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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

Food & Water Action Europe Transparency Registry number: 42119616334-41

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

Environment, food, agriculture, climate, energy, water

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

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

* **2. Have your members taken or planned to take measures to protect themselves from unintentional use of NGT-products?**
  - Yes
  - No
  - Not applicable

* **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

* **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

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

- ○ Yes
- ○ No
- ◉ Not applicable

* **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

We consider that traceability strategies are part of the existing EU GMO legislation. Experiences from conventional, organic as well as GMO-free value chains show that a combination of labelling, paper documentation, traceability tools and testing methods/strategies are most effective against contamination and fraud. Regulations (EC) 1829/2003 and (EC) 1830/2003 also specify that GMOs must be identified through documentation systems if technical proof is not possible. This practice is acknowledged and implemented for oil from soy and sugar from sugar beet.
The European Commission has experience in coordinating actions to avoid imports of non-authorised genetically modified rice from the US (2006) and linseed from Canada (2009), which involved validated testing methods and standard sampling procedures for imports to the EU]http://europa.eu/rapid/press-release_MEMO-06-310_en.htm. In light of these successful experiences, a comparable initiative should be coordinated for soy and rapeseed imports from USA and Canada in order to avoid that any non-authorised NGTs (such as Calyxt High Oleic Soybean and Cibus SU Canola) are entering the EU food chain. In this context, an EU wide coordination approach would be most effective to avoid costs that would be associated with each national laboratory developing detection protocols individually.

To detect unauthorized imports, researchers from the EU's Joint Research Centre clarified in 2017 that reviewing authorisations, patent applications and other information yields the best results in a targeted approach for testing on imports. During the 30th annual plenary meeting of ENGL, detection methods /strategies for NGTs were discussed that are based on a system that collects mutations to distinguish between a mutation that was introduced by NGTs and one that occurred naturally. In this context, the data that is stored in a reference database serves as a marker to detect induced mutations.This emphasizes that a European databank with comparison material, as suggested in regulation (EC) 1830/2003, is essential.

* **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 explain why not

The food sector has avoided the use of GM ingredients for more than a decade and adapted their supply chains and suppliers to avoid contamination with GM products. Whilst more than 80 GM events are authorised in the EU, they are faced with very strong market rejection in the food sector. The costs to minimize risks of GMO contamination have been covered by the food sector and not by the biotech sector.

The exclusion of NGTs from GMO labelling requirements would increase the costs and measures taken by the food sector. Without strict traceability applied, NGT products could contaminate non-GMO products which could have a severe economic impact for the breeding, farming, food processing and retailing sectors.

There is a regulation in place (1829/2003) setting the rules for labelling of GMO, it is applicable for new AND old GMOs. So there is no need for specific measures of labelling new GMO.

* 8 bis. What challenges have you encountered?

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

The maximum file size is 1 MB

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

No, The European Green Deal, with its ambitions for greener and more climate friendly way of food production, should prioritise non-NGT related breeding concepts that have the potential to deliver a wide range of benefits for agriculture and society.

On the contrary to the hype about GM, conventional breeding is still more efficient and quicker in delivering desirable traits, such as drought tolerance, higher yields etc.

There are still a lot of non-answered questions related to risks of NGT and in general to GMO-plants.

Please see our report https://www.foodandwaterwatch.org/sites/default/files/GMO%20Consensus%20IB%20Sept%202014_0.pdf

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

- ○ Yes
- ○ No
- ◉ Not applicable

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

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

- ○ Yes
- ◉ No
- ○ Not applicable

* Please explain why not

no

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

- ◉ Yes
- ○ No
- ○ Not applicable

* Please provide concrete examples/data

Research that would provide benefits would for instance explore the potential impacts of a wider application of “genome-editing” on issues such as

· farmers' rights to save and reproduce seeds and to breed animals, given the patents and licensing agreements on these techniques,
· Rights to produce and consume conventional and organic products, not contaminated with NGT
· concentration in the European seed market, which is currently supplied by a variety of companies including many small and independent local breeders,
· the capacity to effectively monitor potential adverse outcomes through post-market surveillance.
· assessment of socio-economic, health and environmental impacts of using and importing NGT

And most urgent need is a research that
· delivers standardized detection methods
· unintended modifications crucial for better understanding of side-effects

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

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

* Please provide concrete examples/data

We experience a general lack of research focusing on protection of environment and health and driven by the precautionary principle. Instead, most of the research in this field is driven by an interest to develop, apply and profit from the technology. In addition, public research policy encourages researchers to patent their NGT-applications. This creates a conflict of interest for involved scientists: they consequentially hold a financial interest in acquisition of funds for research, the exploitation of their patents and the deregulation of NGTs. This conflict of interest prevents numerous scientists and their associations and academies from delivering an objective assessment of potentials vs. risks of the technology which is founded on rigorous scientific standards. This problem is becoming evident from recent statements made by scientific institutions, such as the statement by the Vlaams Instituut voor Biotechnologie (VIB) signed by researchers from hundred scientific institutions and research centers (1), the statement by the European Academies of Science Advisory Council (EASAC) just recently circulated in the EU Parliament (2), the statement by the Group of Chief Scientific Advisors SAM (3) as well as the report by the German Leopoldina (4). Taking a closer look at the authors and experts behind those reports, many of them applied for patents or are involved in the development for specific applications (see https://www.testbiotech.org/content/vertrauen-in-die-wissenschaft).
Research on possible risks for environment and health, on the other hand, is severely underfunded. This results in a situation which exaggerates the perceived potential and opportunities of NGTs, as opposed to their risks.

This situation prevails despite the Recital Nr 21 enshrined in GMO-directive 2001/18, which reads: “Member States and the Commission should ensure that systematic and independent research on the potential risks involved in the deliberate release or the placing on the market of GMOs is conducted.”

Without the existence of such a precaution-oriented, non-interest-based risk research, government authorities cannot properly fulfill their obligation to protect health and environment from possible risks of genetic engineering and biotechnology. When confronted with GMO products in the context of the approval process, government agencies must be able to critically question the data and results presented by industry applicants. A mere plausibility check, which only reproduces the results submitted by industry, does not guarantee that the public protection obligations are met.

(1)http://www.vib.be/en/news/Pages/Open%20Statement%20for%20the%20use%20of%20genome%20editing%20for%20sustainable%20agriculture%20and%20food%20production%20in%20the%20EU.aspx
(2)https://mailchi.mp/26c7ad4d43b4/european-gmo-laws-no-longer-fit?e=47f8603050
(3)https://ec.europa.eu/info/publications/status-products-derived-gene-editing-and-implications-gmo-directive_en
(4)https://www.leopoldina.org/publikationen/detailansicht/publication/wege-zu-einer-wissenschaftlich-begruendeten-differenzierten-regulierung-genomeditierter-pflanzen-in/

*** 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

We already mentioned research needs in the answers to questions 10 and 13. Beyond those, there is a lack of research on the development of sustainable alternatives to NGTs.

Research on NGT risks related to health and environment is very scarce. Many advocates of NGTs claim or imply that these techniques are “precise” and thus safe, even though a large body of research shows that they are not precise, but lead to unintended alterations both at the on-target site of the intended edit and at off-target sites of the genome. No one knows yet what are the implications for health and environment of this lack of precision and controllability, because the required risk research has not been done. In particular, we are not aware of any animal feeding studies in which foods or crops produced using NGTs have been fed to animals to ascertain the biological effects.

Research gaps relate to genetic errors caused by the genome editing process, and the resultant unexpected effects in the resulting GMO. As yet, there is no standardised protocol for the examination of off-target effects, and unintended on target effects (including unintended genetic insertions) are quite likely to be missed because the in depth studies DNA studies required are rarely performed. Therefore, there is a research need for standardised protocols to detect such errors.

Similarly, for unexpected effects in the resulting GMO, there are now a wealth of profiling technologies (collectively known as “‘omics”) that can examine the products of gene expression. These should be further developed, including standardisation of protocols so they can be utilised to detect any unexpected effects.

New findings show natural mechanisms of gene regulation that can impact, direct or even control spontaneous or induced genetic modification by naturally occurring mechanisms in the cells. These differences translate into specific risks of NGTs and need further investigation.
More generally, genome editing opens up new possibilities by making the whole genome accessible for changes (Kawall, 2019), while conventional mutagenesis does not bypass the named natural factors and mechanisms. This technical potential of genome editing is also highlighted in the COGEM (2019) report as follows: “Now that we are sequencing genomes, we know that the genes that 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 now able to change genes we have never had access to before.”

Similarly, Duensing et al., (2018) state: “One important difference is that some crop genes lie in low or non-recombinogenic regions of the chromosome. (...) Genome editing ensures all genes are amenable to allele replacement.” Duensing et al., (2018) specifically refer to the possibility of changing all gene copies by applying methods such as SDN1: “(...) 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.”

Due to the methods used in genetic engineering, the resulting patterns of genetic change as well as biological characteristics and associated risks can be substantially different compared to those derived from conventional breeding. For example, the application of CRISPR/Cas on wheat (Sanchez-Leon et al., 2018) enabled the targeted change of up to 35 copies within one specific group of genes. This is different to the results of conventional mutation breeding. Furthermore, so-called multiplexing might be applied, which means that not just one, but several gene families will be affected (Shen, L. et al., 2017).

To decide whether such organisms are safe, detailed examination of their genetic and overall biological characteristics is needed. Thus, there is a need for regulation as foreseen by current EU GMO regulation, even if no additional DNA sequences are inserted. The aforementioned differences between new genetic engineering techniques and conventional breeding enable the generation of plants that carry new genetic combinations and novel traits. Both the differences and the genome edited plants need to be further analyzed.

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

The maximum file size is 1 MB

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

No, the sustainability of NGT has not been yet assessed, thus using products or organisms that haven't been assessed in regards of environmental, economic or social impacts is not supported by Food & Water Action Europe.

In any case, no one should think that NGTs could lead to a reduction of the use of pesticides, because plants selected for their resistance to a certain pathogen that are derived from these techniques and cultivated in an industrial and not adaptive framework will quickly cause these pathogens to mutate and become even more dangerous. Moreover, it will be necessary to use even more dangerous pesticides.

None of these solutions can be sustainable, their obsolescence is programmed from their conception.

* **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

Promises associated with NGTs/NGT-products are crops which resist the climate crises, stop biodiversity loss and secure the competitiveness of the EU economy.

With these promises it is suggested that complex societal, political and economic problems can be solved by screwing on the plant genome or with a technical intervention through NGTs, respectively. This is a threat for society in general: Such a narrow view bears the danger of seeking a simple technical solution to complex problems, continuing a wrong system of agriculture and preventing real solutions.

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 precautionary principle as the foundation of the EU environmental legislation is attacked by lobby groups (in order to abolish the pre-market risk assessment for GMOs), as well as the consumers right to know and the freedom of choice as the foundation of EU consumer policy (in order to abolish GMO labelling and make GMOs invisible to consumers and economic operators), not to mention transparency about the origin of a product and how or with which processes it was produced as the foundation of sustainability concepts (in order to abolish the process-oriented risk assessment for GMOs). This, too, is a danger for society in general.

* **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

No. NGTs are patented as well as the plants developed on that basis. Hence, breeding companies that want to use a technique such as CRISPR to develop a plant and bring it to market need to negotiate with the owner(s) of the patent(s) to get the license to work with the patented “invention” and pay license fees.

For instance, in the field of CRISPR-Cas 9, agri-business corporations such as Bayer and Corteva (formerly DowDuPont) have concluded partly exclusive license treaties with the inventors of the technology in order to use their patents. Many of these patents are pending for authorization, some of them have already been granted. For specific applications, the corporations themselves apply for additional patents. In June 2018, Corteva was in leading position with about 50 international patent applications, followed by Bayer-Monsanto with about 30 applications.[1]Particularly successful, Corteva brought together, in cooperation with the Broad Institute, 48 patents on basic applications of the CRISPR-Cas technology in one so-called patent pool. In order to use CRISPR-Cas-9 in breeding, companies need access to virtually all patents in this pool. In order to get access, they need to negotiate licenses with the administrator of the pool, which is Corteva. This gives the company the possibility to control competitors and further consolidate their market power.[2]

Having to negotiate with large corporations puts small- and medium sized breeding companies in a difficult situation, and license fees are a financial burden. Moreover, patent claims related to CRISPR-Cas 9 are typically drafted very broadly. They therefore give the patent owners the power to create legal monopolies over a wide range of activities related to their invention, with rights reaching far beyond those applications of their invention which they originally anticipated.[3]

In addition to patents there are other obstacles that small- and medium-sized breeders are facing regarding the use of new GM techniques. In order to successfully apply new GM techniques in breeding, breeders need to have a significant amount of knowledge in molecular genetics and bioinformatics. Moreover, they need to have an appropriate laboratory equipment at their disposal. Small-sized breeders, however, often lack this expertise, nor do they dispose of the financial resources or laboratory equipment needed to work with molecular-genetic methods.[4]

[1] Testbiotech 2018: Hintergrund. Neue Gentechnikverfahren: zunehmende Monopolisierung von Landwirtschaft und Züchtung.
[2] Gelinsky, Eva 2019: CRISPR für mittelständische Züchter? Mit Patentfamilien und -pools haben sich die Konzerne ihre Marktmacht bereits gesichert, Bauernstimme 09-2019, 18; Then, Christoph (2019): Neue Gentechnikverfahren und Pflanzenzucht. Patente-Kartell für große Konzerne, in: Forum Umwelt und Entwicklung, Rundbrief 2/2019, 10-11.
[3] Mali, Franc 2020: Is the Patent System the Way Forward with the CRISPR-Cas 9 Technology? Science & Technology Studies. Forthcoming. https://sciencetechnologystudies.journal.fi/forthcoming/article/70114/48385.
[4] A representative of the Dutch vegetable breeding company Rijk Zwaan stated: “We still know very little with respect to which genes and which mutations will have a positive effect on traits in the crops. For every crop effective gene editing methods have to be developed, and how to grow plants from the edited cells. For all these reasons conventional mutagenesis for vegetable seed breeding is still an acceptable alternative.” Source: COGEM 2020: Report of the International Symposium: Gene edited crops; global perspectives and regulation.October 2019, 4-5.

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

- ○ Yes
- ◉ No

* Please explain why not

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

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

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

The patenting of seeds, plants, their harvest and products blocks access to genetic material, and so poses a fundamental risk not only to preserving plant genetic diversity and the traditional use of crop diversity in local communities, but also to future innovation in breeding. This can lead to a loss in diverse, locally adapted varieties and in plant genetic diversity which are vital to ensure that we are able to meet the challenges to our food system associated with the climate and biodiversity crises.
Experience from Canada and US give strong concerns that patents on plants limit availability of seeds for farmers and results in higher seeds costs without delivering increased yields. There are concerns that patented seeds can also hamper the innovation in the breeding sector as well as the development of seeds and crops that can cope with more and more extreme weather conditions.

Clapp, J. 2018. Mega-Mergers on the Menu: Corporate Concentration and the Politics of Sustainability in the Global Food System. Global Environmental Politics 18: 12–33. https://doi.org/10.1162/glep_a_00454
Hendrickson, M., Howard, P.H. & Constance, D. 2019. Power, Food, and Agriculture: Implications for Farmers, Consumers, and Communities. In: Hansen, J., Gibson, J. & Alexander, S. (eds.). Defense of Farmers: The Future of Agriculture in the Shadow of Corporate Power. Lincoln: University of Nebraska Press. p. 13–62. https://doi.org/10.2307/j.ctvgs0crb.7
Howard, P.H. 2015. Intellectual Property and Consolidation in the Seed Industry. Crop Science 55: 2489–2495. https://doi.org/10.2135/cropsci2014.09.0669
Marco, A.C. & Rausser, G.C. 2008. The role of patent rights in mergers: Consolidation in plant biotechnology. American Journal of Agricultural Economics 90: 133–151. https://doi.org/10.1111/j.1467-8276.2007.01046.x
OECD 2018. Concentration in Seed Markets: Potential Effects and Policy Responses. Paris: OECD Publishing. https://doi.org/10.1787/9789264308367-en
Solberg, S.O. & Breian, L. 2015. Commercial cultivars and farmers' access to crop diversity: A case study from the Nordic region. Agricultural and Food Science 24:150–163. https://doi.org/10.23986/afsci.48629

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

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

Non-regulated NGT-products would 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 would come onto the market untested and invisible to manufacturers, marketers and consumers. Even if the non-GMO producers would act in accordance with a changed EU law. The organic sector depends on the traceability of GMOs, as transparency is the 1st precondition to protect organic markets. Without traceability, organic producers are unable to show that their products are free of GMOs as demanded by the Organic Regulation 834/2007.

Extra risks and costs for non-GM sector

NGTs will increase the costs of organic and non-GMO quality chains. These negative impacts will be multiplied if NGT-products are not labelled and traced as it would become extremely expensive, if not impossible, for the non-GMO sector to keep NGT-products out of the production chain. Most of the time irreversible and without any sustainable benefits, these risks and negative impacts are socially unfair and unacceptable.

Seed producers and breeders need to take measures to prevent contamination, e.g. testing breeding material and seed lots of crops at risk of GMO contamination or checking on GMO cultivation and field trials with cross-fertile species near their fields. The costs associated with that and those arising when a contamination is discovered are borne by those who want to produce GM-free. Without GMO labelling and traceability, an implementation of the zero tolerance for unauthorised GMOs in seed and any obligation for companies to provide methods and reference materials in order to detect new GMOs, breeders would have no means to know if breeding material for which they cannot reconstruct the biography was developed, at any stage, using new GM techniques or interbreeding material produced on the basis of new GM techniques. Consequently, they would need to renounce from using external material with unknown biography in order to protect their breeding lines from contamination. This would severely limit their activities, as successful breeding is based on the exchange and diversity of genetic resources. Varieties received by other breeders often serve as comparison for assessing the performance of own lines in terms of quality, yield and plant health. And breeders interbreed external material with their own material in order to enlarge their gene pool.

Contamination

Controlling the risks arising from intentional or unintentional genetic modification by overcoming natural barriers to the multiplication and/or recombination of plants, animals and micro-organisms is not possible. Any use of genetic engineering generates, beyond the claimed modifications, numerous unintentional genetic or epigenetic modifications.
Breeders could not afford to risk a contamination of their genetic resources. Such contamination could have devastating consequences. The contaminated lot or plants would need to be destroyed, which could mean that many years of breeding work (time and money) could be lost. In addition to that, contamination might

already have spread to other breeding lines, a variety as a whole or other breeding projects (due to exchanges with other breeders), possibly leading to the destruction of even wider parts of the gene pool, more seed lots, a whole variety and more breeding projects. Moreover, if not discovered at early stage, contamination could spread into seed production as well as farming supplied with the seed. This could cause cost for farmers and for the processing and trading industries along the value chain.

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

Loss of consumer trust

EU food law as well as EU treaties enforce consumers rights this includes labelling as a precondition for the right to information for consumers (Art 169 TFEU). Only the strict implementation of GMO law ensures this core right of consumers.

Food sovereignty as a whole

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

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

- (●) Yes
- ( ) No

* Please explain

Non-regulated NGT-products would 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 would come onto the market untested and invisible to manufacturers, marketers and consumers. Even if the non-GMO producers would act in accordance with a changed EU law. The organic sector depends on the traceability of GMOs, as transparency is the 1st precondition to protect organic markets. Without traceability, organic producers are unable to show that their products are free of GMOs as demanded by the Organic Regulation 834/2007.

Extra risks and costs for non-GM sector

NGTs will increase the costs of organic and non-GMO quality chains. These negative impacts will be multiplied if NGT-products are not labelled and traced as it would become extremely expensive, if not impossible, for the non-GMO sector to keep NGT-products out of the production chain. Most of the time irreversible and without any sustainable benefits, these risks and negative impacts are socially unfair and unacceptable.

Seed producers and breeders need to take measures to prevent contamination, e.g. testing breeding

material and seed lots of crops at risk of GMO contamination or checking on GMO cultivation and field trials with cross-fertile species near their fields. The costs associated with that and those arising when a contamination is discovered are borne by those who want to produce GM-free. Without GMO labelling and traceability, an implementation of the zero tolerance for unauthorised GMOs in seed and any obligation for companies to provide methods and reference materials in order to detect new GMOs, breeders would have no means to know if breeding material for which they cannot reconstruct the biography was developed, at any stage, using new GM techniques or interbreeding material produced on the basis of new GM techniques. Consequently, they would need to renounce from using external material with unknown biography in order to protect their breeding lines from contamination. This would severely limit their activities, as successful breeding is based on the exchange and diversity of genetic resources. Varieties received by other breeders often serve as comparison for assessing the performance of own lines in terms of quality, yield and plant health. And breeders interbreed external material with their own material in order to enlarge their gene pool.

Contamination

Controlling the risks arising from intentional or unintentional genetic modification by overcoming natural barriers to the multiplication and/or recombination of plants, animals and micro-organisms is not possible. Any use of genetic engineering generates, beyond the claimed modifications, numerous unintentional genetic or epigenetic modifications.
Breeders could not afford to risk a contamination of their genetic resources. Such contamination could have devastating consequences. The contaminated lot or plants would need to be destroyed, which could mean that many years of breeding work (time and money) could be lost. In addition to that, contamination might already have spread to other breeding lines, a variety as a whole or other breeding projects (due to exchanges with other breeders), possibly leading to the destruction of even wider parts of the gene pool, more seed lots, a whole variety and more breeding projects. Moreover, if not discovered at early stage, contamination could spread into seed production as well as farming supplied with the seed. This could cause cost for farmers and for the processing and trading industries along the value chain.

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

Loss of consumer trust

EU food law as well as EU treaties enforce consumers rights this includes labelling as a precondition for the right to information for consumers (Art 169 TFEU). Only the strict implementation of GMO law ensures this core right of consumers.

Food sovereignty as a whole

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

* **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

Environmental concerns

1) as with old GMO there is the unclear risk NGT pose to the environment and the balanced ecosystem, plus the question if the GMO can be taken back out of the environment once released (retrievability)
2) The fact of of non-retrievability of NGT and unknown risks conflicts with respecting the precautionary principle as guidance for all environmental legislation of the EU.
3) Specific risk of NGT are for examples gene drives, including gene drive insects with the specific goal of changing whole ecosystems. This is an unprecedent risk to the environment and ecosystems specific to NGT. In addition they might disseminate in natural populations since they are more likely to reproduce.

Societal and Economic challenges

Promises associated with NGTs/NGT-products are crops which resist the climate crises, stop biodiversity loss and secure the competitiveness of the EU economy.
With these promises it is suggested that complex societal, political and economic problems can be solved by screwing on the plant genome or with a technical intervention through NGTs, respectively. This is a threat for society in general: Such a narrow view bears the danger of seeking a simple technical solution to complex problems, continuing a wrong system of agriculture and preventing real 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 model of local selections of diverse plants adapted to each local agro-ecosystem can ensure sufficient resilience to the impacts of climate change. The economic model of NGTs is incompatible with local adaptive selections and relocation of the food chain. Political, financial and legal support for the development of NGTs removes all support for sustainable agro-ecological alternatives and hinders their development.
The economic model behind NGTs places the control of the food chain in the hands of a few transnational corporations.

Challenges for society also lie in the unknown effects of using new GMO as well as the current challenge of not yet having developped testing protocols and methods, and thus not being able to guarantee the freedom of choice not to use NGT for breeders, farmers, food processors, food retailers and consumers.

Consumer concerns:

EU general food law (178/2002) ensures that citizens need to have access to safe and wholesome food of highest standards as well as ensures a high level of protection of human life and consumers' interests in relation to food. The EU treaties enforce consumers rights, this includes labelling as a precondition for the right to information for consumers (Art 169 TFEU). Only the strict implementation of GMO law ensures this core right of consumers.
The exclusion of NGTs from GMO labelling requirements would increase the costs and measures taken by the food sector. Without strict traceability applied, NGT products could contaminate non-GMO products

which could have a severe economic impact for the breeding, farming, food processing and retailing sectors as well as for the environment.

1) There are many concerns connected to NGT, and some specific to NGT as well as their products.
2) Questioning the legal status of new GMO poses a huge risk for transparency and free choice of consumers, farmers, breeders and food processors as well as trade
3) as with old GMO, risks connected with using the GMO have to be considered as well, calling for assessing the environmental risks of Herbicide-resistant GM-plants just as well as the risks for human or animal-nutrition in case of GM-plants with new nutritional contents.
This is so far missing in the risk assessment and approval system, but should be considered for old as well as new GMO.

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

See answers to previous questions

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

- (•) Yes
- ( ) No

* Please explain

See above

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

- (•) Yes
- ( ) No

* Please explain and provide concrete examples and data

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

For instance, in the field of CRISPR-Cas 9, agri-business corporations such as Bayer and Corteva (formerly DowDuPont) have concluded partly exclusive license treaties with the inventors of the technology in order to use their patents. Many of these patents are pending for authorization, some of them have already been granted. For specific applications, the corporations themselves apply for additional patents. In June 2018, Corteva was in leading position with about 50 international patent applications, followed by Bayer-Monsanto with about 30 applications.[1]Particularly successful, Corteva brought together, in cooperation with the Broad Institute, 48 patents on basic applications of the CRISPR-Cas technology in one so-called patent pool. In order to use CRISPR-Cas-9 in breeding, companies need access to virtually all patents in this pool. In order to get access, they need to negotiate licenses with the administrator of the pool, which is Corteva. This gives the company the possibility to control competitors and further consolidate their market power.[2]

Having to negotiate with large corporations puts small- and medium sized breeding companies in a difficult situation, and license fees are a financial burden. Moreover, patent claims related to CRISPR-Cas 9 are typically drafted very broadly. They therefore give the patent owners the power to create legal monopolies over a wide range of activities related to their invention, with rights reaching far beyond those applications of their invention which they originally anticipated.[3]

In addition to patents there are other obstacles that small- and medium-sized breeders are facing regarding the use of new GM techniques. In order to successfully apply new GM techniques in breeding, breeders need to have a significant amount of knowledge in molecular genetics and bioinformatics. Moreover, they need to have an appropriate laboratory equipment at their disposal. Small-sized breeders, however, often lack this expertise, nor do they dispose of the financial resources or laboratory equipment needed to work with molecular-genetic methods.[4]

[1] Testbiotech 2018: Hintergrund. Neue Gentechnikverfahren: zunehmende Monopolisierung von Landwirtschaft und Züchtung.
[2] Gelinsky, Eva 2019: CRISPR für mittelständische Züchter? Mit Patentfamilien und -pools haben sich die Konzerne ihre Marktmacht bereits gesichert, Bauernstimme 09-2019, 18; Then, Christoph (2019): Neue Gentechnikverfahren und Pflanzenzucht. Patente-Kartell für große Konzerne, in: Forum Umwelt und Entwicklung, Rundbrief 2/2019, 10-11.
[3] Mali, Franc 2020: Is the Patent System the Way Forward with the CRISPR-Cas 9 Technology? Science & Technology Studies. Forthcoming. https://sciencetechnologystudies.journal.fi/forthcoming/article/70114/48385.
[4] A representative of the Dutch vegetable breeding company Rijk Zwaan stated: “We still know very little with respect to which genes and which mutations will have a positive effect on traits in the crops. For every crop effective gene editing methods have to be developed, and how to grow plants from the edited cells. For all these reasons conventional mutagenesis for vegetable seed breeding is still an acceptable alternative.” Source: COGEM 2020: Report of the International Symposium: Gene edited crops; global perspectives and regulation.October 2019, 4-5.

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

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

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

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

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

Experience from Canada and US give strong concerns that patents on plants limit availability of seeds for farmers and results in higher seeds costs without delivering increased yields. There are concerns that patented seeds can also hamper the innovation in the breeding sector as well as the development of seeds and crops that can cope with more and more extreme weather conditions.

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

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E - Safety of NGTs/NGT-products

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

It has been already explained in previous answers

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

- (●) Yes
- ( ) No

* Please explain

They have been summarized in previous answers

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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**

Food & Water Action Europe considers that our food, water and climate are under constant assault by corporations who put profit over the survival of humanity. They have seized control of the very institutions that were built to protect us. We mobilize people to reclaim their political power, hold our elected officials accountable, and resist corporate control—ensuring we all have the essential resources we need to thrive.

We are working to create a healthy future for all people and generations to come—a world where everyone has food they can trust, clean drinking water and a livable climate.

Under this framework, we consider that when assessing technologies, this should involve looking at how they are connected to production systems, visions of the future, how they can reproduce inequalities, etc. We can demand a broader than science-based-risk-assessment approach, ie an integral sustainability evaluation. (Herrero et al.)

The 25 years of experience with GMOs have mostly resulted in herbicide-tolerant (HT) crops. Large scale HT-monocultures have shown a massive raise in the total amount of herbicides used in weed control, farmers and rural communities suffering health impacts, impacts on their crops, water pollution, etc. HT crops contribute strongly to biodiversity loss.

This experience shows that values being displayed by biotech corporations are often: profit-driven,

irresponsible, cooperation, competition, control, not respecting organism's integrity . We defend values such as environmental justice & protection, health protection, solidarity, equality, freedom of choice, …

The consequences of the deployment of new GM techniques for different actors need to be assessed. Who will benefit most, and who will carry the risks, especially in a scenario of de-regulation?

Society at large, and all living beings and ecosystems, will carry the wider risks for the environment /biodiversity from the release of new GMOs. Damage to ecosystems may be irreversible. Rigorous risk assessment is therefore of paramount importance. Environmental costs include the disappearance of agrobiodiversity, which is of huge importance to food security, food sovereignty, and represents cultural values.

Regulation does not replace the not-knowing, but can help to recognize the absence of certainty. The Precautionary Principle is there to help guide action in case of absence of full information (which is always the case when a new GMO is introduced).

The introduction of a technology can change economic and social relationships. GM technology has led to an increased concentration of ownership and power in agrifood systems through patents and contracts and license agreements. This is no different for NGTs. These impacts should be taken into account when deciding whether to support their development.
Alongside risk assessment, seed savers, breeders, farmers and consumers should be able to make an informed choice about whether they access NGT-products, which is only possible through rigorous traceability and clear labelling as per the current GMO regulatory regime.
In the way GMOs are currently risk assessed, there is no space for assessing the opportunity costs. There are different approaches to (often complex) problems. The question is, who frames what those problems are, and what the solutions should be. Which solutions get the benefit of public and private funding? Other innovation views get marginalized, like agroecology, agroforestry, regenerative agriculture, etc.

The push by GM developers for deregulation of new GM techniques poses questions on power asymmetries in decision making, that favor certain interests more than others. In general, GM developers (biotech corporations) have the resources and multiple opportunities to help shape the way their products are risk assessed, provided with privileged access to decision makers by the EU institutions themselves.

There are many examples that show genome editing in farm animals is by no means free of side effects and is often associated with animal suffering. Interests in marketing these animals can lead to serious conflicts with well-established social and ethical standards as well as the consensual values of European society.

Ethical debates should address the potential for these technologies to be used to produce gene drives or biological warfare, with potentially devastation consequences.

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

- (●) Yes
- ( ) No

* Please explain

Please see previous answer

Please upload any supporting documentation for this section here

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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**

GMO labelling for NGT-products is important for consumers and economic operators (breeders, farmers, beekeepers, food and feed processors, retailers). It 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.

GMO labelling is the precondition for freedom of choice for consumers and economic operators, this is why a legally binding obligation for NGT-products is essential. The GMO labelling regime is prescribed in Regulation 1830/2003. It ensures this freedom of choice and also contributes to the effective functioning of the internal market.

Consumers are reflecting increasingly about their food choices and labelling schemes are an essential indicator for consumers to make a well-educated choice.

In the General Food Law Regulation 178/2002 Article 8 on „Protection of consumers' interests“ states: „Food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume.“ Consequently new GMOs/NGT-products have to be labelled as GMOs.
And Article 18 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.“ Consequently new GMOs/NGT-products have to be labelled as GMOs.

In addition Article 169 in the Treaty on the Fonctioning of the EU ensures the consumer‘s right to information.

We welcomed the European Court of Justice ruling. According to the ruling all NGT-products are GMOs and have to be labelled as GMOs. The ruling brought legal certainty for economic operators, the scientific community and consumers. It prevents that feed and food produced with NGTs would be channelled onto the agri-food market in a manner not recognisable for manufacturers, marketers and consumers.

Without a labelling of NGT-products the whole EU agriculture, feed and food sector would run the risk to unwittingly and unintentionally sell GMOs to its customers.

Since their market introduction in 1996 GMOs in the EU have been an offer without demand. Consumers do not want to eat GMOs, retailers do not want to sell them (19 out of 27 member states have voted to rule out the cultivation of GMOs on their territory). Accordingly labelled GMO food products in EU supermarket shelves are extremely rare.

A GMO label guarantees freedom of choice and transparency for economic operators and consumers. People can decide whether they want to support or not support a certain production method or technique, respectively. This is a valuable achievement of EU consumer policy. The abolition of the GMO label for NGT-products would be a step backwards that cannot be communicated to a GMO critical public.

Companies in the food industry focus more and more on sustainability - and all sustainability concepts include knowledge about the origin of a product and how or with which processes/techniques it was produced. Not only economic operators, but also consumers increasingly want to know how their food was produced. This is becoming more and more the standard. Abolishing the GMO label for NGT-products would contradict these higher demands on food production.

It would be developers, manufacturers and marketers of NGT products who would benefit from a non-labelling of NGT-products, not other economic operators and consumers.

If NGT-products are so convincing and precious as promised they should be successful with a GMO label. Otherwise a question would arise: Can people trust a technology and its products which can only succeed if it stays invisible for the public?

One of the aims of the Green Deal is to increase transparency and consumer information in the food system. Hence current GMO labelling has to remain mandatory for NGT-products.
We strongly oppose any change of the current EU GMO legislation and the labelling requirements for NGT-products.

For more information on our position on GM labelling, please check https://www.foodandwaterwatch.org/sites/default/files/Case%20for%20GMO%20Labeling%20FS%20Jan%202015_0.pdf

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H - Final question

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

- (●) Yes
- ( ) No

Please provide your comments here

For this study as well as for the political assessment of the legal frame for new GMO, it stays important to clearly differentiate between findings of studies and unproven promises. The debate between science and politics often seems driven by promises at the moment - promises neither proven nor likely to come true (Thinking of promises of drought resistance as well as ending world hunger). NGT are tools, in the debate right now it often seems that people forget considering alternative tools.

But the last 30 years of GMO , having started with exactly the same promises, quite clearly showed: you cannot end hunger, you cannot reach a more sustainable agriculture with a tool like GMOs.

Term "NGT/NGT-products" is misleading/not appropriate: In July 2018 the European Court of Justice has made it very clear: Products produced with new genetic engineering techniques are GMOs. So the adequate

term for NGT-products is GMOs and for the techniques resulting in them new genetic engineering techniques, not NGTs.

Fully implementation of ECJ ruling is needed. All NGTs/NGT-products have to remain under the current EU GMO legislation which requires

· comprehensive case-by-case risk assessment according to the precautionary principle;
· methods for detecting, identifying and quantifying the GMO/NGT-product have to be 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;
· a global transparency register: it shall cover all GMOs worldwide, bot hold and new.

A deregulation of NGTs/NGT-products would mean

· abolishing of the precautionary principle for NGTs/NGT-products
· elimination of approval procedures, risk assessment and labelling requirements
· health and environmental impacts would no longer be examined by national and EU regulatory authorities
· not intended side effects like on-target effects and off-target effects would not be not examined
· no obligation for biotech companies to provide detection methods
· NGT-products would be channelled into the market untested and unlabelled
· serious problems for organic and conventional non-GMO sector - sooner or later they would loose control over their supply chains (note: organic agriculture uses to at least 90 percent conventional seeds)

We consider that none of this is acceptable.

A deregulation of NGT-products entails the risk of damaging the organic sector as the most sustainable form of agriculture. The organic sector excludes GMOs but uses at least 90 percent of conventional seeds (which are propagated organically). Hence organic breeders need information with which techniques seeds have been developed. Otherwise they would run the risk to use NGT-seeds inwittingly and unwillingly. This would destroy consumers confidence. One main argument for buying organic is „no GMOs“. The Green Deal has identified organic farming as one of the best approaches to improve biodiversity and one of the solutions to make agriculture more sustainable. A deregulation of NGTs/NGT-products would contradict the Green Deal’ s aim of promoting organic agriculture.

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. This would be perceived as legal trickery and “regulating GMOs out of existence” in favour of the GMO industry.

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