLOG and DVT letter to German ministry for Food and Agriculture (BMEL): Urgent need for research into detection methods for GMOs produced with new genetic engineering techniques, 2nd of October 2019.

- Repeated meetings with the Austrian government (Ministries of Health and Agriculture), in order to support the strict position of the Austrian government of a regulation of NGTs/NGT-products and to call upon the government’s support to the non-GMO industry in this matter.

On behalf of our members we addressed the following key demands to the Commission:
- Proper implementation of the ECJ judgment
- Access to detection methods for new GMOs
- Effective controls for the import of agricultural goods
- A global transparency register for old and new GMOs

On behalf of our members we addressed the following key demands to the German BMEL and the Austrian BMG (Federal Ministry of Health):
1. support of research into detection methods for products obtained from targeted mutagenesis, make financial resources available from the BMEL and BMG budgets for this purpose
2. use BMEL‘s influence on the trading partners United States and Canada to make its knowledge of the relevant DNA changes available to the European authorities, as well as reference material and detection methods, inter alia for CIBUS oilseed rape, Calyxt soya and other new plant varieties entering the market
3. work for uniform regulations throughout Europe and, if necessary, to implement them legally.

* 2 bis. Have you encountered any challenges?
- (●) Yes
- ( ) No

* Please provide details

Neither the German BMEL nor DG SANTE seem to feel responsible for the development of detection methods in order to avoid non-authorized NGT products from third countries entering the EU markets, with the result that nobody seriously takes it on. In an answer to VLOG the BMEL (24th of October 2019) refers to intensive discussions at national and EU level and states to strive for a common EU approach. At the meeting with DG SANTE (13th of June 2019) the biotech unit refers to the responsibility of operators to develop detection methods. This reference to applicable EU law unfortunately does not solve the main problem of the EU food and feed sector: the absence of detection methods for NGT-products without authorization in the EU. As long as they do not exist there are no effective EU import controls of agricultural goods possible.

*** 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

* Please provide details

The unintentional use of NGT-products is a threat for the complete EU food and feed sector and cannot be limited to the non-GMO sector. The whole sector has to safeguard against it. At present there are no NGT-products authorized for the EU market. Not even an application has been submitted. Consequently, any use of a NGT-product in European food and feed production is illegal.
Hence information is crucial: Which NGT-products can enter the EU supply chains and how can they be detected, stopped and recalled, if necessary? To our knowledge the EU food and feed sector currently primarily has to safeguard against two NGT-products: CIBUS oilseed rape and Calyxt soy, which are cultivated in the US and in Canada. Agricultural goods entering the EU markets could contain traces of them. If this were to happen, it would be an infringement of the EU GMO legislation and its zero tolerance policy for non-authorized GMOs (which of course applies for NGT-products as well).
In the future, more NGT-products can be expected to be grown in third countries. As long as NGT-products enter the EU markets only from third countries and none of them has an EU authorization, we clearly do not see it as task of economic operators („initiatives in your sector“) to safeguard against unintentional use of NGT-products. This by any means is the clear responsibility of the competent national authorities: to prevent illegal imports of NGT through effective controls of imports onto the European market.
As long as companies like CIBUS and Calyxt do not submit an application for an EU authorization – which would consequently have to be accompanied by detection methods for each of the NGT-products – the Commission has to urge the US and Canada to make their knowledge about the relevant DNA changes available to the European authorities, as well as all reference material and all detection methods. The EU Commission has to guarantee that the Rapid Alert System on Food and Feed (RASFF) is functioning also for NGT-products.
Generally the responsible political entities, be it national or at EU-level, have to secure that public and private inspection bodies get detection methods for NGT-products. Otherwise they create a legal vacuum and undermine the trust in state institutions.

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

- (●) Yes
- ( ) No

* Please provide details

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Generally the responsible political entities, be it national or at EU-level, have to secure that public and private inspection bodies get detection methods for NGT-products. Otherwise they create a legal vacuum and undermine the trust in state institutions.

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

Our members have informed all their trade partners from non-EU countries about the EU GMO legislation regarding organisms obtained by NGTs. They are explicitly requiring a full compliance of all their suppliers with a) the EU GMO legislation and b) the requirements of the relevant national non-GMO production and monitoring standard that supplies the basis for their non-GMO labelling.
It is daily business of our members to comply with the EU GMO legislation and to avoid GMOs in their value chains and products. Our members secure their non-GMO production along the entire value chain by extensive control and certification systems, specified in a strict standard. It can be correctly stated that non-GMO products go through one of the strictest monitoring and certification processes of all food products.
According to the ARGE Gentechnik-frei standard all food products with the label „Ohne Gentechnik hergestellt“ (produced without GMOs) are regularly monitored by external monitoring and certification bodies to ensure that all products fully comply with the requirement of not using any genetic engineering procedures, from the field to the final product.
The monitoring is carried out as “process controls”. Therefore, not only the final product is being analyzed for potential traces of GMOs; in addition, the whole production process of food and feed products is being

checked for the absence of GMOs – from seed to cultivation on the fields to processing and to the final packaging including the correct us of the non-GMO label.
A harmonization of analytical procedures to detect potential GMOs has been taken place between VLOG and ARGE Gentechnik-frei, by harmonizing the two guidelines on analytical work on GMO detection in most aspects.
A harmonized approach to GMO certification for all companies of the non-GMO industry has been published in guideline L25: see attachment, point 1.
VLOG has developed a uniform GMO-free production and testing standard. This standard was designed together with representatives of producers of animal feed and food industry, certification bodies, interest groups and public representatives. It supports production facilities in the implementation of the legal requirements of GMO-free labelling and establishes uniform inspections for certification companies.
The application of the standard for obtaining a license for the use of the state-owned seal „Ohne GenTechnik" (without genetic enigneering) is compulsory.
VLOG exclusively accepts analysis results from laboratories that are recognized by VLOG. Certification must be conducted by such institutions accredited according to ISO/IEC 17065 and also recognized by VLOG.
The current version of the VLOG standard 20.01 and provides comprehensive checklists for all stages of production. See attachment, point 2.
Feed with "the verified by VLOG " seal must be certified to the same standard as food with the "Ohne GenTechnik" seal.
Donau Soja has initiated the Non-GMO Danube Region Standard as the first regional harmonized Non-GMO quality standard in South East Europe. This comprises standards for production and inspection. They were developed with the support of the 15 Ministries of Agriculture within the Danube region, the Organisation for International Cooperation of Germany (GIZ), the Austrian Development Agency (ADA) VLOG and ARGE Gentechnik-frei as well as the Environment Agency Austria (UBA) and Donau Soja Organisation.
The Non-GMO Danube Region Standard in combination with the regional “NON GMO Produced” label allows consumers to make an informed choice. The Non-GMO Danube Region Standard has already in April 2016 (“Vienna Declaration”, see attached) been declared a potential basis for a harmonized pan-European non-GMO standard – by two ministers of the Austrian government and by all pan-European non-GMO labelling initiatives existing at that time. See attachment, point 3.
IKC Institut za kontrolo in certifikacijo UM regularly monitors the presence or absence of GMOs during a certification process. Only accredited laboratories under contract of IKC UM are accepted. This ensures that all products fully comply with the requirement of not using any genetic engineering procedures, from the field to the final product.
IKC UM also encourages processors to take samples as part of the internal quality system, to monitor incoming supplies and to take active measurements to prevent any contamination with GMOs. Feed mills are also monitored for GMOs by national authorities, to control its possible presence and labelling of the animal feed.
IKC Institut za kontrolo in certifikacijo UM’ s standard is not publicly available. It is send to applicants on request. See www.ikc-um.si.
Sennereiverband Südtirol follows Accredia Standard RT 11. See attachment, point 4.

For further information from members see attachment, point 5.

* What best practices can you share?

It is daily business of our members to comply with the EU GMO legislation and to avoid GMOs in their value chains and products. Our members secure their non-GMO production along the entire value chain by extensive control and certification systems, specified in a strict standard. It can be correctly stated that non-GMO products go through one of the strictest monitoring and certification processes of all food products.
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The monitoring is carried out as “process controls”. Therefore, not only the final product is being analyzed for potential traces of GMOs; in addition, the whole production process of food and feed products is being checked for the absence of GMOs – from seed to cultivation on the fields to processing and to the final packaging including the correct us of the non-GMO label.
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Sennereiverband Südtirol follows Accredia Standard RT 11. See attachment, point 4.

For further information from members see attachment, point 5.

* 5 bis. What challenges have you encountered?

There are no detection methods for NGT-products at risk of illegal imports available, currently for soy from Calyxt company and oilseed rape from CIBUS company which are already cultivated in the US and Canada.

* **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?

We have asked the German Ministry for Food and Agriculture (BMEL) and the biotech unit of DG SANTE for support in developing detection methods for NGT-products. Unfortunately none of these institutions felt responsible.
VLOG and its member DVT (German Association for Animal Nutrition) stressed in a letter, dated 2nd of October 2019, to the German BMEL the „Urgent need for research into detection methods for GMOs produced with new genetic engineering techniques". In its answer (24th of October 2019) the BMEL refers to intensive discussions at national and EU level and states to strive for a common EU approach. It does not even answer our request concerning own activities like commissioning research on detection methods.
At the meeting of ARGE Gentechnik-frei and VLOG with DG SANTE (13th of June 2019) the biotech unit referred to the responsibility of operators for developing detection methods. In other communication the biotech unit stressed that member states are responsible for inspections of food and feed.
Even if these statements are legally correct, our non-GMO business segment needs more support from the EU Commission, as currently it is one of the strongest and most dynamic consumers and food trends in Europe. The need for support applies in particular to detection methods for effective import controls of agricultural goods and protecting the single market and the EU food and feed sector against the unintentional use of NGT-products. Neither for CIBUS oilseed rape (ODM) nor for Calyxt soy (TALENs) – the two NGT-plants currently being cultivated in the US and in Canada - detection methods exist in the EU.
To enable member states to meet their responsibilities in protecting the EU market against non-authorized GMOs from third countries we suggest that the Commission organizes a call for tender on detection methods as soon as possible in an adequate framework. This would be in line with the report of the European Network of Genetic Engineering Laboratories (ENGL) dated March 2019. ENGL has asked for „additional resources (which) will need to be made available". To our knowledge the EU Commission has not taken up the results of the ENGL report so far, i.e. initiated the research needed and made available additional resources.
With regard to detection methods it needs a clear, coherent and transparent policy, ideally coordinated and communicated by the EU Commission / DG SANTE.

* **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

Traceability strategies are part of the existing EU GMO legislation. The regulations (EC) 1829/2003 and (EC) 1830/2003 stipulate that GMOs must be identified through documentation systems if technical proof is not possible. This is a long-established practice – for example, for oil from genetically engineered soy and sugar from genetically engineered sugar beet. Verification in organic agriculture also takes place based on documentation systems.

We would like to add that traceability is a general standard in the EU General Food Law and not specific to GMOs or NGT-products. Article 18 in Regulation 178/2002 on „traceability“ states: „Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.“

* **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

Please see under "Please explain why not"

* What best practices can you share?

Please see under "Please explain why not"

* Please explain why not

In the EU no NGT-product is authorized at present; not even an application for an authorization has been submitted so far. Any labelled NGT-product on the EU market would be illegal.

Our members take specific and very extensive measures to exclude “old” GMOs from their value chains and thus fully ensure the compliance with the labelling requirements for non-GMO products. These measures are frequently checked by the producers’ own quality management system, plus by external monitoring and certification bodies, and also national food and feed control authorities.

Our members are of course intensively following the debate on NGTs/NGT-products, as they are fully aware that NGT-products entering the European markets could cause a significant threat to their successful business model with certified non-GMO production.

* 8 bis. What challenges have you encountered?

Please see under "Please explain why not"

*

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 has described the activities of the US company CIBUS to obtain a cultivation permit for its ODM canola in the EU by bypassing the EU GMO legislation and the responsible EU authority, the EFSA.
(Inside Lobbying on the Regulation of New Plant Breeding Techniques in the European Union: Determinants of Venue Choices. Review of Policy Research. 2020. https://onlinelibrary.wiley.com/doi/abs/10.1111/ropr.12366)
Between 2011 and 2014, CIBUS has selected six national authorities - in Finland, Spain, the UK, Sweden, Ireland and Germany - to get green light for a cultivation of its herbicide-resistant canola. Ulrich Hartung wrote: "Two factors seem to have influenced CIBUS' decisions for these countries: high-level political support for agribiotech and the high relevance of the biotech sectors in these countries.“ According to him it was also important that these authorities act rather isolated from the outside world („institutional ‚closedness “"). For CIBUS, this attitude reduced the risk that the push for deregulation of its NGT-plant might become public and trigger a debate.
With regard to the responsible German authority, the Federal Agency for Consumer Protection and Food Safety (BVL), Hartung said that a major selection factor was the BVL associated Central Commission for Biological Safety (ZKBS). ZKBS had already presented an expert opinion on the classification of new genetic engineering methods in 2012, pleading that ODM techniques do not result in GMOs. The lobby agency Perseus commissioned by CIBUS had been very aware that the BVL would ask ZKBS for an opinion on CIBUS‘ ODM canola and that would be: this is no GMO.
What the lobby agency Perseus had underestimated - according to U. Hartung - was the strong critical movement against GMOs in Germany. When it became known that the BVL had approved the cultivation of CIBUS‘ ODM canola without risk assessment and monitoring, a storm of protest broke out. The BVL approval was challenged in court by German NGOs. The EU Commission made clear that CIBUS would have to wait for a uniform EU regulation. However, this regulation was not issued by the Commission. After the European Court of Justice stated that organisms produced with new genetic engineering techniques are subject to GMO law the BVL withdrew its CIBUS ODM canola approval.

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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

The answer is “no, but …” there is some research on detection methods (see below).

Members from all sectors of food and feed production and agriculture fully and consciously refrain from NGTs and NGT-products. NGT-related research would contradict their objectives, commitment and business model.

The Austrian association ARGE Gentechnik-frei, the German association VLOG, Donau Soja and IKC Institut za kontrolo in certifikacijo UM follow a strict non-GMO policy. This comprises old and new GMOs produced with new genomic techniques, throughout all levels of the production chain.

NGTs/NGT-products are considered as a clear and severe threat to the non-GMO sector. ARGE Gentechnik-frei members know from market research (e.g. Austria – marketagent.com; October 2019: “Positions to Genetical Engineering”, see attachment) that Austrian consumers want to see a strict regulation of NGT-products (84,1%), strictly reject NGTs/NGT-products in agriculture and food production (62,6%) and would not buy food produced with the aid of NGTs (69,3%). Due to the strict rejection of Austrian consumers, there is no base for NGT-related research.

VLOG members know from various surveys that German consumers do not want GMOs in their food, neither old nor new. In the "Nature Consciousness Study 2017" published in July 2018 by the Federal Agency for Nature Conservation, 79 percent of those questioned were in favor of a ban on GMOs in agriculture. (https://www.bfn.de/themen/gesellschaft/naturbewusstsein/studie-2017.html)

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 classify these processes as genetic engineering, oppose their use in the food sector and argue in favor of strict regulation and labelling. (https://www.bfr.bund.de/de/presseinformation/2017/44 /risikowahrnehmung_von_genome_editing__vorbehalte_und_grosses_informationsbeduerfnis_vorhanden-202430.html)

The BfR consumer conference on genome editing in September 2019 comes to similar conclusions: Freedom of choice for consumers, freedom of information and transparency, priority of social aspects over economic interests, reform of patent law: no patent protection on living organisms, liability regulation for unexpected damage by the producer, labelling of genetically modified food are the most important demands of consumers. (https://www.bfr.bund.de/de/presseinformation/2019/35/fazit_der_bfr_verbraucherkonferenz)

Regulated NGT-products on the European market would require complex segregation systems, as our members are obliged and committed to keep NGTs out of their value chains. Due to the absence of a polluter-pays principle in the EU GMO legislation, any introduction of NGT-products onto the European market will be a significant cost factor for the non-GMO sector. The more NGT-products on the EU market the more comprehensive the segregation measures will have to be. NGT-products on the EU markets have the potential to be seen discriminative and anti-competetive by the very successful pan-European non-GMO industry.

Non-regulated NGT-products have the potential to cause huge potential losses to the non-GMO sector or even destroy it completely. The non-GMO claim is based on trust; consumers rely on it. With a softening of EU GMO legislation, food and feed produced with NGTs could potentially come onto the market untested and invisible to manufacturers, marketers and consumers. This could not only result in significant damages to the non-GMO market, but could consequently also lead towards complex and long-lasting liability cases against those factors and players, who are responsible for any such damages.

For the last ten years at minimum, non-GMO is acknowledged as a well-established and well trusted quality standard in numerous European countries. At present in Austria, France, Germany, Luxemburg, Slovenia, Italy, Hungary, Poland and Bosnia-Herzegowina laws or industry agreements allow non-GMO labelling on a voluntary basis. In Belgium and Serbia effort s are underway to introduce a non-GMO labelling system.

The only research members are carrying out is research to defend their business and their sector: research on detection methods. Two laboratories (VLOG members) are working on detection methods for a specific NGT-product. ARGE Gentechnik-frei and VLOG are supporting the development of detection methods for a specific NGT-product.

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

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

* Please specify

ARGE Gentechnik-frei and VLOG as well as two laboratories that are VLOG members are supporting or working on detection methods for a specific NGT-product.

*** 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 our sector NGTs/NGT-products are strictly excluded. NGT-related research on detection methods has not been affected by the ruling.

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

- ○ Yes
- ◉ No
- ○ Not applicable

* Please explain why not

No. With one exemption: the development of detection methods for NGT-products.
Our sector follows a strict non-GMO policy. This comprises both old GMOs and new GMOs produced with new genomic techniques. NGT-related research and resulting products - experimental releases of plants and their commercial cultivation - are clearly seen as a threat to our sector. The non-GMO industry (seed, agriculture, feed, production, retail) has to protect its products against GMO contamination, from the production of seeds till the fully processed product in the supermarket shelves. Hence our members secure their non-GMO production along the entire value chain by extensive control and certification systems, specified and published in a specific standard.

See ARGE standard:
http://www.gentechnikfrei.at/downloads
/leitfaden_l25_risikobasierte_kontrolle_gentechnikfreiheit_v03_20150304.pdf

See VLOG standard:
https://ohnegent.sp-kunde.de/fileadmin/ohne-gentechnik/das_siegel/og-standard_english/Version_20.01
/VLOG_Ohne_Gentechnik_Standard_V20.01_incl._Annexes_190901.pdf

See Non GMO Danube Region Production and Labelling Standard:
https://www.donausoja.org/fileadmin/user_upload/Danube_Soya/Guidelines/Standard_production_labelling.pdf

See Non GMO Danube Region Inspection Standard:
https://www.donausoja.org/fileadmin/user_upload/Danube_Soya/Guidelines
/Standard_on_risk_based_control.pdf

Sennereiverband Südtirol follows Accredia Standard RT 11.

IKC Institut za kontrolo in certifikacijo UM's standard is not publicly available. It is send to applicants on request, via www.ikc-um.si.

The more research and the more NGT-products exist the more expensive and complex our protection measures will have to be.

Even if there were detection methods available for NGT-products and our members could use them to protect their products from unintended use of new GMOs - this is a highly cost intense and solely defensive measure, only necessary because of the absence of a polluter-pays-principle in the EU GMO legislation which would be a much better suitable instrument of protection.

It is foreseeable that liability cases could result from successfully operating non-GMO industry representatives that have invested significant budgets into the development of their production, against all those responsible for possible contamination of their products by NGT-products.

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

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

* Please provide concrete examples/data

Our sector urgently needs research on detection methods for NGT-products, in order to be able to secure the non-GMO value chains. We strongly propose that national and EU political institutions commission, finance and coordinate a fast and thorough development and introduction process of detection methods for NGT-products.
The European Network of Genetic Engineering Laboratories (ENGL) has described the way forward to overcome the current challenges in its report from March 2019: „Several issues with regard to the detection, identification and quantification of genome-edited products cannot be solved at the present time, for example due to lack of experimental verification, and will require further consideration. Technologies different from the currently applied qPCR methods may need to be implemented in the enforcement laboratories; additional resources will need to be made available and experience has to be developed. For known genome-edited events, alternative screening strategies targeting all known genome-editing events simultaneously may have to be developed to facilitate routine enforcement.“
We insistently request that the Commission starts transferring this analysis to concrete research programs at the earliest possible date. To enable member states to meet their responsibilities in protecting the EU market against non-authorized GMOs from third countries we suggest that the Commission organizes a call for tender on detection methods as soon as possible in an adequate framework.
For a start detection methods primarily for products at risk of illegal import are needed, in order to create legal certainty for EU feed and food operators. Currently soy from the Calyxt company and oilseed rape from the CIBUS company are commercially cultivated in the US and Canada and may sooner or later enter the EU market in traces. Both NGT-products have no EU authorization; no detection methods are available.

* **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

Our sector urgently needs research on fully working detection methods for NGT-products which are already authorized in third countries, in order to prevent any illegal imports of non-authorized NGTs into the EU. Detection methods are needed for all products produced with new genomic techniques such as CRISPR /Cas, ODM, Zincfinger Nucleases, TALENs in order to meet the GMO labelling requirements and to prevent an illegal placing on the market of NGT-products. The Commission should follow the ENGL recommendations (report from March 2019) and initiate appropriate research. In order to support the development of detection methods the Commission has to insist that producing companies and trade partners allow access to all reference materials.

We need research on health and environmental impacts of NGT-products. Currently the alleged safety of NGTs and NGT-products is a mere claim, not substantiated by any systematic scientific studies. Most publications focus on what is feasible with the new techniques, but not on potential adverse effects. Therefore

- we need high-quality and independent studies on potential health impacts of NGT-products for animals

and humans. This should include unintended side effects that may result from the changes introduced, e.g. modification of the ingredients of a foodstuff, new allergens and toxins. In this context long-term animal feeding studies should be conducted.

• we need high-quality and independent studies on potential environmental impacts of NGT-products. This should include impacts on the food web, interaction with herbivores, increased invasiveness, gene flow to wild relatives and weedy species, herbicide use, agricultural practice.

The following EFSA guidances must be considered in a case-specific risk assessment for NGT-products:

Guidance for risk assessment of food and feed from genetically modified plants
https://www.efsa.europa.eu/en/efsajournal/pub/2150

Guidance on the environmental risk assessment of genetically modified plants
https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2010.1879

We recommend to take the results of the research project RAGES (risk assessment of genetically engineered organisms in the EU and Switzerland) with its focus on gaps in the current risk assessment into account:
https://www.testbiotech.org/en/content/research-project-rages

The molecular characterization of products from NGT applications should verify whether unintentional transgenic DNA fragments are present in the final product. In addition, unwanted off-target alterations or other genetic alterations that may cause different phenotypic effects should be searched for. See: An EU Perspective on Biosafety Considerations of Plants Developed by Genome Editing and Other New Genetic Modification Techniques (nGMs). https://www.frontiersin.org/articles/10.3389/fbioe.2019.00031/full

Most of all we need the maintaining of the current EU GMO legislation and the pre-market risk assessment it requires. Given the complexity of the genome and its interactions with other elements in the cell and the environment, it is impossible to predict the effects of the DNA changes produced by the new genetic engineering. Therefore, a comprehensive risk assessment is absolutely necessary before any GMOs (old or new) should be allowed to enter the market and the environment.

The currently very successful non-GMO industry might consider litigation if the European market is not being accordingly protected by the developing of detection methods and by effective control measures on the European borders to ward of non-authorized NGT- products.

Please upload any supporting documentation for this section here. For each document, please indicate which question it is complementing

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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

The non-GMO industry (agriculture, production, retail, marketing) clearly considers NGTs/NGT-products as an economic and safety threat to the conventional and the organic non-GMO sector.

NGT-products regulated according to the existing GMO legislation will increase the full cost structure and thus the consumer prices of our production. Regulated NGT-products require complex segregation systems, as our members will have to reliably keep them out of their value chains. Due to the absence of a polluter-pays principle in the EU GMO legislation, NGT-products will have significant cost effects on the non-GMO sector. The more NGT-products will enter the EU market, the more comprehensive the segregation measures have to be.

Non-regulated NGT-products could cause huge potential losses to the non-GMO sector, with the potential of destroying it completely. A deregulation of NGTs/NGT-products would have significant consequences for the conventional and organic non-GMO sectors:

- Loss of control over the value chain due to absent GMO labelling.

- The need to develop separate value chains (from seeds to agriculture to feed to food production to retail) would be highly complex and expensive, hardly feasible or even impossible.

- Loss of consumer trust: Any non-GMO label needs to be able to fully guarantee “produced without use of genetic engineering” – including old as well as new methods of genetic engineering. Without such a comprehensive claim to consumers, any label would become senseless. This is just as valid for the organic sector: For organic products, the absence of GMOs is a major selling point that would be in risk by a deregulation of NGT-products.

- Loss of investments for non-GMO production at all levels: changing recipes and formulations, developing quality management systems, establishment of segregation in production and transport, developing certification systems by external certification bodies, marketing.

- Interference or even destruction of the non-GMO market, which has been booming throughout Europe for the last ten years and is considered as a strong future market.

All these significant setbacks could result in defensive litigation by a now highly successful non-GMO industry.

* **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

Currently NGTs/NGT-products are promises, not a market reality.
Promises associated with NGTs/NGT-products are crops which contribute to a sustainable agriculture, resist the climate crisis, stop biodiversity loss and secure the competitiveness of the EU economy. These promises are quite similar to those made for old GMOs – and were never kept. They are used tactically by proponents of a deregulation of NGTs/NGT-products. It is hardly ever being concretely communicated in which state of research and development they are, when they will be market-ready and marketed.
With these promises it is suggested that complex societal, political and economic problems can be solved by changing the plant genome with genetic engineering or with a technical intervention through NGTs, respectively. Such a narrow view bears the danger of seeking a simple technical solution to complex problems, continuing a system of agriculture with problematic impacts on the environment and society and preventing sustainable solutions. It obscures the fact that resilience and diversity of agricultural systems are far more important for the adaptation of plants to global warming than the fixation on the genome of a plant. A good condition of the entire agro-ecosystem is more important for long-term stable harvests in the wake of climate change than isolated, genetically modified DNA segments.
The debate on NGTs/NGT-products is often a debate on deregulation, i.e. on questioning societal and political key achievements and key values of the European Union: The current lobby attempts with the aim to abolish the pre-market risk assessment for GMOs are seriously questioning and thus endangering the precautionary principle, the consumers' right to know and the freedom of choice as the solid and socially fully acknowledged foundation of EU environment and consumer policy. Also traceability and transparency about the origin of a product and how / through which processes it was produced are thus being questioned and being endangered – even as those qualities form the foundation of the current sustainability concepts.
The demand for softening or abolishing the precautionary principle is not specific to NGTs/NGT-products, it is also risen for pesticides, for example. One reason might be that often the same companies develop and sell GMOs and pesticides.
From our point of view it is crucial to defend and strengthen these key achievements and key values of the EU. A softening of environmental and consumer protection standards is not acceptable. This would go against the EU's self-image to have one of the highest food standards in the world.
Currently in the USA two NGT-products are deregulated (but not marketed) that are clearly misleading consumers: the non-browning arctic apple (RNAi) and the non-browning mushroom (CRISPR/Cas) pretend a freshness of the product that in reality does not exist. They are solely constructed and genetically modified for a longer shelf life – which only benefits marketers, but not consumers.
What could become a threat to society in general (at least to the environment), is that NGTs are not only aimed at agriculture use and crops (like old GMOs) but at nature itself and in addition to crops also at farm animals, insects, wild animals, trees and grasses. In the case of so-called 'gene drives', the NGT CRISPR /Cas aims at the genetic modification of a natural population or at all individuals of this population, up to and including their extinction.
'Gene drives' use the CRISPR/Cas system to transfer one or more traits 100% to all offspring of a population or even species. While offspring of sexually reproducing organisms have a 50 percent probability of inheriting a gene from their parents, 'gene drives' have a probability of almost 100 percent. This means that the next generation and all further offspring carry the genetically modified trait.
What should be avoided with old GMOs (at least theoretically) - the spread beyond the field planted with them ('genetic contamination') - is intended with 'gene drives'. 'Gene drives' are intended to spread, modify wild organisms and establish them in the ecosystem. According to the German Federal Agency for Nature Conservation, this will move the laboratory into the environment and lead to a change from the release of a finished and tested product to the release of a tool for genetic modification. (https://www.ncbi.nlm.nih.gov /pmc/articles/PMC5934763/)
It is not possible to predict what the release of 'gene drives' organisms into the environment, into agricultural and non-agricultural ecosystems would mean, which food chains would be affected, or what would happen in interaction with other living organisms.

* **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

Small and medium seed companies can never compete with the research and development departments of large corporations such as Corteva or Bayer. Even the supposedly "simple" application of NGTs requires knowledge of molecular genetics, bioinformatics and appropriately equipped laboratories, trained personnel and financial resources.

"Low cost use" is an argument especially associated with the CRISPR/Cas system, but only as long as SMEs are researching with it. It becomes expensive for small and medium-sized plant breeders as soon as they want to bring a variety to the market and offer it commercially. Then they are confronted with patents. They have to pay license fees for patented processes or patented material or will face patent infringement proceedings. (Leopoldina et. al. Towards a scientifically justified, differentiated regulation of genome edited plants. https://www.leopoldina.org/uploads/tx_leopublication /2019_Stellungnahme_Genomeditierte_Pflanzen_web.pdf) Here, too, the structural superiority of the big companies applies: The patent system with strategically defined claims, expensive lawyers and legal disputes can only be afforded by financially strong corporations.

As with the old GMOs, it is again the large corporations that have the most patent applications in the field of NGTs/NGT-products. Corteva is the leader in the field of crop plants with around 50 international applications, followed by Bayer/Monsanto with around 30. The US company Cellectis with its subsidiary Calyxt has more than 20, Syngenta and BASF have considerably fewer, while breeding companies such as KWS and Rijk Zwaan have applied for a few patents. The companies then apply for further patents for special applications. These usually cover methods, seeds, plants and often also harvests. (Christoph Then, Ruth Tippe: Neue Gentechnikverfahren: Zunehmende Monopolisierung von Landwirtschaft und Züchtung. https://www.testbiotech.org/sites/default/files/Hintergrund%20Patente%20%26%20Genome%20Editing.pdf)

The problem of SME seed companies with regard to developing and marketing GMOs is not, as is often suggested, the EU GMO legislation with its time-consuming and costly approval procedure. And it is not them who would primarily benefit from a deregulation of NGTs/NGT-products. As with old GMOs, it is once again the market leaders of the chemical and agricultural industry. Rather, small and medium-sized seed breeding companies are used to push through the deregulation of NGTs/NGT-products.

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

- ○ Yes
- ◉ No

* Please explain why not

GMOs are attractive for biotech/seed companies and scientists because of patents. Patents for old GMOs have expired or are about to expire. That is one reason why biotech/seed companies and scientists are developing NGT/NGT-products. With NGTs and NGT-products a new round for GMO patents has started. Patents are monopoly rights: For 20 years, patent holders have the right to prohibit all others from commercially exploiting the patented invention and have the right to demand license fees for its use. With genetic engineering, patent law has been systematically applied to plant breeding for the first time. Large

agrochemical companies, which had previously protected their pesticides with patents, now also applied for patents on GMO seeds and at the same time bought up many traditional breeders. This strategy made Monsanto, and later Bayer, number 1 in the seed market. With NGTs/NGT-products this development is being systematically continued and even expanded.
For NGTs/NGT-products in agriculture Corteva is the number 1 patent holder, number 2 is Bayer/Monsanto. Both companies are definitely not SMEs.
Patents are a means to control the seed market and thus food production. They are of strategic importance. (Christoph Then: Neue Gentechnikverfahren und Pflanzenzucht. Patentkartelle für große Konzerne. https://www.forumue.de/wp-content/uploads/2019/06/5_Neue-Gentechnikverfahren-und-Pflanzenzucht_Then.pdf)
The non-GMO sector does not see any benefits from patenting or accessing patented NGTs/NGT-products.

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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 non-GMO industry (agriculture, production, retail, marketing) clearly considers NGTs/NGT-products as an economic and safety threat to the conventional and the organic non-GMO sector.

Members from all sectors of food and feed production and agriculture fully and consciously refrain from NGTs and NGT-products. NGTs/NGT-products would contradict their objectives, commitment and business model.

NGT-products regulated according to the existing GMO legislation require complex segregation systems, as our members will have to reliably keep them out of their value chains. Regulated NGT-products will increase the full cost structure (by additional need for monitoring, separation along the full value chain, informative measures towards consumers) and consequently the consumer prices of our production. Due to the absence of a polluter-pays principle in the EU GMO legislation, NGT-products will have significant cost effects on the non-GMO sector. The more NGT-products will enter the EU market, the more comprehensive the segregation measures have to be.

Non-regulated NGT-products could cause huge potential losses to the non-GMO sector, with the potential of destroying it completely. A deregulation of NGTs/NGT-products would have significant consequences for the conventional and organic non-GMO sectors:

- Loss of control over the value chain due to absent GMO labelling.

- The need to develop separate value chains (from seeds to agriculture to feed to food production to retail) would be highly complex and expensive, hardly feasible or even impossible.

• Loss of consumer trust: Any non-GMO label needs to be able to fully guarantee “produced without use of genetic engineering” – including old as well as new methods of genetic engineering. Without such a comprehensive claim to consumers, any label would become senseless. This is just as valid for the organic sector: For organic products, the absence of GMOs is a major selling point that would be in risk by a deregulation of NGT-products.

• Loss of investments for non-GMO production at all levels: changing recipes and formulations, developing quality management systems, establishment of segregation in production and transport, developing certification systems by external certification bodies, marketing.

• Interference or even destruction of the non-GMO market, which has been booming throughout Europe for the last ten years and is considered as a strong future market.

All these significant setbacks could result in defensive litigation by a now highly successful non-GMO industry.

Currently the unintentional use of NGT-products is a threat for the whole EU food and feed sector, not only for the explicit non-GMO sector. At present there are no NGT-products authorized for the EU market, not even an application has been submitted. Consequently any use of a NGT-product is illegal. Hence information is crucial: Which NGT-products can enter the EU supply chains and how can they be detected, stopped and recalled, if necessary?

For the time being to our knowledge the EU food and feed sector has to guard against two NGT-products, CIBUS oilseed rape and Calyxt soy, which are cultivated in the US and in Canada. Agricultural goods entering the EU markets could contain traces of them. If this were to happen, it would be an infringement of the EU GMO legislation and its zero tolerance policy for non-authorized GMOs which applies for NGT-products as well.

In the future, more NGT-products are expected to be grown in third countries. As long as NGT-products enter the EU markets only from third countries and none of them has an EU authorization primarily it is up to the competent national authorities to prevent illegal imports through effective controls at European borders. The EU Commission has to guarantee that the Rapid Alert System on Food and Feed (RASFF) contributes in identifying and stopping non-authorized NGT-products in the EU.

In general the responsible political entities, be it national or at EU-level, have to secure that public and private inspection bodies get detection methods for NGT-products. Otherwise they create a legal vacuum and undermine the trust in state institutions.

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

- (●) Yes
- ( ) No

* Please explain

For the non-GMO sector these challenges/concerns are specific to GMOs which include NGT/NGT-products. But different to old GMOs there is a lack of detection methods for 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

I.
The debate on NGTs/NGT-products is often a debate on deregulation, i.e. on questioning societal and political key achievements and key values of the European Union: The current lobby attempts with the aim to abolish the pre-market risk assessment for GMOs are seriously questioning and thus endangering the precautionary principle, the consumers' right to know and the freedom of choice as the solid and socially fully acknowledged foundation of EU environment and consumer policy. Also traceability and transparency about the origin of a product and how / through which processes it was produced are thus being questioned and being endangered – even as those qualities form the foundation of the current sustainability concepts.

II.
The debate on deregulation is based on promises associated with NGTs/NGT-products: Promises are being made that NGT create crops which contribute to a sustainable agriculture, resist the climate crisis, stop biodiversity loss and secure the competitiveness of the EU economy. These promises are quite similar to those made for old GMOs – and were never kept. They are used tactically by proponents of a deregulation of NGTs/NGT-products. It is hardly ever being concretely communicated in which state of research and development they are, when they will be market-ready and marketed.
With these promises it is suggested that complex societal, political and economic problems can be solved by changing the plant genome with genetic engineering or with a technical intervention through NGTs, respectively. Such a narrow view bears the danger of seeking a simple technical solution to complex problems, continuing a system of agriculture with problematic impacts on the environment and society and preventing sustainable solutions.

III. Economic challenges/concerns
Conventional and organic non-GMO product lines are a direct response to consumer demand for GMO-free products. Both product lines represent sustainability, transparency and quality. They stand for values that continue to increase in societal relevance. Both product lines stand for booming and future markets. The Austrian and German non-GMO market has been about 12, 8 billion Euro in 2019, the EU organic market has been about 40, 7 billion Euro in 2018 (latest available figures: https://orgprints.org/37391/11/1-Willer-2020-Europe.pdf).

NGTs/NGT-products are a threat for both product lines (see answers to question 16 and 20).
Thus defensive litigation by a now highly successful non-GMO industry could be a reaction to economic losses caused by NGTs/NGT-products.

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

1. A deregulation of NGTs/NGT-products.

2. A misinterpretation of the study's aim by the EU Commission.

The draft F2F roadmap (as of mid-March 2020) states:

"Climate change brings new threats to plant health. The sustainability challenge in the field calls for measures to strengthen the protection of plants from emerging pests and diseases and for innovation. The Commission will adopt EU rules to reinforce vigilance on imports of plants and surveillance of the Union territory. New innovative techniques, including biotechnology, may play a role in increasing sustainability provided they are safe for consumers and the environment while bringing benefits to society as a whole. The Commission is carrying out a study to assess the potential of new genomic techniques to improve sustainability along the food supply chain."

In its most ambitious project („man-on-the moon-moment"), the Green Deal, the Commission is mentioning in its draft F2F roadmap just one technique, new genomic techniques, to tackle the problem of plant health caused by the climate crisis. This is sub-complex and suggests that the right technique creating the right plants will be the silver bullet solution. It obscures the fact that resilience and diversity of agricultural systems are far more important for the adaptation of plants to global warming than the fixation on the genome of a plant. A good condition of the entire agro-ecosystem is more important for long-term stable harvests in the wake of climate change than isolated, genetically modified DNA segments.

The way the draft F2F roadmap describes the aim of the study is extremely irritating. It is definitely not the potential of new genomic techniques to improve sustainability along the food supply chain. This is not the mandate the Council gave the Commission. The Council has highlighted „practical questions" around the implementation of EU GMO law for new GMOs and wants guidance on that. It is misleading to reduce the study to an assessment of potential benefits of NGTs.

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

- (●) Yes
- ( ) No

* Please explain

There is no other technique that is promoted with so many promises – promises that are rarely questioned or challenged by inquiries such as: „Which concrete plant with which concrete trait is in which concrete state of research and development, when will it be market-ready and definitely marketed?"

The demand for softening or abolishing the precautionary principle is not specific to NGTs/NGT-products, it has also been raised for pesticides, for example.

*** 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

Small and medium seed companies can never compete with the research and development departments of large corporations such as Corteva or Bayer. Even the supposedly "simple" applications of NGTs require knowledge of molecular genetics, bioinformatics and appropriately equipped laboratories, trained personnel and financial resources.

"Low cost use" is an argument especially associated with the CRISPR/Cas system, but only as long as SMEs are researching with it. It becomes expensive for small and medium-sized plant breeders as soon as they want to bring a variety to market and offer it commercially. Then they are confronted with patents. They have to pay license fees for patented processes or patented material - or will face patent infringement proceedings. (Leopoldina et. al. Towards a scientifically justified, differentiated regulation of genome edited plants. https://www.leopoldina.org/uploads/tx_leopublication /2019_Stellungnahme_Genomeditierte_Pflanzen_web.pdf) Here, too, the structural superiority of the big companies applies: The patent system with strategically defined claims, expensive lawyers and legal disputes can only be afforded by financially strong corporations.

As with the old GMOs, it is again the large corporations that have the most patent applications in the field of NGTs/NGT-products. Corteva is the leader in the field of crop plants with around 50 international applications, followed by Bayer/Monsanto with around 30. The US company Cellectis with its subsidiary Calyxt has more than 20, Syngenta and BASF have considerably fewer, while breeding companies such as KWS and Rijk Zwaan have applied for a few patents. The companies then apply for further patents for special applications. These usually cover methods, seeds, plants and often also harvests. (Christoph Then, Ruth Tippe: Neue Gentechnikverfahren: Zunehmende Monopolisierung von Landwirtschaft und Züchtung. https://www.testbiotech.org/sites/default/files/Hintergrund%20Patente%20%26%20Genome%20Editing.pdf)

The problem of SME seed companies with regard to developing and marketing GMOs is not, as is often suggested, the EU GMO law with its time-consuming and costly approval procedure. And it is not them who would primarily benefit from a deregulation of NGTs/NGT-products. As with old GMOs, it is once again the market leaders of the chemical and agricultural industry. Rather, small and medium-sized seed breeding companies are used to push through the deregulation of new genetic engineering.

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

The non-GMO sector views patenting very critically because patents are a main driver of developing NGTs /NGT-products and pushing them on the markets.
GMOs are attractive for biotech/seed companies and scientists because of the patents. Patents for old GMOs have expired or are about to expire. That is one reason why biotech/seed companies and scientists are developing NGT/NGT-products. With NGTs and NGT-products a new round for GMO patents has started. Patents are monopoly rights: For 20 years, patent holders have the right to prohibit all others from commercially exploiting the patented invention or to demand license fees for its use. With genetic engineering, patent law has been systematically applied to plant breeding for the first time. Large agrochemical companies, which had previously protected their pesticides with patents, now also applied for patents on GMO seeds and at the same time bought up many traditional breeders. This strategy made Monsanto, and later Bayer, number 1 in the seed market. With NGTs/NGT-products this development is being systematically continued and even expanded.
For NGTs/NGT-products in agriculture Corteva is the number 1 patent holder, number 2 is Bayer/Monsanto. Patents are a means to control the seed market and thus food production. They are of strategic importance. (Christoph Then: Neue Gentechnikverfahren und Pflanzenzucht. Patentkartelle für große Konzerne. https://www.forumue.de/wp-content/uploads/2019/06/5_Neue-Gentechnikverfahren-und-Pflanzenzucht_Then.pdf)

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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**

The safety of all NGT/NGT-products has to be thoroughly assessed according to EU GMO law and in accordance with the precautionary principle. The alleged “higher safety” of NGTs and its products remains a mere claim and has not yet substantiated by systematic scientific studies. Most publications focus on what is feasible with the new techniques, not on potential adverse effects.

It needs a competent third instance (national and EU authorities) to carry out a thorough risk assessment before placing any NGT-product on the market. Otherwise, the same institutions or companies who did the research or who have the intention to market and/or patent NGTs/NGT-products would at the same time provide themselves an attest that their products are safe.

Given the complexity of the genome and its interactions with other elements in the cell and the environment, it is impossible to predict the effects of the DNA changes produced by old and new genetic engineering. Therefore, a comprehensive risk assessment is necessary before GMOs shall be permitted to be released into the environment and to enter the market.

We do not consider NGTs/NGT-products as safe. The following text on risks is provided by Dr. Janet Cotter, Logos Environmental, UK (sources: please see attachment).

Off-target effects
One of the principal concerns of genome editing is “off-target” effects — changes to other genes that were not intended. Off-target effects could unintentionally alter important genes, causing changes in chemistry or protein production — both of which are important for food and environmental safety. Most studies on the potential uses of gene editing techniques in agriculture consider off-target effects to be both a major challenge and a major concern,[i]and many studies have now detected off-target effects in gene-edited plants and animals.

Unexpected on-target effects
Genome editing can cause unexpected “on-target” effects, where the intended change occurs at the intended location, but has a different outcome than expected. A small insertion or deletion of DNA within a gene, even if on-target, could change the way a gene is read and processed into proteins in problematic ways. Studies have found that CRISPR can inadvertently cause extensive deletions and complex re-arrangements of DNA.[ii] These deletions and re-arrangements of DNA by CRISPR may cause important parts of the gene (those coding for protein production) to be “missed” when the DNA is read.[iii] This misreading of DNA has the potential to produce altered proteins. Food allergens are mostly proteins, so altered proteins could have significant implications for food safety.[iv]
The misreading of DNA in a genome-edited plant or animal could impact biodiversity. For example, if the chemistry of a genome-edited plant or animal were changed by the misreading of DNA, it could produce a compound that is toxic to the wildlife that feeds on it. These types of concerns regarding human and ecological safety mean that gene-edited organisms need to be analyzed for any on-target effects, and the implications of on-target effects need to be carefully evaluated.

Inserted DNA (intentional and unintentional)
Often, a DNA “cassette” containing the genome editing components is inserted into the organism’s genome at a random location — in exactly the same way that earlier GMOs were created. However, it is inevitable that, in some cases, not all the inserted DNA will be removed and some of the DNA encoding for gene editing components will inadvertently remain in the gene-edited organism.[1]
Unintended integration of gene-editing components (including residual DNA coding for the CRISPR components, additional copies and fragments), have been found in both plants and animals, not only from CRISPR, but also from TALENs.[4]A recent publication highlighted the problem of unintended insertions of DNA coding for CRISPR components, compounded by the failure to identify these events using conventional detection protocols.[5] Cows that had been gene-edited, via TALENs, to be hornless[6] were found to have unintentionally incorporated DNA from the gene editing process, including antibiotic resistance genes.[7]
Integration of unwanted DNA during the gene editing process appears to be more common than previously thought.[8]
Unintended insertions of DNA (DNA coding for CRISPR components) and additional fragments or rearrangements of DNA can give rise to unexpected effects in gene-edited organisms, creating the same concerns as first generation GMOs. It is therefore important that checks for unintended effects from DNA insertion (where intended or unintended) are carried out.

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

- (●) Yes
- ( ) No

* Please explain

We share the risk considerations with the European Court of Justice and consider the following passage from the ECJ judgment (C-528/16) to be decisive:

„As the referring court states in essence, the risks linked to the use of those new techniques/methods of mutagenesis might prove to be similar to those which result from the production and release of a GMO through transgenesis. It thus follows from the material before the Court, first, that the direct modification of the genetic material of an organism through mutagenesis makes it possible to obtain the same effects as the introduction of a foreign gene into that organism and, secondly, that the development of those new techniques/methods makes it possible to produce genetically modified varieties at a rate and in quantities quite unlike those resulting from the application of conventional methods of random mutagenesis.“

NGTs/NGT-products have not been used in a significant number of applications and do not have any proven track record of safe use. The most prominent technique, CRISPR/Cas, was described for the first time in 2012, for use in the laboratory. Publications on TALEN have been appearing since 2010, on zinc finger nucleases (ZNF) since the mid-1990s.

With genome editing methods, genomes can be modified to a previously impossible extent and at a previously impossible speed, even without inserting foreign genes. Because they can be applied - individually or in combination - repeatedly, simultaneously or consecutively in one and the same organism, they can be used to modify organisms to a far greater extent than was or is the case with old genetic engineering or conventional breeding. So-called multiplexing targets several genes at once. This causes profound alterations in an organism even without introducing any additional DNA sequences. All these organisms/NGT-products have to be regulated according to EU GMO law. An exemption for SDN1 and SDN 2 techniques which do not insert foreign DNA is not justified.

Genome editing opens up new possibilities by making the whole genome accessible for changes. This is new, specific to NGTs – and clearly requires a regulation according to the EU GMO legislation.

COGEM (2019) describes the potential of gene editing as follows:
„Now that we are sequencing genomes, we know that the genes the breeders select and cross out are located at the ends of the plant chromosomes. But the genes in the middle, that is about 30 percent of the genes, are not accessible to breeders. With gene editing we are able to change genes we have never had access to before.“ (COGEM: Gene Edited Crops. Global Perspectives and Regulations (https://ebsaweb.eu/event/symposium-gene-edited-crops-global-perspectives-and-regulation)

Duensing et al. (2018) stress how thoroughly genome editing is knocking out the genes it targets:
„(…) genome editing can be targeted to a specific gene. However, few plant genes are found as single genes. (…) genome editing is adept at knocking out genes present in multiple copies. Thus whenever a crop is found with multiple copies of the same gene knocked out, it will be almost certain that genome editing was used.“ (Duensing, N. et al., 2018, Novel features and considerations for ERA and regulation of crops produced by genome editing. https://www.frontiersin.org/articles/10.3389/fbioe.2018.00079/full)

Compared to old genetic engineering NGTs/NGT-products broaden the trait spectrum and target a broader range of species. All this has to be taken into account when a risk assessment is carried out.

In our view, the process used to produce a GMO must, as before, be taken into account in the regulatory process. Both old and new GMOs are the result of a technical process whereby nucleic acid molecules are produced outside the organism in the laboratory or in a test tube and introduced into a host organism by means of vectors. The CRISPR/Cas system, for example, is assembled in the laboratory, either as a protein complex of Cas protein and guide RNA or as DNA encoding Cas and guide RNA. In order to introduce nucleic acid molecules assembled in the laboratory into the plant cell, the new genetic engineering often uses methods of old genetic engineering, i.e. the infection of the target plants with Agrobacterium tumefaciens or the bombardment of the cells with DNA-coated gold or tungsten particles. In our eyes, in gene editing procedures, it must always be transparent how the "genetic scissors" enter the cell and which procedure has produced a GMO or a product, respectively. Only in this way is an adequate risk assessment possible.

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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**

I. Narrow view on plant genome changes can prevent sustainable agriculture solutions

NGTs/NGT-products are linked with promises – promises that suggest that complex societal, political and economic problems can be solved by changing the plant genome with genetic engineering or with a technical intervention through NGTs, respectively. Such a narrow view bears the danger of seeking a simple technical solution to complex problems, continuing a system of agriculture with problematic impacts on the

environment and society and preventing sustainable solutions. It obscures the fact that resilience and diversity of agricultural systems are far more important for the adaptation of plants to global warming than the fixation on the genome of a plant. A good condition of the entire agro-ecosystem (e.g. fertile soils with a high amount of organic matter, clean water without herbicide residues instead of vast monocultures) is more important for long-term stable harvests in the wake of climate change than isolated, genetically modified DNA segments.
The EU agriculture has made a very good experience with its predominantly anti-GMO stance and the very limited cultivation of GMOs in member states. This critical approach helped to avoid the negative impacts being watched in the main GMO cultivating countries: loss of biodiversity because of large scale cultivation of herbicide resistent crops, insect resistent Bt crops or crops with a combination of traits (‚stacked events'), as well as massive problems with glyphosate resistant weeds.
A lesson from the experience with the COVID-19 pandemic should be a much more self-sufficient EU agriculture with production on EU land and a strive for a decrease of GMO feed imports.

II. The use of NGTs in animal breeding could further threaten animal welfare

GM farm animals, modified with old or new genetic enigineering techniques, raise concerns about animal welfare:

- Genetically engineered animals may suffer as a result of the new genetically engineered trait, e.g. if they are too heavy to walk easily, or over-produce milk;
- Herds or flocks of genetically engineered animals or birds may be more vulnerable to some diseases if they are all genetically similar;
- Genetic engineering technologies could be even more harmful as they may strive to push animals even further beyond their physiological limits.

These concerns also apply to GM animals produced using new genetic engineering techniques. It is highly troubling that such technologies will mainly be used to further intensify the livestock sector and will entrench the use of intensive animal farming systems with inherently poor welfare. New genetic engineering techniques have the potential to further damage the health and welfare of farm animals.

We have quoted here a passage from the Transatlantic Consumer Dialogue - TACD, 2016, „Resolution on consumers concerns about new genetic engineering techniques“ - because we are in complete agreement (http://tacd.org/wp-content/uploads/2016/09/TACD-Resolution-new-genetic-engineering-techniques_with-appendix_7-September.pdf).

III. The application of NGTs/NGT-products in nature and the use of ‘gene drives’ to change natural populations would extent the environmental risks of GMOs to a currently unknown dimension

What could become a threat to society in general (at least to the environment), is that NGTs are not only aimed at agriculture use and crops (like old GMOs) but at nature itself and in addition to crops also at farm animals, insects, wild animals, trees and grasses. In the case of so-called 'gene drives', the NGT CRISPR /Cas aims at the genetic modification of a natural population or at all individuals of this population, up to and including their extinction.
‘Gene drives’ use the CRISPR/Cas system to transfer one or more traits 100% to all offspring of a population or even species. While offspring of sexually reproducing organisms have a 50 percent probability of inheriting a gene from their parents, ‘gene drives’ have a probability of almost 100 percent. This means that the next generation and all further offspring carry the genetically modified trait.
What should be avoided with old GMOs (at least theoretically) - the spread beyond the field planted with them ('genetic contamination') - is intended with 'gene drives'. ‘Gene drives' are intended to spread, modify wild organisms and establish them in the ecosystem. According to the German Federal Agency for Nature

Conservation, this will move the laboratory into the environment and lead to a change from the release of a finished and tested product to the release of a tool for genetic modification (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5934763/).
It is not possible to predict what the release of ‘gene drives’ organisms into the environment, into agricultural and non-agricultural ecosystems would mean, which food chains would be affected, or what would happen in interaction with other living organisms.

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

- (●) Yes
- ( ) No

* Please explain

In accordance with the Swiss Federal Ethics Committee on Non-human Biotechnology (ECNH) we want to stress that a risk assessment has to cover the final product and the entire process that results in a NGT-product. In 2016, the ECNH has drawn up a report on ethical issues concerning new breeding techniques. In its recommendations it comes to the following conclusions:

"In risk situations, only statistically based probability statements are possible. An approval decision for the application and use of plants, which originate from NPZV [=NGTs], can always only be a decision under reservation. An appropriate risk assessment requires that the risk data on approved plants are regularly updated and that the handling of them is adjusted if necessary. The ECNH therefore recommends the early development of a monitoring concept for plants produced by means of NPZV and the establishment of systematic accompanying research.

In view of the risk-ethical considerations, the ECNH sees no reason in the context of the NPZV [=NGTs] to lower the requirements both for procedures in which genetic engineering is involved and for products in which genetic engineering modifications remain detectable. The ECNH also recommends that in those cases in which no genetic modifications are detectable in the products (possibly even only using current methods), the risk assessment should not be limited to the products. An appropriate risk assessment of the products can only be carried out taking into account the process by which they were manufactured".

(https://www.ekah.admin.ch/inhalte/ekah-dateien/dokumentation/publikationen/EKAH_New_Plant_Breeding_Techniques_2016.pdf)

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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**

A GMO labelling for NGT-products is highly important for consumers as well as all economic operators in the value chain (breeders, farmers, beekeepers, food and feed processors, retailers). A GMO label enables freedom of choice, transparency, traceability, post marketing monitoring and product recalls in case a product placed on the market is subsequently found to be harmful.

For the non-GMO sector labelling of NGT-products touches the core of its business. Without labelling of NGT /NGT-products, the non-GMO sector (and consequently, the whole EU feed and food sector) would run the risk to unwittingly and unintentionally sell GMOs to its customers.
The entire non-GMO sector has welcomed the European Court of Justice ruling very much. According to the ECJ judgment all NGT-products are GMOs and have to be labelled as GMOs. At least for now the ruling has freed us from the worry that feed and food produced with NGTs could be introduced onto the market in a manner not recognisable for manufacturers, marketers and consumers.
We strongly oppose any change of the current EU GMO legislation. This could cause huge economic losses within the non-GMO system due to contamination of parts of the value chain, and it has the potential to destroy the non-GMO sector completely. This also has the potential for substantial liability cases that would have to be clarified at court.
For the non-GMO sector references to an amended EU GMO legislation would not offer a solution. A general public that is critical of GMOs would hardly find it acceptable that products previously classified by the highest EU court as genetically modified should suddenly lose this designation merely due to an amendment to the legislation.
In particular, the strong and explicit non-GMO claim, combining intensive certification with a high credibility by consumers, could quickly become vulnerable because it would not be able to exclude NGT-products, primarily because NGT-products would not be labelled as GMOs. If the very successful non-GMO labels were to be silently withdrawn, this would give rise to the question whether corresponding products might now include GMOs. The honest response would have to be: “We don’t know.” The same would apply to the organic sector. Since this sector is overwhelmingly dependent on conventional seeds (which are organically propagated and cultivated), uncertainty and disorientation for producers and marketers as well as for consumers would be the logical consequence.
Only developers, manufacturers and marketers of NGT-products would be the ones benefitting from a non-labelling of NGT-products. However, questions, critical inquiries or anger of consumers would not be addressed to them. These would be targeted to retailers, national governments and “the EU”. This is not the way a fair and transparent discourse about food quality should be handled.
If NGT-products are as convincing and successful as it is promised, they should easily be also convincing and successful under the current EU GMO legislation and its labelling regime. Otherwise a question would arise: Can people trust a technology and its products which can only succeed if it stays invisible for the public including economic operators and consumers?

Non-GMO labelling
The associations representing non-GMO producing companies consider the existing non-GMO labels as a pragmatic solution under the current EU GMO legislation. The preferred solution would be an EU-wide mandatory "with GMOs" labelling for animal products produced from genetically engineered plants.
However, as long as the European legislator does not introduce such a labelling - and there is no sign of this happening - the non-GMO label is the only way for consumers in the animal product segment to express their rejection of GMOs in agriculture with their purchase decision. Non-GMO clearly offers the freedom of choice and full transparency for consumers that we would wish for in an ideal world through "with GMOs" labelling.

(Consumer surveys: Please see answers to questions 1 and 10)

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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

I.In accordance with the ECJ ruling we would have preferred the term GMOs or new GMOs instead of „NGTs /NGT-products“.

II. We strongly support the maintenance of the current EU GMO legislation for NGTs/NGT-products. That means: A full implementation of the ECJ ruling is needed. All NGTs/NGT-products have to remain under the current EU GMO legislation. This requires

- a comprehensive case-by-case risk assessment according to the precautionary principle;
- methods for detecting, identifying and quantifying NGT-products that have to be made publicly available in an EU database;
- traceability systems: documentation to track NGTs/NGT-products at all stages of the supply chain;
- labelling of all NGT-products;
- post-market monitoring;
- public GMO location registers at national level.

In addition a global GMO transparency register has to be established. It shall cover all GMOs worldwide, both old and new.

III. The currently very successful non-GMO industry might consider litigation if the European market is not being accordingly protected by the developing of detection methods and by effective control measures on the European borders to ward of non-authorized NGT-products. It is also foreseeable that liability cases could result from successfully operating non-GMO industry representatives that have invested significant budgets into the development of their production, against all those responsible for a possible contamination of their products by NGT-products.

IV. The EU competitiveness does definitely not depend on GMOs – and not on the seed market. The EU seed market is about 7 billion euros (in total, with large companies like Bayer/Monsanto or Corteva and all SMEs). In comparison the EU organic market is about 40,7 billion euros in 2018.

V. The EU seed market should focus on the EU single market and develop non-GMO seeds - most seeds developed by EU seed companies are traded within the EU. Non-GMO seed from the EU could become a brand and export product for the world market.

VI. The current global COVID-19 pandemic is a clear and upsetting proof that nature provides a very complex and delicate set-up, where even a tiny anomaly can have massive impacts on the entire globe. Therefore it is high time to realize that issues and challenges in agriculture and food production cannot be met with any pointcast high-tech countermeasures such as e.g. heat-resistant genetically engineered wheat

to address the climate crisis.
Instead, a comprehensive approach is needed! We need a social and political debate: What is the share of agriculture regarding the climate crises? How can this be reduced? What are measures to strengthen the sovereignty of EU farmers and their family-owned businesses? How can we increase the availability of regional, healthy, risk-free and non-patented seeds?
Europe has a very high range of small-structured, quality conscious, family owned agricultural and food producing business. Strengthening them and working towards a circular economy and a European sovereignty in agriculture and food will be the key challenge – much more relevant than new, uncertain high-tech experiments such as NGTs and NGT-products.
In our opinion, these are the real tasks for the EU food and feed business – much more important than to promote NGTs/NGT-products which would benefit most of all large corporations and third party countries.

VII. We strongly oppose a „race to the bottom“ with the EU GMO legislation in order to protect the allegedly vulnerable competitiveness of the EU or to find allegedly sustainable agriculture solutions based on NGT-poducts. The precautionary principle as part of the European treaties should become the world standard. Higher standards should be the objective in the EU agri-food sector, not the opposite. An EU Commission that is striving for a Green Deal including a more sustainable agriculture cannot weaken the GMO legislation due to lobby pressure – this would undermine trust in European institutions and contradict political coherence.

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Attachment to question 1

I. Non-GMO products and consumer's preference in Germany and Austria

According to the German Ministry for Food and Agriculture (BMEL) Food Report 2019, 80 per cent of consumers consider the reference to non-GMO to be important.
https://www.bmel.de/DE/Ernaehrung/_Texte/Ernaehrungsreport2019.html

Research in Austria shows, that "gmo-free-production" is important for consumers' purchasing decisions: (AMA 2016, n = 1.045; see https://amainfo.at/fileadmin/user_upload/Konsumverhalten_Allgemein.pdf)

- 56% of the respondents said GMO-free production is extremely important
- 27 % of the respondents said GMO-free production is partially important

II. Latest EU surveys on GMOs

Eurobarometer „Food Safety in the EU 2019" (published in June 2019) :
https://www.efsa.europa.eu/en/corporate/pub/eurobarometer19

Question "Which of these topics have you heard about concerns you most when it comes to food?"

People could give a maximum of 5 answers.

27 % of those surveyed (EU 28) answered: „GMOs". „GMOs" are ranked 8th out of 15. „Antibiotic, hormone or steroid residues in meat" is on place 1 with 44 %, then "Pesticides residues in food" is on place 2 with 39 %, and "Genome Editing" is on place 15 with 4 %. (see p. 43)

According to the ECJ's ruling in 2018, it is strange that in a 2019 survey, Genome Edting forms an extra category and is not - as would be legally correct - covered by GMOs. In creating a special question EFSA seems not to accept the ECJ judgement.

Special Eurobarometer 354, Food-related risks,(published in November 2010):
https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/reporten.pdf

Question: "Please tell me to what extent you are worried or not about the following issues."

Pesticides are in 1st place (72 %), in 2nd place residues in meat with 70 %, and in 5th place GMOs with 66 %. (p. 21)

III. Information on organisations that contributed to the questionnaire

Donau Soja, founded in 2012, is a truly European non-profit organisation with more than 290 members from all sectors of the value chain (from farm to fork) as well as civil society organisations: https://www.donausoja.org/en/become-a-member/presentation-of-members/

The Association is open to all interested companies, industry-, associations, institutions and individuals that are interested in using and/or producing, processing, marketing or supporting non-GM produced and origin-controlled soya. The goal of the Association is to make a significant contribution to development of agricultural systems by promoting the sustainable cultivation and use of soybean in

Europe to secure and guarantee GMO free supplies of soya. The Association supports a healthy environment and healthy diets while aiding the development of non-GM value chains.

For this purpose Donau Soja provides quality standards and respective product labels for the exemplary production, processing, control and traceability of European, sustainable Non GM soya from the Danube region and Europe. Donau Soja was essentially involved in the development of the Non GMO Danube Region standards and is providing a Non GMO label for companies that produce accordingly.
Further information about Donau Soja's statutes please find here:
https://www.donausoja.org/fileadmin/user_upload/Member_Service/Statutes/DS_Statutes__Donau_Soja.pdf

IKC Institut za kontrolo in certifikacijo UM registered and implemented private non-GMO certification in Slovenia in 2011. It grants licences for the seal "Pridelano/proizvedeno brez GSO – brez gensko spremenjenih organizmov" (produced/processed without GMO – without genetically modified organisms) and non-GMO animal feed. In 2019 certified producers and processors have labelled more than 650 non-GMO products. All Slovenian feed mills are part of the certification process to deliver non-GMO feed for certified producers. In Slovenia an important part of the milk and also egg and poultry supply is from non-GMO production. Non-GMO production is also very important for family farms with small processing units, who sell their products to local market and public institutions (like schools, kindergartens…). There are still many opportunities to expand GMO production to other food processors in the state.

Sennereiverband Südtirol is the representation of the interests of the nine cooperative milk processors in South Tyrol.

ARGE, VLOG, Donau Soja and IKC Institut za kontrolo in certifikacijo UM have member companies in Austria, Germany, Slovenia, Poland, the Netherlands, Belgium, Denmark, Croatia, Czech Republic, Spain, Italy, Luxemburg, Hungary, Lithuania, Estonia, Finland Slovakia, Slovenia, Greece, France and in the non-EU countries Norway, Switzerland, Serbia, Bosnia, Moldova, Ukraine, Romania, Russia, Argentina, USA and the United Kingdom. Members of Sennereiverband Südtirol are from South Tyrol.

Attachment question 5

Information on non-GMO standards

1. A harmonized approach to GMO certification for all companies of the non-GMO industry has been published in guideline L25: see attachment

http://www.gentechnikfrei.at/downloads/leitfaden_l25_risikobasierte_kontrolle_gentechnikfreiheit_v03_20150304.pdf

2. The current version of the VLOG standard 20.01 and provides comprehensive checklists for all stages of production.

https://ohnegent.sp-kunde.de/fileadmin/ohne-gentechnik/das_siegel/og-standard_english/Version_20.01/VLOG_Ohne_Gentechnik_Standard_V20.01_incl._Annexes_190901.pdf

3. The Non-GMO Danube Region Standard in combination with the regional "NON GMO Produced" label allows consumers to make an informed choice.

Non GMO Danube Region Production and Labelling Standard:
https://www.donausoja.org/fileadmin/user_upload/Danube_Soya/Guidelines/Standard_production_labelling.pdf

Non GMO Danube Region Inspection Standard:
https://www.donausoja.org/fileadmin/user_upload/Danube_Soya/Guidelines/Standard_on_risk_based_control.pdf

4. Sennereiverband Südtirol follows Accredia Standard RT 11.
https://www.accredia.it/en/documento/rt-11-rev-00-minimal-requirements-for-product-certification-with-non-gmo-characteristic-requirement/

5. Information from members on costs for non-GMO production

The German feed industry has provided the following information on additional costs of feed not subject to GMO labelling:

Production expenses consist either of the expenses for dual production at one location (total expenses for spatial or temporal separation) and/or the higher logistics costs for relocating production due to the increasing specialization of the locations. In principle, this applies to the entire chain and particularly to warehousing:

- Reduction of the available storage space through strict allocation of storage capacities based on the GMO status

- Conversion measures to separate the production of GMO and non-GMO feed in the factory as far as possible
- Block formation in raw material reception, production in all stages, loading and complex rinsing batch management
- Loss of production output and product range restrictions: this can be up to 10 or 20%, depending on the location
- Costs for higher logistics expenses, in particular due to specialisation of locations (depending on the required GMO status, raw and finished goods are driven past logistically favourable production locations)

We currently do not have a summary figure for the above-mentioned production and related logistics costs - a determination of these costs would be extremely time-consuming and cannot be provided by us at present.

The second major complex of expenses is the area of raw material supply. In connection with the question of the classification of the new genetic engineering, this is likely to be of greater importance.

- In our opinion, the current cost situation in the procurement of raw materials cannot be projected into the future.
- Example: A further decline in rapeseed cultivation areas (also due to a decrease in the flow of oil into biodiesel) and another dry growing season could lead to significant premiums being traded for non-GM rapeseed as early as next year; the first GM rapeseed is already being used in Germany.
- It is probably not possible to transfer the costs related to the old genetic engineering to a situation with new genetic engineering.
- If, depending on the orientation of EU legislation, the state of analytics and the extent to which the new genetic engineering is used, entire regions of supply may be lost, the consequences for us cannot be calculated at present.

The German poultry sector has provided the following information on additional costs for the non-GMO production:

Additional costs are caused by ingredients in poultry products and by non-GMO feed.

In particular the costs for ingredients are subject to very strong variations. The risk of a GMO contamination during production or within the supply chain fluctuates greatly. For example, non-GMO mustard is said to be 320% more expensive than standard mustard, corn starch is almost 200% more expensive, whereas some other ingredients are available practically without any extra costs. Based on the current mix of ingredients (which, however, is regularly adjusted due to the customers' willingness to innovate), the additional costs for ingredients are currently around 10%.

Unfortunately, the additional costs for non-GMO feed and ingredients cannot be recovered one-to-one from the trading partners. The non-GMO surcharges for chickens are currently 0.025 €/kg live weight. Since only about 2/3 of this is the slaughter weight, the surcharge for a grilled non-GMO chicken must be 0.0375 €/kg, and for the fillet even then considerably higher. In addition to this, there are audit costs of several hundred thousand euros over the production stages.

NGT-products can lead to a completely different scenario, up to the risk that non-GMO ingredients can no longer be secured at all (the same applies then also to feed components).

A German regional non-GMO brand meat program for pig production has provided the following data:

For each non-GMO fed pig the additional costs amount to 11,32 €. These are composed as follows:

Costs for non-GMO feed	€	9,00
Costs feed Europe Soya	€	2,00
Costs for certification	€	0,28
Licence fees	€	0,03
sum:	**€**	**11,32**

MINISTERIUM FÜR EIN LEBENSWERTES ÖSTERREICH

BUNDESMINISTERIUM FÜR GESUNDHEIT

VLOG Lebensmittel ohne Gentechnik

OHNE gen TECHNIK HERGESTELLT

Vienna Declaration

A Call for a Common European Approach to GMO-free Labeling

GMO-free labeling of food and feed products has been actively and successfully expanding in Europe over the last years. Market research and monitoring of consumer preferences show a significant public awareness towards the use of GMOs in food and feed, with a large number of consumers expecting their food to be grown, produced and processed without the use of GMOs.

Currently several different national GMO-free labeling systems exist in European countries, including the newly developed "Non-GMO Danube Region Standard". The undersigned therefore see an evident necessity for the development and implementation of a common European approach to GMO-free labeling. The undersigned believe that such a common approach will enhance consumer confidence, as consumers expect transparent, comparable and credible criteria for food and feed labeling. Moreover it will support food and feed producers, processers and marketers who act in an increasingly pan-European market, with the clear need for equal requirements for production and certification of food and feed. It will also help European farmers producing GMO-free food and feed.

The undersigned commit to actively work towards such a common European approach on GMO-free labeling and to thus support the further expansion of certified GMO-free production and transparent and traceable GMO-free labeling across Europe.

A common European approach on GMO-free labeling requires:

- a pan-European process to work towards a common understanding of the key criteria for production, labeling and certification of GMO-free food and feed.
- to establish these criteria as mutually agreed cornerstones for GMO-free labelling, which may also result in future in a common European standard. The new "Non-GMO Danube Region Standard" could serve as a basis for this.
- to establish national processes to work towards equivalent standards, with the short-term goal to devise procedures for mutual acceptance and recognition between existing national GMO-free labeling systems.
- to be based on high standards with a balance between a reliable and scientifically valid system on the one hand, and practicality regarding implementation on the other hand.
- For the sake of not misleading information to consumers and joint support of GMO-free agriculture, such an approach needs to be in line with the requirements of organic production with regard to the use of GMOs.
- to provide the basis for a broad system covering the complete food and feed chain, including clear regulations for production as well as for certification and labeling.
- an increased and systematic information exchange between all relevant players in the field of GMO-free labeling.

Vienna, April 25, 2016

Attachment to question 10

Market research “Positions to Genetical Engineering” done in Austria in October 2019 (n = 1.002) by marketagent.com. See attachment “Kurzfassung …” as well, especially pages 12 till 20.

Austrian consumers

- want to see a strict regulation of NGT & NGT-products, in the same intensity as existing GMOs (84,1%),
- strictly reject the use of NGTs in agriculture and food production (62,6%)
- would not buy food produced with the aid of NGTs (69,3%). Due to the strict rejection of Austrian consumers, there is no base for NGT-related research on the market.
- explicitly called upon the Austrian government to enforce within the EU that NGTs are subject to the same controlling mechanisms as existing GMOs (94%).

MARKETAGENT.COM
Digitale Markt- und Meinungsforschung

Einkaufsverhalten und Einstellung zu Gentechnik

Oktober 2019

Inhalt

Studien-Basics

Einkaufsverhalten

Gentechnik-Freiheit

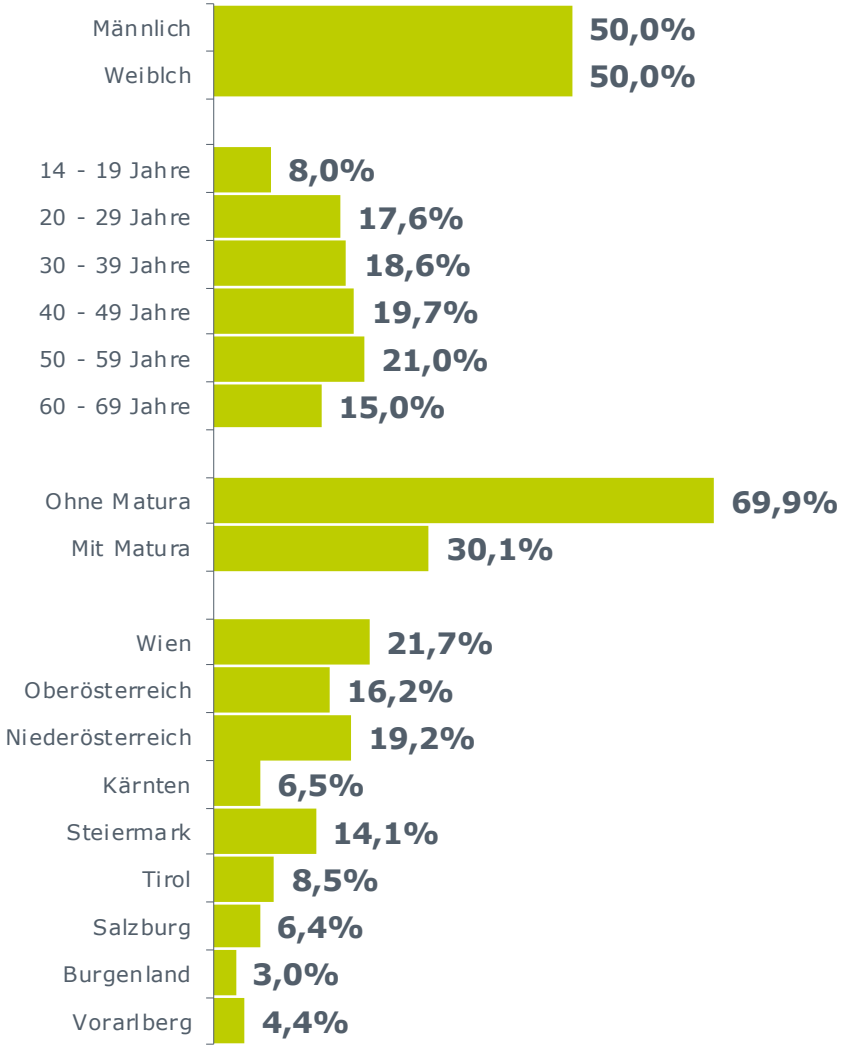
Neue Gentechnik

Umfrage-Basics

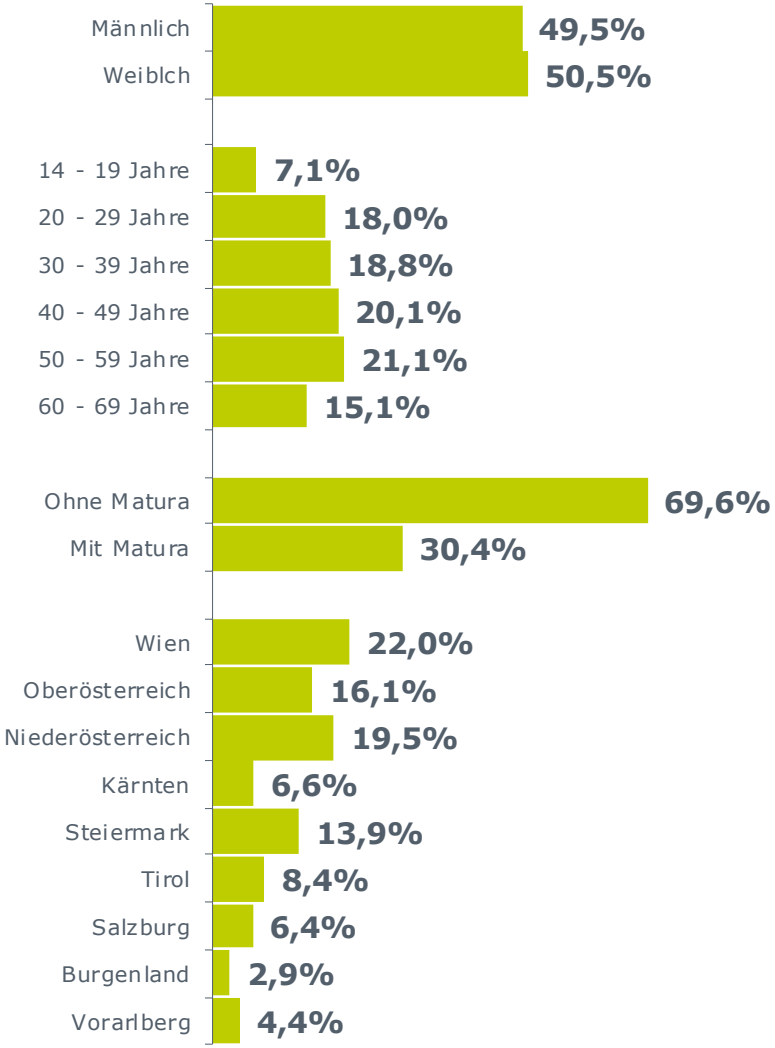
Methode	CAWI | Marketagent.com Online Access Panel
Sample-Größe	n = 1002 Interviews (Kernzielgruppe)
Kernzielgruppe	Personen im Alter zwischen 14 und 69 Jahren, die in Entscheidungen bzgl. dem Einkauf von Dingen des täglichen Bedarfs eingebunden sind (Inzidenz: 97,1%)
Quotensteuerung	Sample repräsentativ für die österreichische Bevölkerung | Random Selection
Feldzeit	23.09.2019 – 29.09.2019
Ø Antwortdauer	25 Fragen | 8 Min. 26 Sek.
Mobile Teilnahme	54,7%
Daten-Cleaning	67 Respondenten

Zusammensetzung des Samples

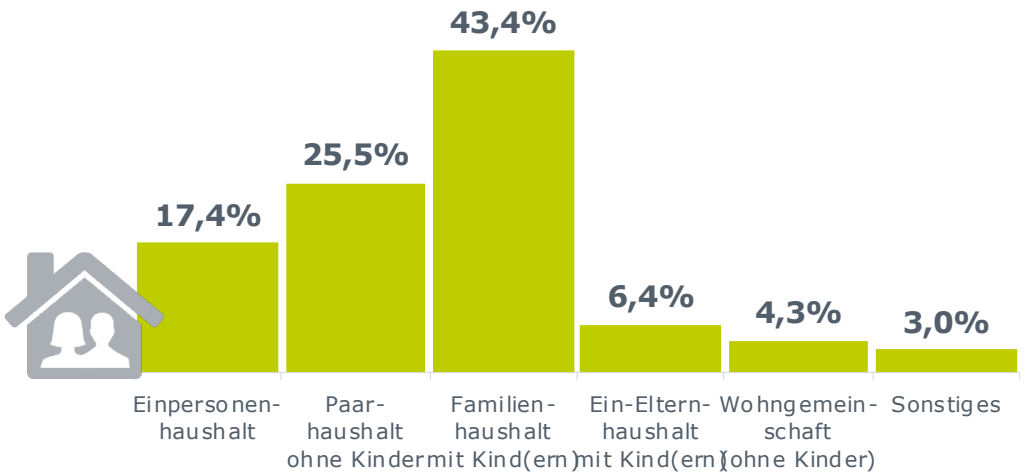
Eingangssample (n=1.032)



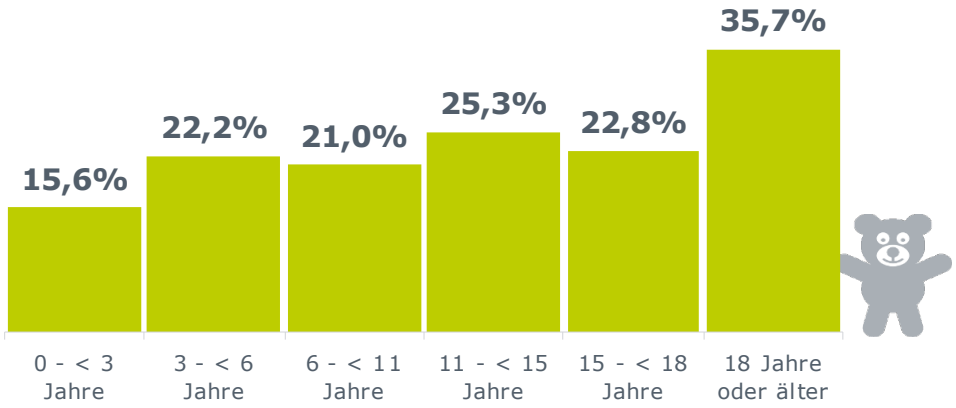
Kernzielgruppe (n=1.002)



Soziodemographie (n=1.002)

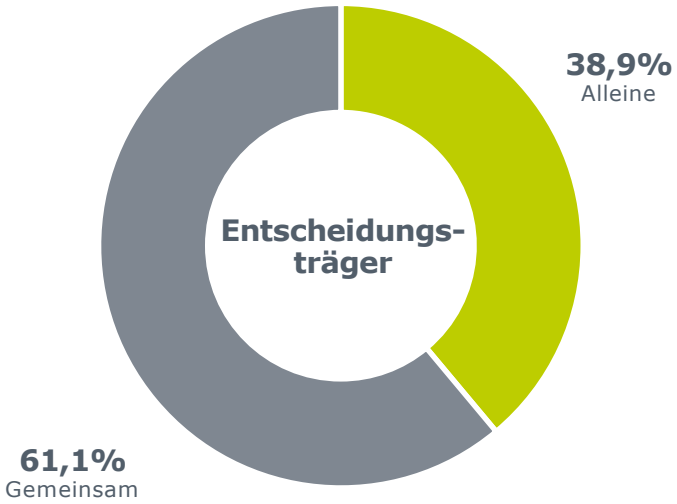


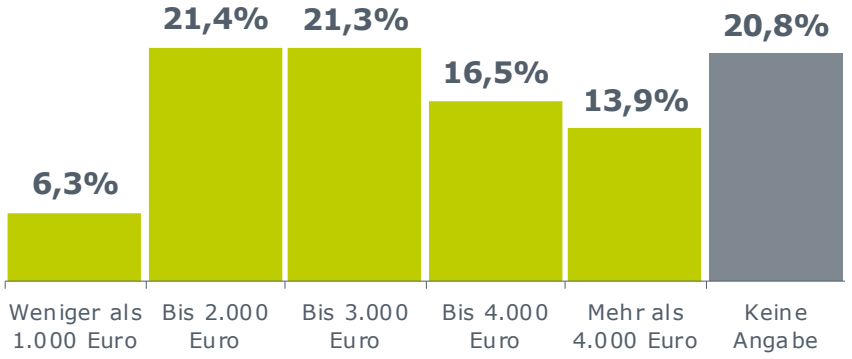
Wohnsituation



Alter der Kinder (n=499)*

*Kinder im Haushalt





Monatliches Haushalts-Nettoeinkommen

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Inhalt

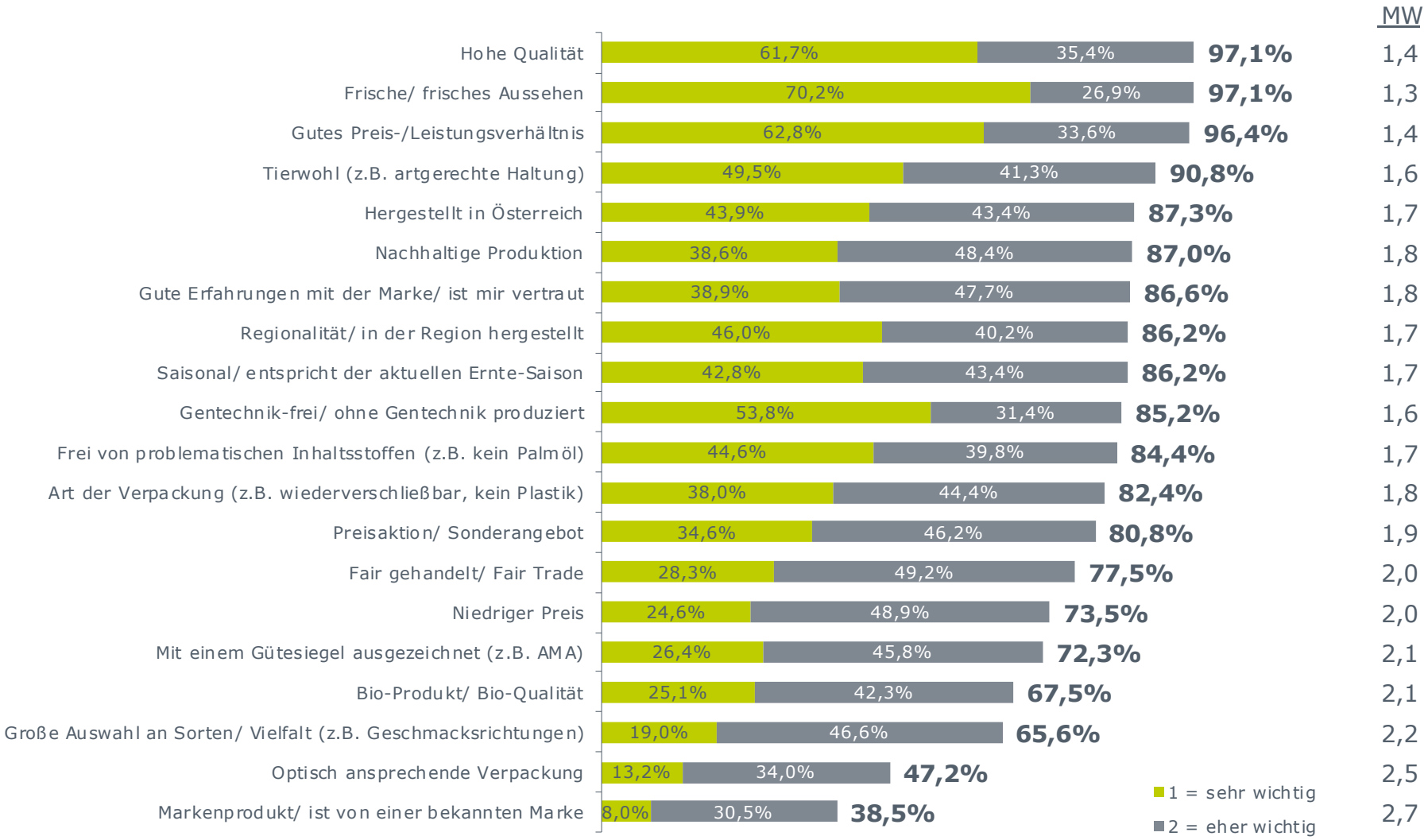
Wichtige Aspekte beim Einkauf von Lebensmitteln

	Mittelwert	sehr wichtig	eher wichtig	eher weniger wichtig	überhaupt nicht wichtig
Frische/ frisches Aussehen	1,3	70,2%	26,9%	2,7%	0,2%
Gutes Preis-/Leistungsverhältnis	1,4	62,8%	33,6%	3,1%	0,5%
Hohe Qualität	1,4	61,7%	35,4%	2,6%	0,3%
Tierwohl (z.B. artgerechte Haltung)	1,6	49,5%	41,3%	7,1%	2,1%
Gentechnik-frei/ ohne Gentechnik produziert	1,6	53,8%	31,4%	11,1%	3,7%
Regionalität/ in der Region hergestellt	1,7	46,0%	40,2%	12,0%	1,8%
Hergestellt in Österreich	1,7	43,9%	43,4%	10,9%	1,8%
Saisonal/ entspricht der aktuellen Ernte-Saison	1,7	42,8%	43,4%	11,6%	2,2%
Frei von problematischen Inhaltsstoffen (z.B. kein Palmöl)	1,7	44,6%	39,8%	12,9%	2,7%
Nachhaltige Produktion	1,8	38,6%	48,4%	10,8%	2,2%
Gute Erfahrungen mit der Marke/ ist mir vertraut	1,8	38,9%	47,7%	11,2%	2,2%
Art der Verpackung (z.B. wiederverschließbar, kein Plastik)	1,8	38,0%	44,4%	14,6%	3,0%
Preisaktion/ Sonderangebot	1,9	34,6%	46,2%	17,3%	1,9%
Fair gehandelt/ Fair Trade	2,0	28,3%	49,2%	19,4%	3,1%
Niedriger Preis	2,0	24,6%	48,9%	23,8%	2,8%
Mit einem Gütesiegel ausgezeichnet (z.B. AMA)	2,1	26,4%	45,8%	22,8%	5,0%
Bio-Produkt/ Bio-Qualität	2,1	25,1%	42,3%	25,1%	7,4%
Große Auswahl an Sorten/ Vielfalt (z.B. Geschmacksrichtungen)	2,2	19,0%	46,6%	30,6%	3,8%
Optisch ansprechende Verpackung	2,5	13,2%	34,0%	41,0%	11,8%
Markenprodukt/ ist von einer bekannten Marke	2,7	8,0%	30,5%	44,9%	16,6%

4. [...] Inwieweit sind Ihnen die folgenden Aspekte beim Einkauf von Lebensmitteln wichtig? ||
Basis: Entscheidungsträger bzgl. dem Einkauf von Dingen des täglichen Bedarfs || n=1.002

Wichtige Aspekte beim Einkauf von Lebensmitteln

Top-2-Box: sehr wichtig / eher wichtig | 4-stufige Skalierung



4. [...] Inwieweit sind Ihnen die folgenden Aspekte beim Einkauf von Lebensmitteln wichtig? ||
Basis: Entscheidungsträger bzgl. dem Einkauf von Dingen des täglichen Bedarfs || n=1.002

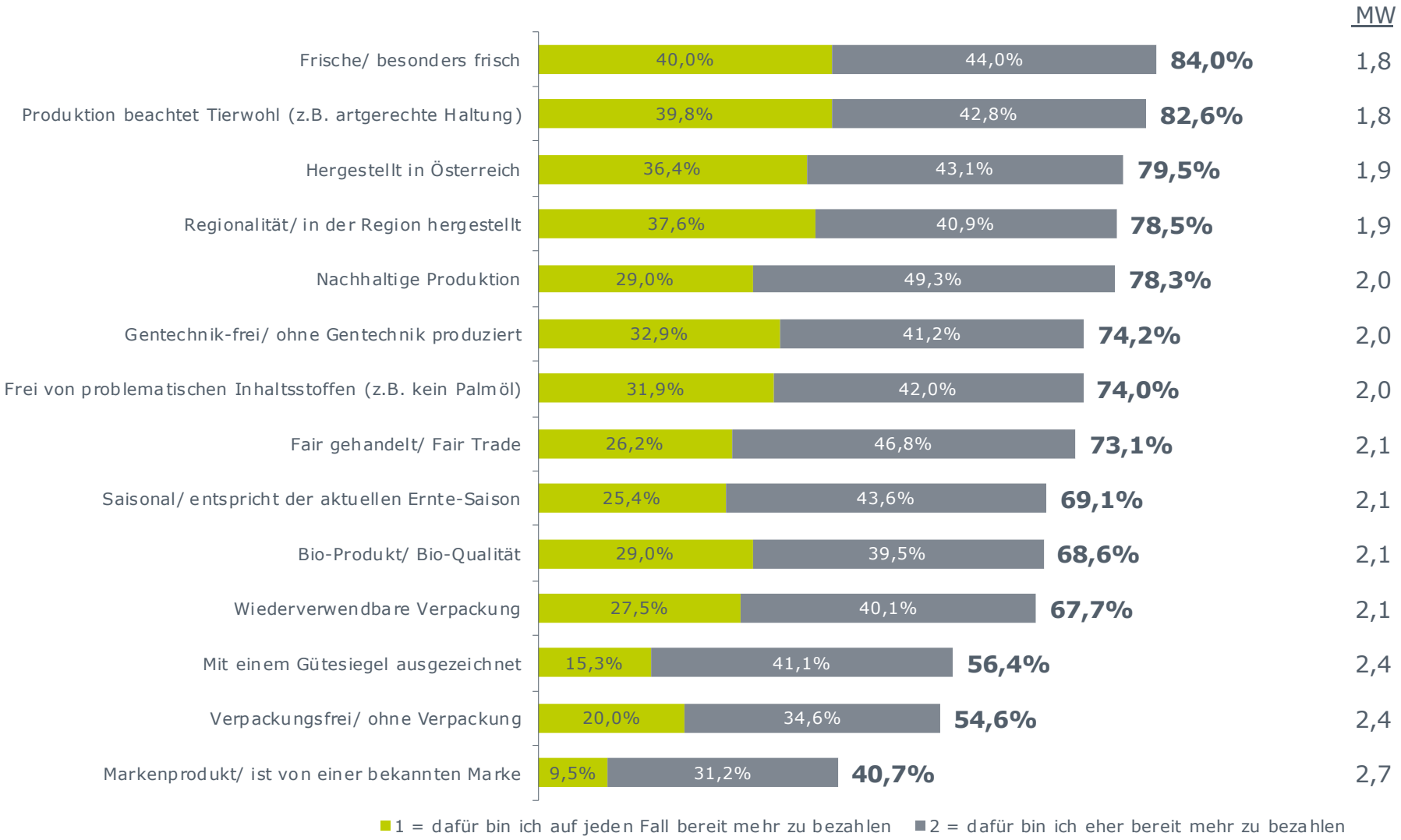
Aufpreisbereitschaft für Lebensmitteln mit folgenden Eigenschaften

	Mittelwert	dafür bin ich auf jeden Fall bereit mehr zu bezahlen	dafür bin ich eher bereit mehr zu bezahlen	dafür bin ich eher weniger bereit mehr zu bezahlen	dafür bin ich auf keinen Fall bereit mehr zu bezahlen
Frische/ besonders frisch	1,8	40,0%	44,0%	11,7%	4,3%
Produktion beachtet Tierwohl (z.B. artgerechte Haltung)	1,8	39,8%	42,8%	13,3%	4,1%
Regionalität/ in der Region hergestellt	1,9	37,6%	40,9%	16,5%	5,0%
Hergestellt in Österreich	1,9	36,4%	43,1%	15,4%	5,1%
Nachhaltige Produktion	2,0	29,0%	49,3%	16,7%	5,0%
Gentechnik-frei/ ohne Gentechnik produziert	2,0	32,9%	41,2%	18,1%	7,8%
Frei von problematischen Inhaltsstoffen (z.B. kein Palmöl)	2,0	31,9%	42,0%	19,1%	7,0%
Fair gehandelt/ Fair Trade	2,1	26,2%	46,8%	21,7%	5,3%
Bio-Produkt/ Bio-Qualität	2,1	29,0%	39,5%	22,7%	8,8%
Wiederverwendbare Verpackung	2,1	27,5%	40,1%	23,8%	8,6%
Saisonal/ entspricht der aktuellen Ernte-Saison	2,1	25,4%	43,6%	23,0%	8,0%
Verpackungsfrei/ ohne Verpackung	2,4	20,0%	34,6%	31,9%	13,5%
Mit einem Gütesiegel ausgezeichnet	2,4	15,3%	41,1%	32,6%	11,0%
Markenprodukt/ ist von einer bekannten Marke	2,7	9,5%	31,2%	39,2%	20,1%

5. [...] Inwieweit sind Sie bereit, für Lebensmittel, die die folgenden Eigenschaften aufweisen, mehr zu bezahlen? ||
Basis: Entscheidungsträger bzgl. dem Einkauf von Dingen des täglichen Bedarfs || n=1.002

Aufpreisbereitschaft für Lebensmitteln mit folgenden Eigenschaften

Top-2-Box: dafür bin ich auf jeden Fall bereit mehr zu bezahlen / dafür bin ich eher bereit mehr zu bezahlen | 4-stufige Skalierung

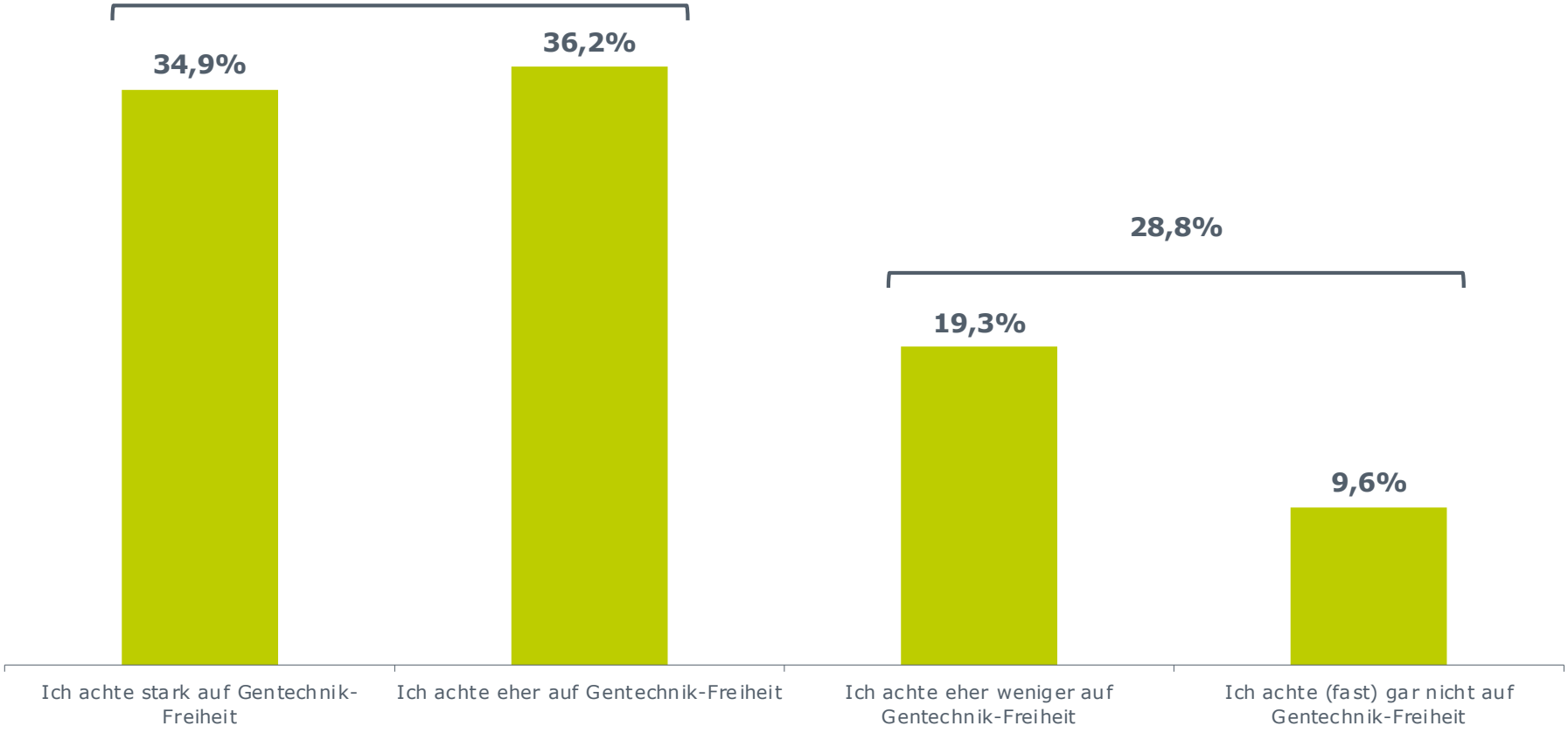


5. [...] Inwieweit sind Sie bereit, für Lebensmittel, die die folgenden Eigenschaften aufweisen, mehr zu bezahlen? ||
Basis: Entscheidungsträger bzgl. dem Einkauf von Dingen des täglichen Bedarfs || n=1.002

Inhalt

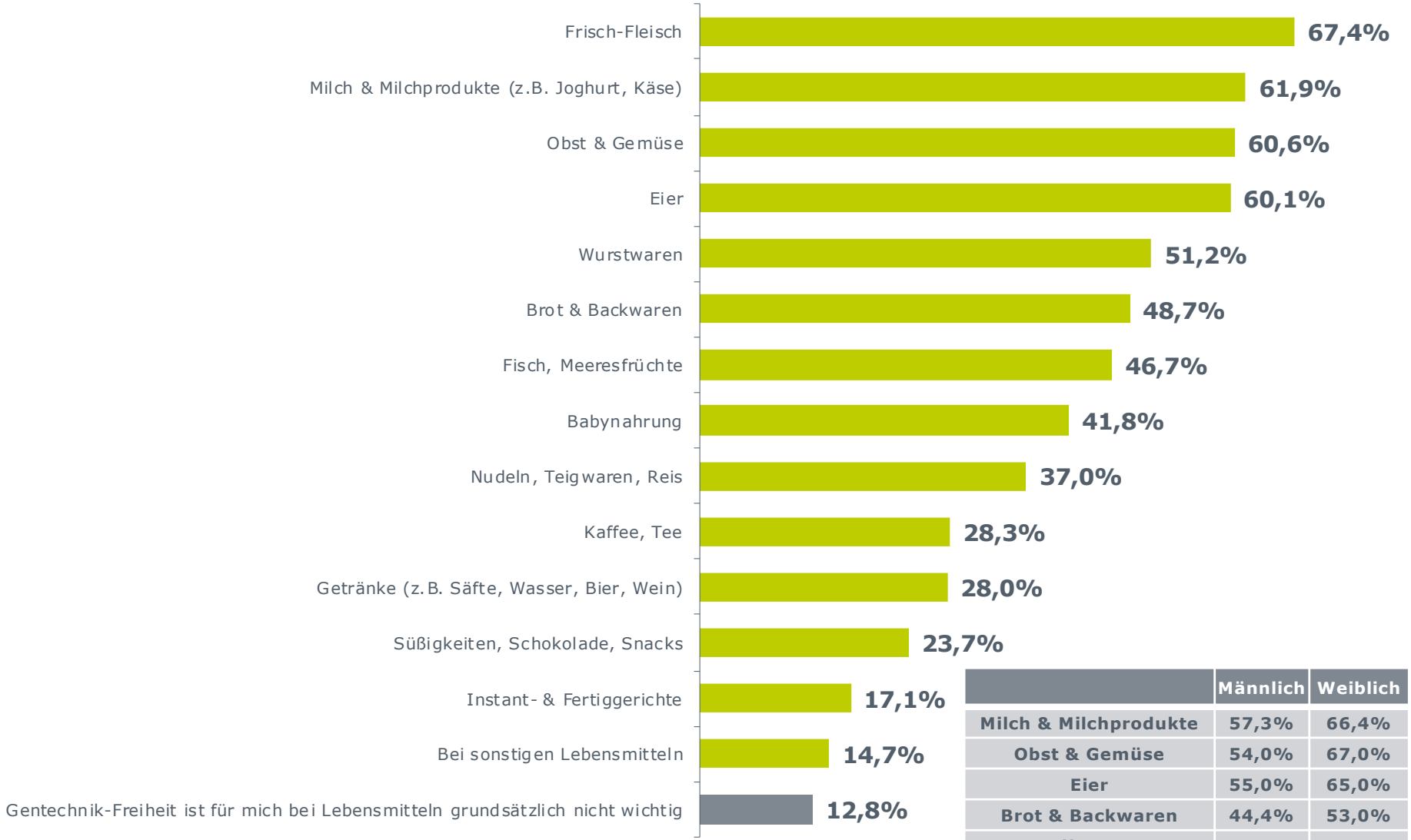
Achten auf gentechnik-freie Lebensmittel beim Einkauf

Sample Total	71,2%
Männlich	67,5%
Weiblich	74,7%
14 - 19 Jahre	53,5%
20 - 29 Jahre	60,0%
30 - 39 Jahre	69,7%
40 - 49 Jahre	74,1%
50 - 59 Jahre	75,4%
60 - 69 Jahre	84,8%



8. [...] Inwieweit achten Sie beim Einkauf von Lebensmitteln darauf, dass bzw. ob das Produkt gentechnik-frei ist? ||
Basis: Entscheidungsträger bzgl. dem Einkauf von Dingen des täglichen Bedarfs || n=1.002 || MW 2,0

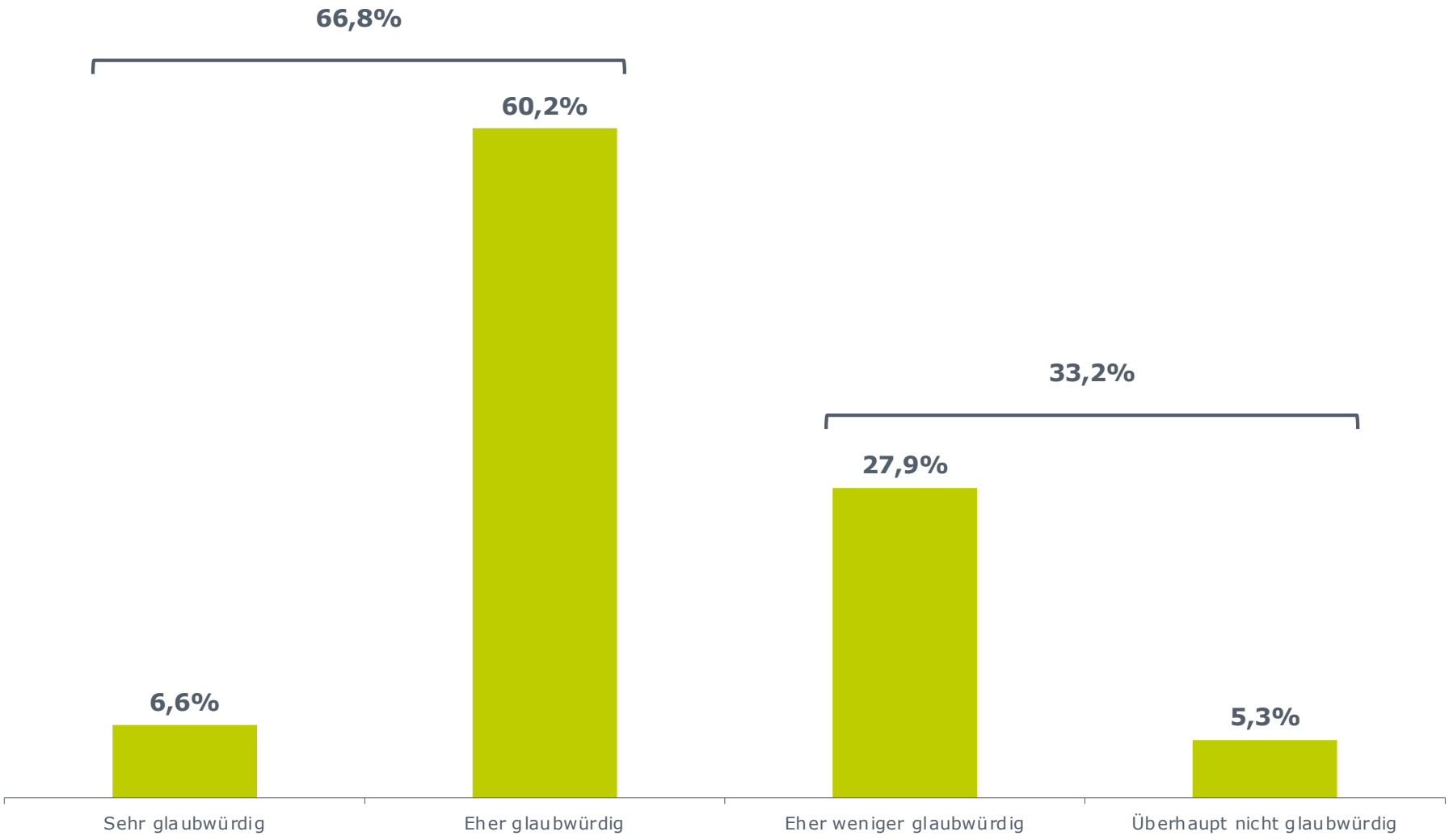
Wichtige Warengruppen bzgl. gentechnik-freien Produkten



	Männlich	Weiblich
Milch & Milchprodukte	57,3%	66,4%
Obst & Gemüse	54,0%	67,0%
Eier	55,0%	65,0%
Brot & Backwaren	44,4%	53,0%
Kaffee, Tee	24,8%	31,8%

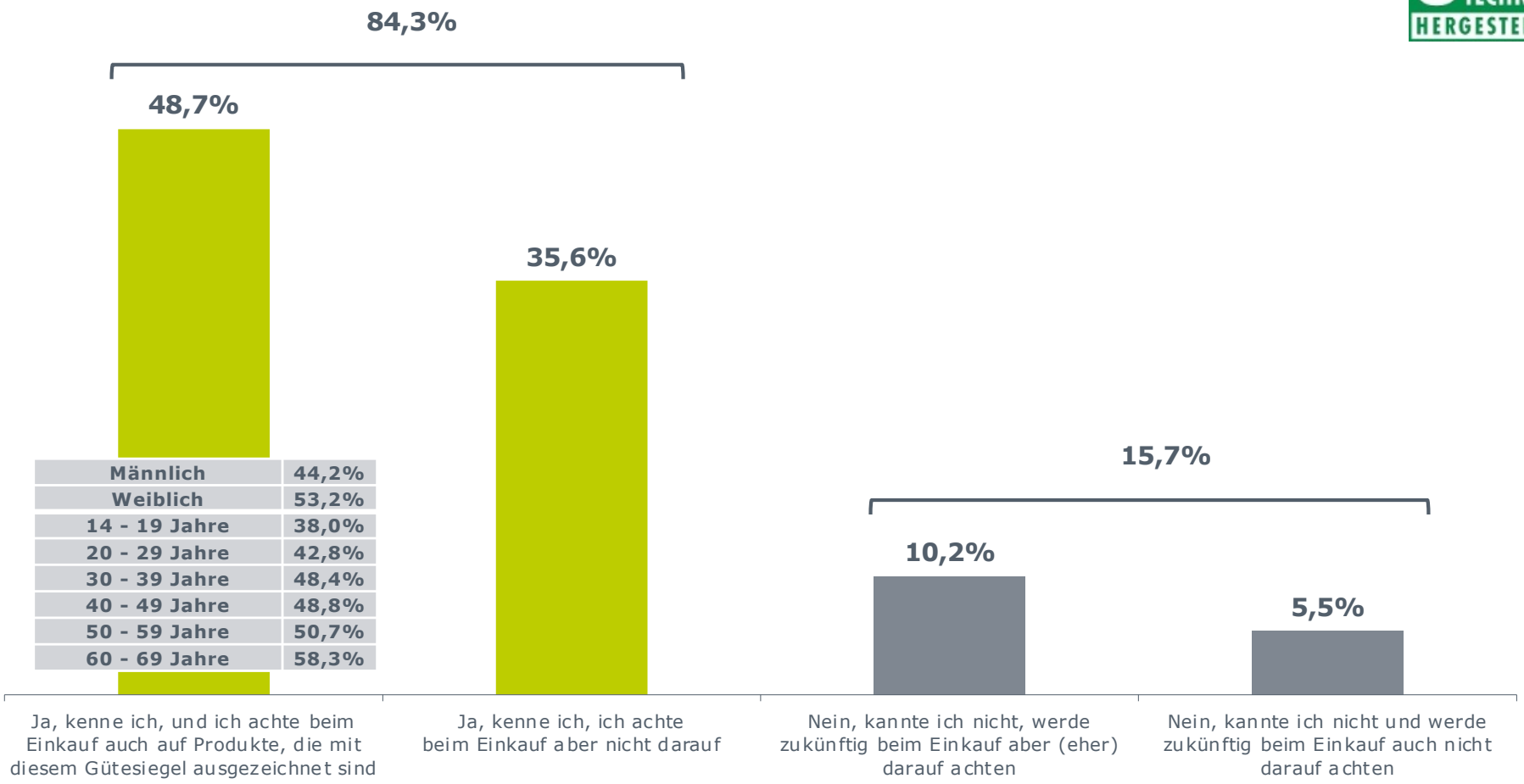
9. In welchen Warengruppen sind gentechnik-freie Produkte für Sie besonders wichtig? ||
Basis: Entscheidungsträger bzgl. dem Einkauf von Dingen des täglichen Bedarfs || n=1.002 || Mehrfach-Nennung möglich

Glaubwürdigkeit der am Markt verfügbaren gentechnik-freien Produkte



11. Wie glaubwürdig sind Ihrer Ansicht nach die am Markt verfügbaren Produkte, die als gentechnik-frei ausgewiesen/ beworben werden? ||
Basis: Entscheidungsträger bzgl. dem Einkauf von Dingen des täglichen Bedarfs || n=1.002 || MW 2,3

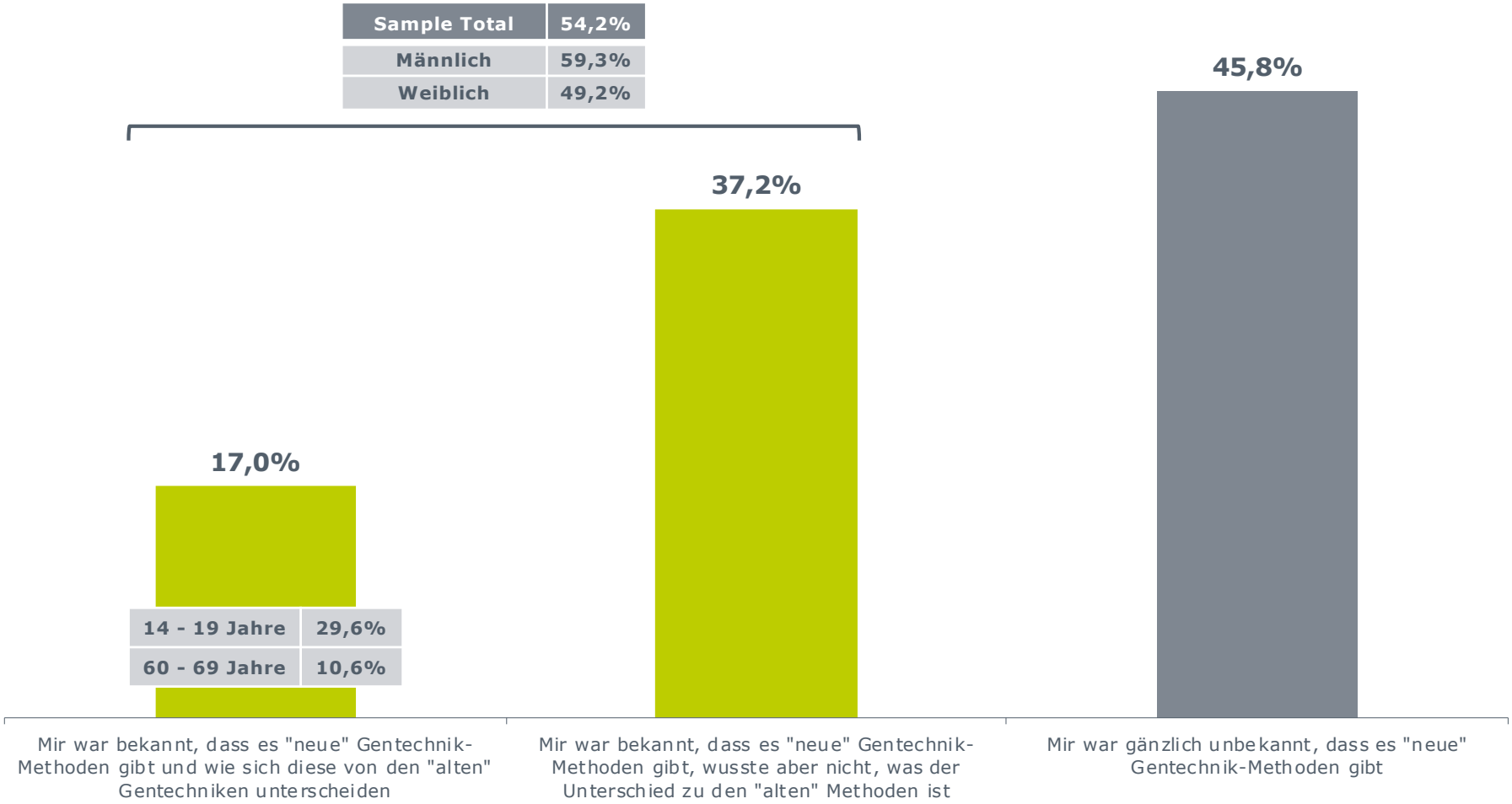
Bekanntheit des Gütesiegels



12. Kennen Sie dieses Gütesiegel? || Basis: Entscheidungsträger bzgl. dem Einkauf von Dingen des täglichen Bedarfs || n=1.002

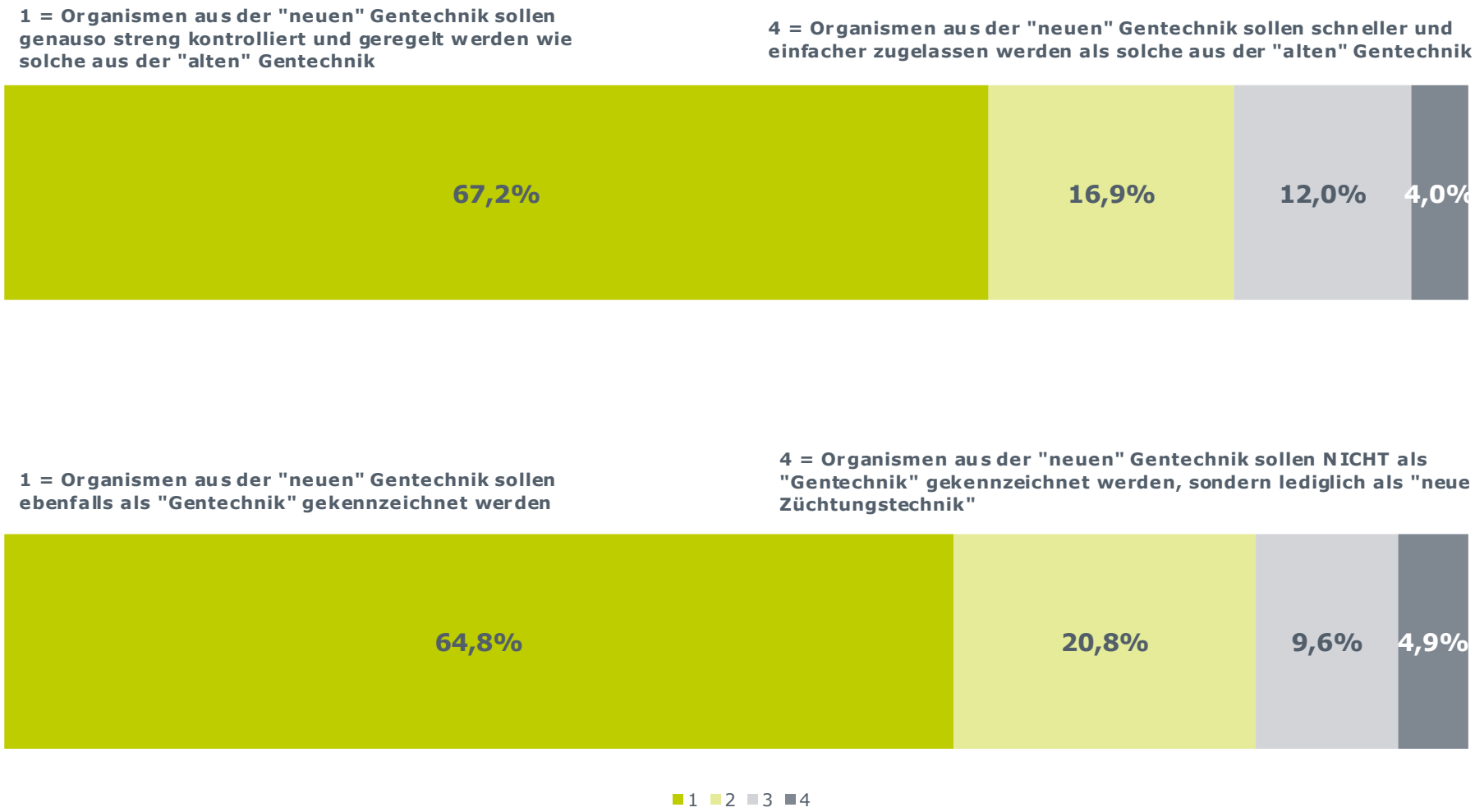
Inhalt

Bekanntheit der "neuen" Gentechnik-Methoden



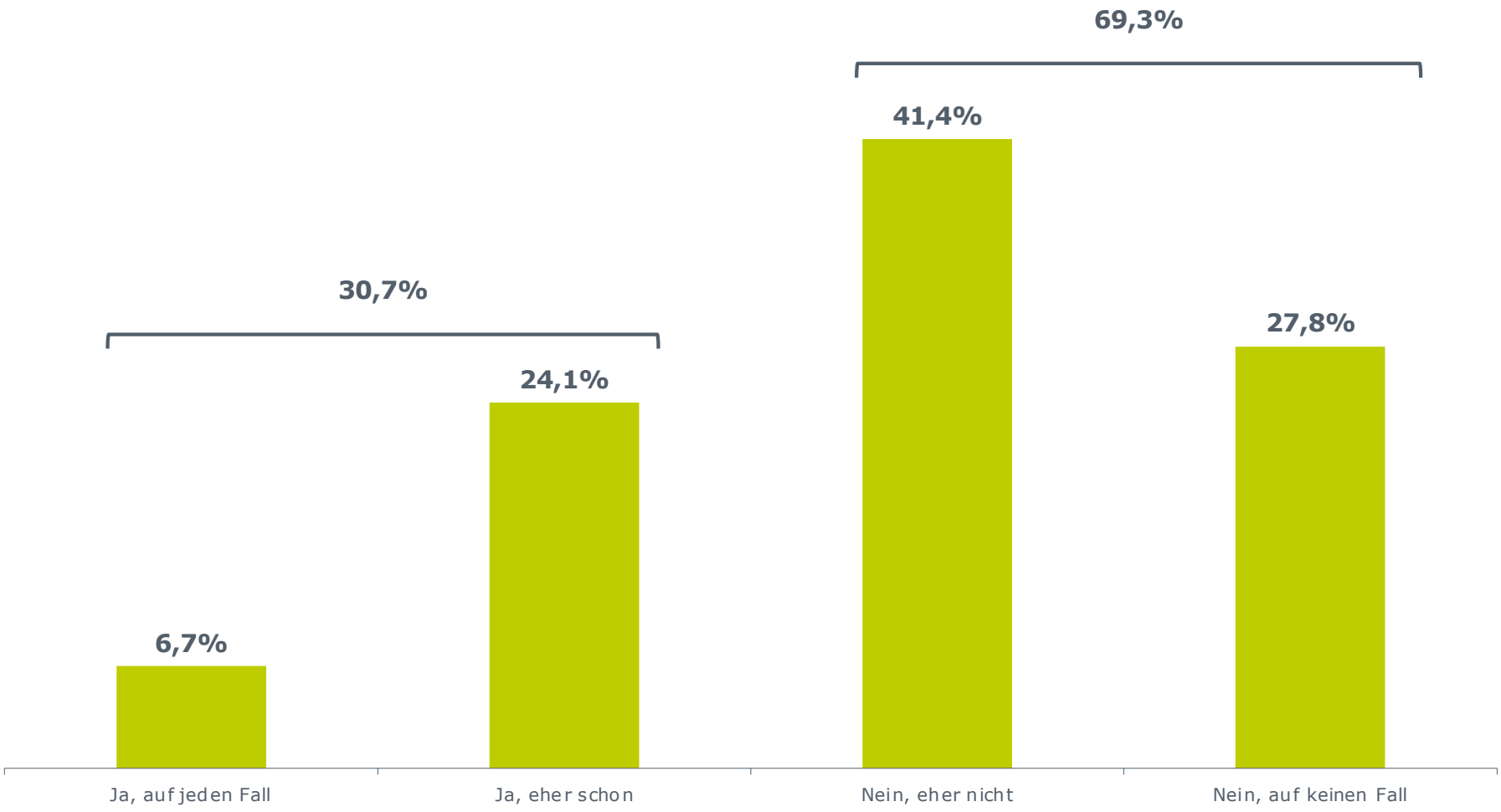
16. […] Inwieweit waren Ihnen diese "neuen" Gentechnik-Methoden vor dieser Umfrage bereits bekannt? ||
Basis: Entscheidungsträger bzgl. dem Einkauf von Dingen des täglichen Bedarfs || n=1.002

Zutreffende Aussagen zur "neuen" Gentechnik-Methoden



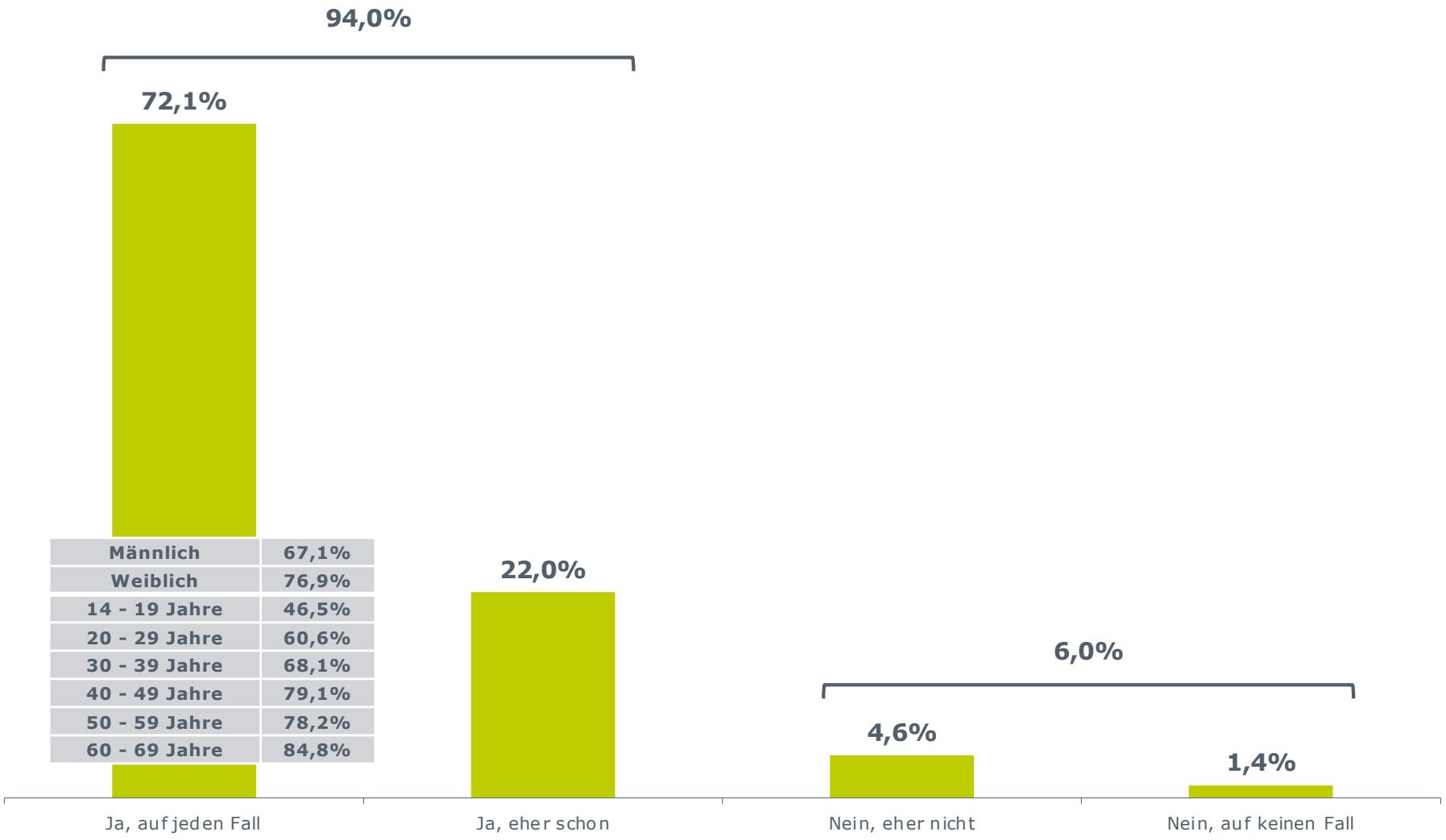
17. Es gibt Überlegungen, Organismen, die mit den Verfahren der "neuen" Gentechnik verändert wurden, nicht als "Gentechnik" zu kennzeichnen und diese auch schneller und einfacher am Markt zuzulassen als solche, die mit der "alten" Gentechnik verändert wurden. Die Anwendung der "alten" Gentechnik ist auf EU-Ebene klar geregelt. Produkte dürfen erst auf den Markt (als Saatgut, Lebens- oder Futtermittel), wenn eine Risikobewertung vorliegt und sie einem Zulassungsverfahren der EU unterzogen wurden. Zudem müssen zugelassene Lebensmittel als gentechnisch verändert gekennzeichnet werden. Welchen der folgenden Aussagen stimmen Sie jeweils am ehesten zu? || Basis: Entscheidungsträger bzgl. dem Einkauf von Dingen des täglichen Bedarfs || n=1.002

Kauf von Lebensmitteln mit der "Neuen Gentechnik"



19. Angenommen, Lebensmittel, die mit Verfahren der "Neuen Gentechnik" produziert wurden, wären in österreichischen Geschäften verfügbar. Würden Sie diese Lebensmittel der "Neuen Gentechnik" kaufen? [...] || Basis: Entscheidungsträger bzgl. dem Einkauf von Dingen des täglichen Bedarfs || n=1.002 || MW 2,9

Dieselben Kontrollen bei der "Neuen Gentechnik" wie bei der der "Alten Gentechnik"



Männlich	67,1%
Weiblich	76,9%
14 - 19 Jahre	46,5%
20 - 29 Jahre	60,6%
30 - 39 Jahre	68,1%
40 - 49 Jahre	79,1%
50 - 59 Jahre	78,2%
60 - 69 Jahre	84,8%

22. Soll sich die österreichische Bundesregierung innerhalb der EU dafür einsetzen, dass Produkte aus der "Neuen Gentechnik" auch weiterhin ebenso streng kontrolliert werden wie Produkte aus der "Alten Gentechnik"? || Basis: Entscheidungsträger bzgl. dem Einkauf von Dingen des täglichen Bedarfs || n=1.002 || MW 1,4

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Attachment to question 24

Off-target effects

One of the principal concerns of genome editing is “off-target” effects — changes to other genes that were not intended. Off-target effects could unintentionally alter important genes, causing changes in chemistry or protein production — both of which are important for food and environmental safety. Most studies on the potential uses of gene editing techniques in agriculture consider off-target effects to be both a major challenge and a major concern,[i] and many studies have now detected off-target effects in gene-edited plants and animals.

Unexpected on-target effects

Genome editing can cause unexpected “on-target” effects, where the intended change occurs at the intended location, but has a different outcome than expected. A small insertion or deletion of DNA within a gene, even if on-target, could change the way a gene is read and processed into proteins in problematic ways. Studies have found that CRISPR can inadvertently cause extensive deletions and complex re-arrangements of DNA.[ii] These deletions and re-arrangements of DNA by CRISPR may cause important parts of the gene (those coding for protein production) to be “missed” when the DNA is read.[iii] This misreading of DNA has the potential to produce altered proteins. Food allergens are mostly proteins, so altered proteins could have significant implications for food safety.[iv]

The misreading of DNA in a genome-edited plant or animal could impact biodiversity. For example, if the chemistry of a genome-edited plant or animal were changed by the misreading of DNA, it could produce a compound that is toxic to the wildlife that feeds on it. These types of concerns regarding human and ecological safety mean that gene-edited organisms need to be analyzed for any on-target effects, and the implications of on-target effects need to be carefully evaluated.

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Inserted DNA (intentional and unintentional)

Often, a DNA “cassette” containing the genome editing components is inserted into the organism’s genome at a random location — in exactly the same way that earlier GMOs were created. However,

it is inevitable that, in some cases, not all the inserted DNA will be removed and some of the DNA encoding for gene editing components will inadvertently remain in the gene-edited organism.[1]

Unintended integration of gene-editing components (including residual DNA coding for the CRISPR components, additional copies and fragments), have been found in both plants and animals, not only from CRISPR, but also from TALENs.[4]A recent publication highlighted the problem of unintended insertions of DNA coding for CRISPR components, compounded by the failure to identify these events using conventional detection protocols.[5] Cows that had been gene-edited, via TALENs, to be hornless[6] were found to have unintentionally incorporated DNA from the gene editing process, including antibiotic resistance genes.[7]Integration of unwanted DNA during the gene editing process appears to be more common than previously thought.[8]

Unintended insertions of DNA (DNA coding for CRISPR components) and additional fragments or rearrangements of DNA can give rise to unexpected effects in gene-edited organisms, creating the same concerns as first generation GMOs. It is therefore important that checks for unintended effects from DNA insertion (where intended or unintended) are carried out.

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