Contribution ID: 45ec3a68-a3ec-4269-8d8d-2b093b189fb5
Date: 15/05/2020 12:05:28

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

Corporate Europe Observatory (CEO) 5353162366-85

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

Corporate capture of decision making, democracy, lobbying, climate, agriculture, trade, finance, research, environment, chemicals, digital, economic governance, corporate accountability

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

Corporate Europe Observatory (CEO)

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

Not applicable

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

* Please explain why not

Corporate Europe Observatory (CEO) is a research and campaign group working to expose and challenge the privileged access and influence enjoyed by corporations and their lobby groups in EU policy making. CEO does not have members, but a broad range of supporters. As consumers, people do not have the means to protect themselves from unintentional use of NGT-products, apart from choosing to buy certified organic food.

As an organisation fighting for social and environmental justice, we co-signed the 2017 joint petition of civil society and farming organisations, demanding the EU and national authorities that organisms derived from the new GM techniques should be regulated like any other GMOs. They should be subject to EU GMO authorisation, which would avoid their unintentional use, and which requires:
•comprehensive case-by-case risk assessment;
•methods for detecting, identifying, and quantifying the GMO that are publicly available in an EU database;
•documentation to track the GMOs and GMO products at all stages of the supply chain;
•consumer labelling of GMO products;
•post-market monitoring;
•GMO location register.
See: https://corporateeurope.org/sites/default/files/attachments
/joint_position_new_techniques_of_genetic_engineering_february_2017.pdf

We repeated this demand in various letters to decision makers. For example, in May 2019 we co-signed a letter to Commission Vice-President Katainen, demanding that the European Commission and the EU Member States “efficiently implement the ruling all over the European Union”. We stated that with the ruling, European consumers, breeders, farmers, food processors and retailers obtain the legal assurance that conventional and organic products cannot be contaminated with undeclared new GMOs. We emphasized that the EU Commission and national governments must strictly implement the ruling that GMOs obtained from new genetic engineering techniques must be marketed only with prior authorisation, must be labelled, and require detection methods to be provided by applicants, according to Directive 2001/18/EC. We also demanded that the EU Commission ensures that imports from third party countries have certificates that they do not contain unauthorised new GMOs.
See: https://www.ifoam-eu.org/sites/default/files/ifoam_eu_policy_kgoo_newgmos_commonletter_20190522.pdf

In this respect CEO documented how in 2015 the American company Cibus stated that its novel herbicide resistant oil seed rape was “likely entering the international commodity chain” and that “it can therefore not be excluded that commodities with RTDS products are imported in the EU”. Cibus has repeatedly and wrongly let it be understood by North American agricultural sectors that its ODM technology is not GM under European law – long before Europe has even come to a formal and final decision on the matter.
https://corporateeurope.org/en/food-and-agriculture/2016/02/us-company-railroads-eu-decision-making-new-gm

Summing up, CEO has contributed with its research and campaigning activities to achieve a situation in which it is possible for consumers, farmers, breeders and the wider food chain to protect themselves from unintentional use of NGTs.

* 2 bis. Have you encountered any challenges?

- (●) Yes
- ( ) No

* Please provide details

Yes, the ruling still does not seem to be fully implemented. Documents obtained by CEO from DG SANTE show how on the one hand, the European Commission holds Member States responsible for implementing the ruling, while Member States point to the EC to provide detection methods. However, as reported by Inf'OGM, in April 2017 the European Commission refused the official European Network of GMO Laboratories (ENGL), in charge of GMO detection and identification, to undertake a specific study on the new techniques of genetic modification.
See: https://www.infogm.org/6361-eu-no-program-to-detect-new-gmos?lang=fr
As stated above, it is entirely possible that non-authorised, illegal products of new GM techniques could appear in imported agricultural goods (such as Calyxt High Oleic Soybean and Cibus SU Canola). Controls and detection methods are needed to prevent the import of non-authorised products.

* **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

See also question 2. Regarding food production and imports, CEO and numerous other organisations have made a clear call on the EU institutions to respect and swiftly implement the ECJ ruling (C-528/16). This includes EU authorities to demand from any company with access to the EU market, to guarantee that there is no presence of unauthorized GMOs in their products. They should also demand from those companies with new GM products to deliver a detection method in order to prevent imports containing illegal products. By holding EU authorities accountable, these organisations have contributed to achieve a situation in which it is possible for consumers, farmers, breeders and the wider food chain to protect themselves from unintentional use from NGTs, thereby ensuring freedom of choice.

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

- ◉ Yes
- ○ No

* Please provide details

Yes, the ruling still does not seem to be fully implemented. Documents obtained by CEO from DG SANTE show how on the one hand, the European Commission holds Member States responsible for implementing the ruling, while Member States point to the EC to provide detection methods. However, as reported by Inf'OGM, in April 2017 the European Commission refused the official European Network of GMO Laboratories (ENGL), in charge of GMO detection and identification, to undertake a specific study on the new techniques of genetic modification.
See: https://www.infogm.org/6361-eu-no-program-to-detect-new-gmos?lang=fr
As stated above, it is entirely possible that non-authorised, illegal products of new GM techniques could appear in imported agricultural goods (such as Calyxt High Oleic Soybean and Cibus SU Canola). Controls and detection methods are needed to prevent the import of non-authorised products. The polluter pays principle and a liability regime must be established in order to ensure that those who contaminate food, seeds and feed with GMOs are held responsible and pay
compensation for the economic damage caused by such contamination.

* **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

Traceability strategies are part of the existing EU GMO legislation. Regulations (EC) 1829/2003 and (EC) 1830/2003 specify that GMOs must be identified through documentation systems also if technical proof is not possible. 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.
The EU has avoided imports of non-authorised products in the past, and the same can be done to avoid imports of any non-authorised NGTs (such as Calyxt High Oleic Soybean and Cibus SU Canola) are entering the EU food chain. An EU wide coordinated effort would be most efficient rather than duplicating efforts at national level.

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.

Also, there should be a public international registry which includes all GMO products that are field trialed, cultivated and placed on the market globally, among them new GM applications, as essential tool to identify products developed by new GM techniques. Transparency is a prerequisite for a free decision whether to use these products or not.

* **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

not applicable

* What best practices can you share?

not applicable

* Please explain why not

No, organisations like CEO do not use new GMOs ourselves and therefore do not need to ensure labelling requirements of the GMO legislation. Regulation 1829/2003 sets out the rules for labelling of GMO, it is applicable for new AND old GMOs. Civil society organisations and farmers demand the enforcement of current GMO laws on new GMOs in order to be protected against unintentional use of new GMOs. This is the responsibility of the Commission and Member States.
The polluter pays principle and a liability regime must be established in order to ensure that those who contaminate food, seeds and feed with GMOs are held responsible and pay compensation for the economic damage caused by such contamination.

* 8 bis. What challenges have you encountered?

not applicable

* **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

In our 2016 report The Biotech Lobby Push, we exposed industry's attempts to circumvent the EU GMO regulations. In that report, we quoted from an early 2015 letter from the American company Cibus stating that its novel herbicide resistant oil seed rape was "likely entering the international commodity chain" and that "it can therefore not be excluded that commodities with RTDS products are imported in the EU". We also showed in that report how since at least 2007, Cibus has repeatedly let it be understood by North American agricultural sectors that its ODM technology is not GM under European law – long before Europe has even come to a formal and final decision on the matter.
This is why CEO and other organisations have called on the European Commission repeatedly to ensure that companies exporting agricultural goods to the EU are held accountable that no unauthorized GMOs enter the EU.
https://corporateeurope.org/en/food-and-agriculture/2016/02/us-company-railroads-eu-decision-making-new-gm

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

Corporate Europe Observatory (CEO) is a research and campaign group working to expose and challenge the privileged access and influence enjoyed by corporations and their lobby groups in EU policy making.

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

- ◉ Yes
- ○ No
- ○ Not applicable

* Please specify

We here list some examples of research on the political debate around NGTs, or on their risks.

Ulrich Hartung describes in Review of Policy Research the activities of the US company CIBUS to obtain permission to hold field trials of its ODM canola in various EU countries in an unregulated fashion. He describes what political factors contributed to the choice for these Member States. (Inside Lobbying on the Regulation of New Plant Breeding Techniques in the Europian Union: Determinants of Venue Choices. Review of Policy Research. 2020. https://onlinelibrary.wiley.com/doi/abs/10.1111/ropr.12366)

In this article, Angelika Hilbeck and Eva Gelinksy observe how "Many of the pros and cons presented are known from the debate around the first generation of genetic engineering techniques. However, what is new is the markedly sharpened tone with which the advocates of the new techniques are speaking out. Furthermore, their highly polarised position dominates the media reporting of the new techniques and of the ECJ judgement." However, the authors conclude that the advocates of deregulation "fail to differentiate between product development and risk research. The advocates in media and biotechnology science circles appear to believe that the benefits of the techniques are so clear that furnishing reliable evidence is deemed not necessary."
https://enveurope.springeropen.com/articles/10.1186/s12302-018-0182-9

Serge Gutwirth and Nils Van Dijk from the University of Brussels published an article about the ECJ ruling in which they "show how legal, scientific, economic and political arguments are used pell-mell, without much attention to their characteristic differences and consequences. Mixing up the regimes of law, science, innovation and politics is all the more detrimental, since it blurs and undermines the possibilities of a salutary cosmopolitics that would be up to the task of setting the beacons for our future agricultural and food policies". Gutwirth, Serge, Van Dijk, Nils 2020 "Judging New Plant Modification Techniques: Law, Science, Innovation and Cosmopolitics", Théorie du Droit, 1/2020, p123 -145.
https://works.bepress.com/serge_gutwirth/136/

The organisation Testbiotech participated in the RAGES project which also dealt with new methods of genetic engineering and their risks (https://www.testbiotech.org/en/content/rages-subreport-new-genetic-engineering-technologies). See also the Testbiotech's report "Overview of genome editing applications using SDN-1 and SDN-2 in regard to EU regulatory issues" (https://www.testbiotech.org/en/node/2569).

The organisation GMWatch systematically screens peer-reviewed research studies that are NGT-related, and summarise the findings. These findings support the need to regulate the products of new genetic engineering technologies, including gene editing.
See: https://www.gmwatch.org/en/news/latest-news/19223

* **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. The ECJ ruling follows the precautionary principle, and this can stimulate research into alternative and less risky innovation pathways that have the potential to deliver a wide range of benefits for agriculture and society without contributing, for instance, to ever more concentration in the food chain. We do see that claims are made that the ECJ ruling inhibits research. However, the judgement is no ban on research.

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

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

* Please provide concrete examples/data

It depends what kind of research is meant.

NGT-related research to develop new GM crops is a distraction taking resources away from from participatory and decentralised innovation pathways to bring solutions for a resilient and fair food system in the face of climate change and biodiversity loss. Developing highly uniform varieties leads to a loss in plant genetic diversity, which threathens our long term food security, nutrition and food sovereignty.

If NGTs would be deployed on a wide scale, we would need independent research on risks and other societal impacts of the use of NGTs, such as:

- Farmers' rights to save and reproduce seeds and to breed animals, given the patents and licencing agreements on these techniques,
- Further undesirable concentration in the global seed market
- Socio-economic impacts of NGTs
- Unintended modifications in order to better understand side-effects
- Health and environmental impacts

We would also need research to develop standardised detection methods for NGTs in order to guarantee freedom of choice.

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

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

* Please provide concrete examples/data

There is too little independent research on possible risks for environment and health. This leads to more claims by researchers who have an interest in overstating supposed benefits, and fewer researchers willing to do research into risks presented by new GMOs. However, recital 21 of GMO-directive 2001/18 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.” Independent risk research is indispensable for authorities to fulfil their obligation to protect health and environment from possible risks of new GMOs. The many studies showing unintended off-target and on-target effects, and the example of the hornless cow, shows that more safety research and thorough risks assessment is needed.
Most NGT-related research however is applied research with a view to obtain patents and commercial products. The researchers involved in this work have a strong interest in these products getting to market. Research institutes that depend on public funding but have direct ties to industry are among the most vocal advocates of deregulation, and lobby alongside the corporations.

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

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

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

There is a lack of research on the development of sustainable answers to agricultural challenges in the face of climate change and biodiversity crisis. These answers need to integrate knowledge of the locality, knowledlge on soil, promote genetic diversity and biodiversity, rely on a bigger diversity of crops, and strongly reduce dependence on chemical inputs.
Over a decade ago, the global international assessment of agriculture S&T for development (IAASTD) supported a reorientation of research towards more holistic, agroecological approaches.
Reasons why such research remain underfunded are outlined in Vanloqueren (2009). This paper identifies the factors that influence research choices within agricultural research systems. These factors led to "a technological regime and a lock-in situation that hinders the development of agroecological engineering".
See: Vanloqueren G, Baret PV 2009: How agricultural research systems shape a technological regime that develops genetic engineering but locks out agroecological innovations. Res Policy 38:971–983.

There are gaps in research into the impacts on health and environment. Despite claims of precision, a growing body of research shows that unintended effects are frequent which can impact food safety and the environment. For instance, the integration of material that was prepared outside the cell, through the use of 'old' genetic engineering techniques often leads to unintended effects such as deletions or rearrangements. In depth studies into these unintended effects are often missing. Technologies known as "'omics" 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.
See: Heinemann, J.A., Kurenbach, B., Quist, D., 2011. Molecular profiling — a tool for addressing emerging gaps in the comparative risk assessment of GMOs. Environment International 37, 1285–1293;

Katharina Kawall's 2019 article in Frontiers in Plant Science discusses possibilities of genome editing to make the whole genome accessible for changes, which would be much less likely to occur using chemical mutagenesis.
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."
The impacts of these potentially very different new organisms that may be dveloped, on food safety and the environment, should be carefully investigated.

CEO has since long investigated the way companies involved in NGTs have been involved in undermining science and public interest decision making, when it comes to keeping their products on the market. [1] This is why it is crucial that research informing policy and decision making, should be carried out by scientists without conflicts of interest with the industry developing those techniques.[2]

[1] https://corporateeurope.org/en/food-and-agriculture/2015/05/toxic-affair-how-chemical-lobby-blocked-action-hormone-disrupting
https://corporateeurope.org/en/food-and-agriculture/2018/03/what-monsanto-papers-tell-us-about-corporate-science
[2] https://corporateeurope.org/en/food-and-agriculture/efsa/chronology

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

CEO aims to defend the public interest: equality, social justice and a healthy planet. Regarding agricultural applications of new GM techniques in agriculture, seeing previous experiences, it is reasonable to expect economic benefits for big corporations; and disadvantages or risks for society, notably farmers, and the environment.
It is easy to make claims of benefits. Decades of experience with false promises from the biotech sector, including reduced pesticide use, should make regulators wary of new promises. Other promises include resistance to pathogens, to climate change or to substantially increase quantities produced. Corporate R&D strategies usually are the wrong starting point in how they define problems in agriculture. Multinational seed corporations prefer patented, uniform seeds, instead of resilient population bred crops that have a genetically diverse basis and are locally adapted.
Conventional breeding techniques have proven to be more successful in producing plants with complex traits. See: Gilbert, Natasha 2016: Frugal Farming. Old-fashioned breeding techniques are bearing more fruit than genetic engineering in developing self-sufficient super plants.

A situation of deregulation would worsen the situation to a large extent. There would be no risk assessment, monitoring or labelling; and likely further concentration in the seed market.

* **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

New genomic techniques can be useful tools in basic research in contained use conditions.

Regarding agriculture, we see much less potential. Claims of future benefits are easily made, while these are often mere hypes in order to attract investment. GeneWatch UK summarises it well in their submission to the Nuffield Council on Bioethics' Call for Evidence on Genome Editing and Farmed Animals: "Exaggerating the likely delivery and effectiveness of potential future technological applications can lead to opportunity costs when alternative solutions are neglected, and can close down public debate about the best ways of developing knowledge collectively in order to tackle societal problems. Alternative approaches to tackling challenges must be a key part of public engagement with the scientific, regulatory and science policy debates: including questions about what kinds of research should be funded".[1]

The key question is whether the claimed solution is actually an appropriate solution for the problem, one that benefits society and the environment at large. Current problems in agriculture, which are multiple, and the context in which they arise, should be the starting point of the search for solutions.
Genome editing applications however are often the result of incentives in research funding policy, or of a corporate strategy, rather than a response to a societal or environmental challenge. The patent system being extended to living organisms has had a huge influence on the direction taken in public and private R&D investments. A specific innovation pathway is then promoted, while alternative solutions are neglected.
When the goal is not corporate profitability, but climate resilience, poverty alievation, food security or biodiversity increase, then a costly, largely homogenic and patented plant variety is not likely to be the desired solution. Claimed benefits from new GMOs should be proven, and compared to other solutions.

Claimed benefits, portrayed as 'innovation', should not be allowed to be used as an excuse for deregulation of new GM techniques. The tobacco and chemical industry (including Bayer) pushed for an unqualified 'innovation principle' to be introduced at EU level to counteract the precautionary principle and to weaken environmental and other protections.

[1] http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4
/GeneWatch_UK_response_to_the_Nuffield_Council_on_Bioethics_fin.pdf

* **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

Patents are a major obstacle for SMEs to bring new products to in this field. Patents allow the market dominance of the large seed companies to expand further. In 2018 just three companies, Monsanto, DuPont (now merged with Dow AgroSciences) and Syngenta, controlled around 50% of the international seed market.

Large corporations like Bayer-Monsanto and Dow-Dupont (Corteva) have established exclusive agreements with the owners of key CRISPR-patents the Broad Institute, the Massachusetts Institute for Technology, and the University of California, about the use of these patents.
With Corteva being in charge of administering a patent pool of 48 patents related to Crispr/Cas technology, it is allowed to consolidate their market power. [1] [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. [3] Small and medium sized breeders cannot survive in the long-term in a patent system, contrary to a scenario when the plant variety protection system is used.

SMEs may be granted evaluation or research licences to the technology. However, commercial licenses will get very expensive. This means their product will get sold to a larger corporations. In this way, large companies can pick and choose the research they see as most promising commercially, while SMEs take the financial risks of the earlier stages of research.

Testbiotech has found that "for specific applications of genome editing in plant breeding, DowDupont is currently leading with around 60 applications. Bayer/Monsanto has filed about 30 applications and the US company Calyxt, which wants to sell the first soybeans derived from genome editing, has filed more than 20 applications". [4]

[1] https://www.testbiotech.org/sites/default/files/Background%20Patents%20%26%20Genome%20Editing.pdf

[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] https://www.euractiv.com/section/agriculture-food/news/gene-editing-regulation-not-the-biggest-hurdle-for-smes-in-eu-says-academic/

[4] https://www.testbiotech.org/en/news/patent-cartel-large-companies

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

- ○ Yes
- ◉ No

* Please explain why not

No.

Patents on living organisms are a threat to independent farmers, to food security, to agrobiodiversity, and are eventually, a theft from society through the privatization of genetic diversity. Patents on seeds threaten farmer's right to use, exchange and sell saved seeds and propagating material as defined in the definition of "Farmer's Rights" in the International Treaty on Plant Genetic Resources for Food and Agriculture. Patenting plants, animals, or plant and animal varieties, fosters further market concentration and the general power balance in the food chain in favour of large corporations. These corporations – usually also pesticide producers – have no track record of working towards a sustainable agriculture, rather the opposite.

Patents furthermore lead to drastic increase in seed prices, reduced choice in seeds and soaring dependencies for farmers. At a conference organised by the European Coordination Via Campesina on 20 February 2020, Mohammad Torshizi, University of Alberta, explained the impact of patents on the seed market (historical trends in North America): Seed prices have risen significantly in the USA and Canada, since the introduction of GM patented products. This is due to the growing consolidation of the seed market, ie a domination by just a handful of firms. When one firm raises its prices, the others will follow. "Common ownership", when the same investor owns shares in different firms in the same sector, there is much less incentive for competition and seed prices go up.
https://www.eurovia.org/report-ecvc-public-conference-new-gmos-seed-patents-and-farmers-rights-to-seeds/

Patents on living organisms means the privatisation of genetic diversity. Biopiracy refers to "the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions that seek exclusive monopoly control (patents or intellectual property) over these resources and knowledge".
https://www.etcgroup.org/issues/patents-biopiracy

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

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

Developers of genome editing techniques have mobilised plentiful resources to wage a political battle to get NGTs unregulated. This raises strong social, environmental, health and ethical concerns.

In order to investigate the lobbying strategy, CEO has systematically requested lobby documents from the European Commission going back to 2012. In our February 2016 report The Biotech Lobby Push, we exposed industry's attempts to circumvent the EU GMO regulations for NGTs until that moment. This included using trade negotiations and via the 'member state route' by aiming to get unregulated field trials of products of NGTs, despite warnings from the European Commission. [1]

In April 2016 we co-authored an article showing how the European Commission shelved a legal opinion confirming that some new techniques fall under EU GMO law, following pressure from the US government. [2]

In May 2018, we reported on the industry's public relations efforts. The global seed lobby group the International Seed Federation (ISF) produced an internal communication toolkit giving seed companies detailed instructions and PR tricks for communication about new GM techniques. A misleading attempt is made to make it seem that NGTs are just a simple continuation of the classical plant breeding "that humankind has done for thousands of years". The suggestion is made that new technologies add tools available to farmers. However, seed companies often seem to want to avoid breeding new varieties, and prefer to quickly build a new (patented) trait into existing commercial varieties. This has caused a genetic erosion of very serious proportions, with many crops and varieties having disappeared from fields and diets. [3]

In June 2019, CEO published an article showing that half of the experts on EFSA's Gene Drive Working Group, tasked to assess the technology's potential risks, have financial links with organisations developing the technology, and others also have conflicts of interest with a company developing GM insects. [4]

In July 2019 we showed how one year after the ECJ ruling, industry groups and the US Government are keeping up pressure on the European Union to deregulate. [5]

The EU institutions should learn from these experiences. With its new ambitions for a European Green Deal including the Farm to Fork Strategy, the focus of public policies should be on the public interest: environmental protection, food safety, the right to information for consumers and farmers, etc. Broad public dialogues should inspire participatory agricultural strategies that can provide responses to today's challenges.

[1] https://corporateeurope.org/en/food-and-agriculture/2016/02/biotech-lobby-push-new-gmos-escape-regulation
[2] https://corporateeurope.org/en/pressreleases/2016/04/commission-fails-regulate-new-gmos-after-intense-us-lobbying
[3] https://corporateeurope.org/en/food-and-agriculture/2018/05/embracingnature
[4] https://corporateeurope.org/en/2019/06/efsa-gene-drive-working-group-fails-independence-test
[5] https://corporateeurope.org/en/2019/07/us-pressure-eu-de-regulate-new-gm

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

- (●) Yes
- ( ) No

* Please explain

The corporate lobby to get NGTs/NGT-products deregulated is specific to these techniques and products. However, many of the arguments are similar or identical to those used 25 years ago for 'old' GMOs.

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

NGTs/NGT-products pose risks that should be - at least - assessed through a case-by-case risk assessment. The European Network of Scientists for Social and Environmental Responsibility (ENSSER) published a statement in 2017 calling for the continued regulation of NGTs:
“Such techniques give rise to predictable as well as inadvertently generated risks when used in a context of agriculture, conservation or ecological management. Therefore, the products of NGMTs in these contexts (viruses, microbes, plants and animals) should be at least as stringently regulated as the organisms produced with the transgenic methods used in currently commercialized GMOs.” [1]

Eckerstorfer et al conducted a literature survey to identify plants developed by new genomic techniques, with relevance for future agricultural use. The authors conclude that all new techniques can result in unintended changes of different types and frequencies; the precision of the techniques cannot be considered an indication of safety per se; and a case-by-case risk assessment should be conducted for new GM plants. [2]

Off-target effects are of a major concern as they can cause changes in chemistry or protein production, both of which are important for food and environmental safety. [3] Genome editing can also generate unexpected “on-target” effects, where the intended change occurs at the intended location, but has a different outcome than expected. Studies have found that CRISPR can inadvertently cause extensive deletions and complex re-arrangements of DNA [4] which can lead to the misreading of DNA. This can have implications for food safety [5] and for biodiversity. If the chemistry in a genome-edited plant or animal were changed this could produce compounds that are toxic to humans or wildlife.

Gene edited organisms, like old GMOs, can pose risks to the environment once released, while taking it back out of the environment is very difficult or impossible. Gene editing techniques can be used to create gene drives, the goal of which is to change whole ecosystems. This poses unprecedented risks to the environment, ecosystems and communities that depend on them. [6]
Specific risks for food safety include unexpected toxicity and/or allergenicity of food products and food crops produced with these techniques. This applies to old and new GMOs. [7]

Gene editing used on animals often fails and causes suffering and deaths. A study on cloned, gene-edited cattle found that out of 83 pregnancies, 20 calves were born, with 11 calves surviving longer than three months.[8] For those cloned animals that survive, birth defects are common.[9] Defects include premature death, pneumonia, liver failure and obesity. For example, a study on cloned mice found that up to 4 percent of the genes were malfunctioning during pregnancy.[10] Genetic engineering can exacerbate and perpetuate the polluting and cruel system of factory farming. Disease resistance can lead to even more animals in even poorer conditions. [11] Off target effects can also have animal welfare implications.[13] Gene editing should not be applied to animals.

Seed multinationals aim for the highest return on investment, and therefore aim for products that can serve a

market as large as possible. For this to work, mechanization and chemical inputs are required. The GM crops feed into a polluting, unstable food system which does not provide nourishing food. Local food production and farmers disappear in the process.

These concerns lead to our call that the ECJ ruling C-528/16 must be implemented. Case by case risk assessment is needed to know whether gene edited crops are safe to eat and safe for the environment. Labelling is needed to guarantee consumers' and farmers' right to know. Currently seed producers and breeders need to take measures to prevent contamination with GM crops. The costs associated with that are borne by the GM-free sector. This situation would further deteriorate if the current EU GMO legislation would not be enforced for new GM techniques, as breeders would have no way to know what techniques were used for certain breeding material. In a deregulation situation, the chance of contamination would steeply increase. Seed producers would not know whether new GM plants are grown within a distance in which cross-pollination with their own crops is possible.

(List of references in attachment)

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

Risks for the environment and food safety need to be assessed in all cases. Knowledge of the functioning of the genome, gene regulation, etc, is by far not developed enough for these techniques not to create unintended effects. Specific uses such as herbicide tolerance add to the risks. Some concerns are specifically related to a situation in which - as it now appears - the same few seed companies that dominate the global market will control the use of NGTs. A situation in which NGTs and products are deregulated, these concerns would become even bigger.

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

- (●) Yes
- ( ) No

* Please explain

Risks for the environment and food safety are specific to how these techniques work and to what extent they are understood. The deregulation campaign by industry is specifically targeting NGTs/NGT-products.

Because I could not add an attachment to this question, the list of references relevant for the first part of this question is below:

[1] https://ensser.org/publications/ngmt-statement/
[2] https://www.frontiersin.org/articles/10.3389/fbioe.2019.00031/full
[3] Jung, C., Capistrano-Gossmann, G., Braatz, J., Sashidhar, N. & Melzer, S. (2017) Recent developments in genome editing and applications in plant breeding. Plant Breeding 137: 1-9; Zhu, C., Bortesi, L., Baysal, C., Twyman, R.M., Fischer, R., Capell, T., Schillberg, S. & Christou, P. (2017) Characteristics of genome editing mutations in cereal crops. Trends in Plant Science 22: 38–52; Wolt, J.D., Wang, K., Sashital, D. & Lawrence-Dill, C.J. (2016) Achieving plant CRISPR targeting that limits off-target effects. The Plant Genome 9: doi: 10.3835/plantgenome2016.05.0047; Yin, K., Gao, C. & Qiu, J-L. (2017) Progress and prospects in plant genome editing. Nature Plants 3: 17107; West, J. & Gill, W.W. (2016) Genome editing in large animals. Journal of Equine Veterinary Science 41: 1–6.
[4] [Kosicki, M., Tomberg, K., Bradley, A. (2018) Repair of double-strand breaks induced by CRISPR-Cas9 leads to large deletions and complex rearrangements. Nature Biotechnology 36: 765-771.
[5] McClain, S., Bowman, C., Fernández-Rivas, M., Ladics, G.S. & van Ree, R. (2014) Allergic sensitization: food- and protein-related factors. Clinical and Translational Allergy 4: 11.
[6] https://ensser.org/publications/2019-publications/gene-drives-a-report-on-their-science- applications-social-aspects-ethics-and-regulations/
[7] No Consensus on GMO Safety, http://www.enveurope.com/content/27/1/4/abstract
[8] Gao, Y., Wu, H., Wang, Y., Liu, X., Chen, L., Li, Q., Cui, C., Liu, X., Zhang, J. & Zhang, Y. (2017) Single Cas9 nickase induced generation of NRAMP1 knockin cattle with reduced off- target effects. Genome Biology, 18: 13. Retrieved fromhttps://doi.org/10.1186/s13059-016- 1144-4
[9] National Institutes of Health (2017) What are the potential drawbacks of cloning animals? National Human Genome Research Institute. Retrieved from https://www.genome.gov/25020028/cloning-fact-sheet /#al-6; Van Eenennaam, A.L. (2017) Genetic modification of food animals. Current Opinion in Biotechnology 44: 27-34; Keefer, C.L. (2015) Artificial cloning of domestic animals. Proceedings of the National Academy of Sciences 112: 8874–8878.
[10] Humpherys, D., Eggan, K., Akutsu, H., Friedman, A., Hochedlinger, K., Yanagimachi, R., Lander, E.S., Golub, T.R. & Jaenisch, R. (2002) Abnormal gene expression in cloned mice derived from embryonic stem cell and cumulus cell nuclei. Proceedings of the National Academy of Sciences 99: 12889-12894.
[11] Bruce, A. (2017) Genome edited animals: learning from GM crops? Transgenic Research26: 385–398; Eriksson, S., Jonas, E., Rydhmer, L., & Röcklinsberg, H. (2018) Invited review: breeding and ethical perspectives on genetically modified and genome edited cattle. Journal of Dairy Science101: 1–17.
[12] Ishii, T. (2017) Genome-edited livestock: ethics and social acceptance. Animal Frontiers7: 24–32.

* **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

Patents are a major obstacle for SMEs to bring new products to in this field. Patents allow the market dominance of the large seed companies to expand further. In 2018 just three companies, Monsanto, DuPont (now merged with Dow AgroSciences) and Syngenta, controlled around 50% of the international seed market.

Large corporations like Bayer-Monsanto and Dow-Dupont (Corteva) have established exclusive agreements with the owners of key CRISPR-patents the Broad Institute, the Massachusetts Institute for Technology, and the University of California, about the use of these patents.
With Corteva being in charge of administering a patent pool of 48 patents related to Crispr/Cas technology, it is allowed to consolidate their market power. [1] [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. [3] Small and medium sized breeders cannot survive in the long-term in a patent system, contrary to a scenario when the plant variety protection system is used.

SMEs may be granted evaluation or research licences to the technology. However, commercial licenses will get very expensive. This means their product will get sold to a larger corporations. In this way, large companies can pick and choose the research they see as most promising commercially, while SMEs take the financial risks of the earlier stages of research.

Testbiotech has found that "for specific applications of genome editing in plant breeding, DowDupont is currently leading with around 60 applications. Bayer/Monsanto has filed about 30 applications and the US company Calyxt, which wants to sell the first soybeans derived from genome editing, has filed more than 20 applications". [4]

[1] https://www.testbiotech.org/sites/default/files/Background%20Patents%20%26%20Genome%20Editing.pdf

[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] https://www.euractiv.com/section/agriculture-food/news/gene-editing-regulation-not-the-biggest-hurdle-for-smes-in-eu-says-academic/

[4] https://www.testbiotech.org/en/news/patent-cartel-large-companies

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

Patents on living organisms are a threat to independent farmers, to food security, to agrobiodiversity, and are eventually, a theft from society through the privatization of genetic diversity. Patents on seeds threaten farmer's right to use, exchange and sell saved seeds and propagating material as defined in the definition of "Farmer's Rights" in the International Treaty on Plant Genetic Resources for Food and Agriculture. Patenting plants, animals, or plant and animal varieties, fosters further market concentration and the general power balance in the food chain in favour of large corporations. These corporations – usually also pesticide producers – have no track record of working towards a sustainable agriculture, rather the opposite.

Patents furthermore lead to drastic increase in seed prices, reduced choice in seeds and soaring dependencies for farmers. At a conference organised by the European Coordination Via Campesina on 20 February 2020, Mohammad Torshizi, University of Alberta, explained the impact of patents on the seed market (historical trends in North America): Seed prices have risen significantly in the USA and Canada, since the introduction of GM patented products. This is due to the growing consolidation of the seed market, ie a domination by just a handful of firms. When one firm raises its prices, the others will follow. "Common ownership", when the same investor owns shares in different firms in the same sector, there is much less incentive for competition and seed prices go up.
https://www.eurovia.org/report-ecvc-public-conference-new-gmos-seed-patents-and-farmers-rights-to-seeds/

Patents on living organisms means the privatisation of genetic diversity. Biopiracy refers to "the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions that seek exclusive monopoly control (patents or intellectual property) over these resources and knowledge".
https://www.etcgroup.org/issues/patents-biopiracy

A 2015 report by the organisation GRAIN explains how in many countries, more aggressive seed laws are being pushed through trade agreements, adapted to the new demands of the seed and biotechnology industry. GRAIN adds: "Social movements worldwide, especially peasant farmers organisations, have resisted and mobilised to prevent such laws being passed. In many parts of the world, the resistance continues and can even count some victories".

https://www.grain.org/article/entries/5142-seed-laws-that-criminalise-farmers-resistance-and-fightback#Intro

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

E - Safety of NGTs/NGT-products

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

NGTs/NGT-products pose risks that should be - at least - assessed through a case-by-case risk assessment. The European Network of Scientists for Social and Environmental Responsibility (ENSSER) published a statement in 2017 calling for the continued regulation of NGTs:
“Such techniques give rise to predictable as well as inadvertently generated risks when used in a context of agriculture, conservation or ecological management. Therefore, the products of NGMTs in these contexts (viruses, microbes, plants and animals) should be at least as stringently regulated as the organisms produced with the transgenic methods used in currently commercialized GMOs.” [1]

Eckerstorfer et al conducted a literature survey to identify plants developed by new genomic techniques, with relevance for future agricultural use. The authors conclude that all new techniques can result in unintended changes of different types and frequencies; the precision of the techniques cannot be considered an indication of safety per se; and a case-by-case risk assessment should be conducted for new GM plants. [2]

Off-target effects are of a major concern as they can cause changes in chemistry or protein production, both of which are important for food and environmental safety. [3] Genome editing can also generate unexpected “on-target” effects, where the intended change occurs at the intended location, but has a different outcome than expected. Studies have found that CRISPR can inadvertently cause extensive deletions and complex re-arrangements of DNA [4] which can lead to the misreading of DNA. This can have implications for food safety [5] and for biodiversity. If the chemistry in a genome-edited plant or animal were changed this could produce compounds that are toxic to humans or wildlife.

Gene edited organisms, like old GMOs, can pose risks to the environment once released, while taking it back out of the environment is very difficult or impossible. Gene editing techniques can be used to create gene drives, the goal of which is to change whole ecosystems. This poses unprecedented risks to the environment, ecosystems and communities that depend on them. [6]
Specific risks for food safety include unexpected toxicity and/or allergenicity of food products and food crops produced with these techniques. This applies to old and new GMOs. [7]

Gene editing used on animals often fails and causes suffering and deaths. A study on cloned, gene-edited cattle found that out of 83 pregnancies, 20 calves were born, with 11 calves surviving longer than three months.[8] For those cloned animals that survive, birth defects are common.[9] Defects include premature death, pneumonia, liver failure and obesity. For example, a study on cloned mice found that up to 4 percent of the genes were malfunctioning during pregnancy.[10] Genetic engineering can exacerbate and perpetuate the polluting and cruel system of factory farming. Disease resistance can lead to even more animals in even poorer conditions. [11] Off target effects can also have animal welfare implications.[13] Gene editing should not be applied to animals.

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

- (●) Yes
- ( ) No

* Please explain

To protect the environment and human health, the ECJ ruling has to be implemented. Products of NGTs should be risk assessed on a case by case basis, under a thorough protocol. These techniques are new and do not have a history of safe use. For instance, the possibilities to alter the genome resulting in novel genetic combinations are more numerous. Kawall, K., 2019. New possibilities on the horizon: genome editing makes the whole genome accessible for changes. Frontiers in Plant Science 10, 525

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

F - Ethical aspects of NGTs/NGT-products

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

The ethical questions raised by New GM are manifold and include impacts on environment and biodiversity, impacts on health, power relations, animal welfare issues, farmer and consumer choice, opportunity costs. The ethical aspects of NGTs become more pronounced in the context of the deregulation attempts by their developers.

The context in which these technologies are developed, and with what goal the products are designed, are highly relevant for ethical questions. This involves looking at how they are connected to production systems, visions of the future, or how they can reproduce inequalities.[1] For instance, when considering the deployment new GM techniques, the consequences for different actors need to be assessed: Who will benefit, who will carry the risks?

Here, we cannot avoid looking at the past experience with biotech crops. 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 and human suffering.

This experience shows the values being displayed by biotech corporations are: profit-driven, irresponsible, competition, control, polluting, not respecting human health or right to a livelihood. This is in direct opposition with values defended by civil society and sustainable farming organisations, which include environmental protection, social justice, health protection, solidarity, equality, freedom of choice, etc.

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

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 rules.

Genome editing in farm animals is often associated with animal suffering. The research is directed to applications making animals sustain cruel factory farming conditions better, rather than improving their welfare. Applying GM techniques, including genome editing, to animals, should be forbidden.

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. Dominance of a handful of firms on the global food chain is highly dangerous and undemocratic.

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 will get the benefit of public and private funding? Other innovation views are currently getting marginalized, like agroecology, agroforestry, regenerative agriculture, etc.

Ethical aspects also include the potential for these technologies to be used to produce gene drives or biological warfare, with potentially devastation consequences.

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

[1] Herrero, Wickson, Binimelis et al: https://link.springer.com/content/pdf/10.1007/s41055-017-0014-4.pdf

Sources:
Preston, Christopher J., and Fern Wickson. "Broadening the lens for the governance of emerging technologies: Care ethics and agricultural biotechnology." Technology in Society 45 (2016): 48-57.

Hicks, D.J., 2017.Genetically modified crops, inclusion, and democracy. Perspectives on Science, 25(4), pp. 488-520.

Daño, Elenita C. Potential socio-economic, cultural and ethical impacts of GMOs: Prospects for socio-economic impact assessment. Third World Network, 2007. http://genok.org/wp-content/uploads/2013/04/Chapter-20.pdf

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

- (●) Yes
- ( ) No

* Please explain

Many concerns related to NGTs are similar to those regarding 'old' GMOs. However, the current deregulation push in combination with unsubstantiated claims of providing solutions to today's biggest challenges, makes it especially important to scrutinise how the political debate around the regulation of these techniques evolves, in particular, who gets most access to decision makers and why.

Please upload any supporting documentation for this section here

The maximum file size is 1 MB

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 is the precondition for freedom of choice for consumers and economic operators. 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.

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. The ECJ ruling brought legal certainty for economic operators and consumers.

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.

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.
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.

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

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

H - Final question

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

- (●) Yes
- ( ) No

Please provide your comments here

- At the beginning of this questionnaire, the term „NGT/NGT-products“ is defined as: techniques that are capable of altering the genetic material of an organism and which have emerged or have been developed since 2001. This is not correct. The ECJ clarified that techniques that need to be regulated did not have a history of safe use in 2001; they may have started to be developed before 2001.

- In previous texts of the Farm to Fork Strategy, it is written that the Commission is carrying out a study to assess "the potential of new genomic techniques to improve sustainability along the food supply chain". This was not the mandate the EU Commission has received by the Council. The Council's mandate has been focused on „practical questions" with regard to the implementation of EU GMO law for new GMOs. The Council has asked for guidance on that, not for an assessment of potential benefits of NGTs, which can easily be overstated while alternative innovation pathways are neglected.

- Full 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 old and new.

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

Contact

SANTE-NGT-STUDY@ec.europa.eu