

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

B a c k g r o u n d

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 / E C) .

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 a f t e r 2 0 0 1 .

I n s t r u c t i o n s

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

[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 as 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

Slow Food

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

Global food movement - consumers, farmers, cooks

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

* Please explain why not

The sustainability of NGT has not been yet assessed, thus using products or organisms that haven't been assessed in regards to environmental, economic or social impacts is not supported by Slow Food.

Our members are particularly focused on this issue and fight the spread of any organism obtained by adopting genetic techniques and, in this particular case, by NGT.

The sustainability policies followed by our Association involve all members and are not exclusively related to agronomic and environmental aspects. Slow Food closely follows the relationships between product, producer and territory with great support for the conservation of biodiversity which, in addition to being very important from a cultural point of view, also represents an element of resilience to climate change.

The attention to the sovereignty of farmers is at the basis of the development of all our projects; sovereignty also means the ability to collect and preserve seeds, to perpetuate their value in the future and to strengthen all traditions linked to the conservation of cultural heritage, also in relation to the conservation of traditional agricultural landscapes. This aspect is completely opposite to any issue related to patenting seeds, varieties, races, and so on.

*** 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

Our members are particularly focused on this issue and follow the activity to fight the spread of any organism obtained by adopting genetic techniques and, in this particular case, by NGT.

The sustainability policies followed by our Association involve all members and are not exclusively related to agronomic and environmental aspects. Slow Food closely follows the relations between product, producer and territory with great support for the conservation of biodiversity which, in addition to being very important from a cultural point of view, also represents an element of resilience to climate change.

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NGT-products fall under the provisions in Directive 2001/18/EC, and we expect the European Commission and national authorities to ensure the provisions of this Directive are fully enforced, including with respect to imports. The onus should NOT lie on seed savers, breeders, or farmers who do not wish to use these products to put in place their own measures. The costs of doing so could be ruinous, especially to small operators, and would therefore represent a significant threat to the conservation and development of plant genetic diversity and the achievement of the EU and Member State's commitments under the Convention on Biological Diversity and the Paris Agreement.

* 2 bis. Have you encountered any challenges?

- Yes
 No

* 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

Transparency and traceability are preconditions for the implementation of the EU's GMO laws (directive 2001 /18, regulations 1829 and 1830/2003) as well as the strict application of regulation 611/2011. The implementation of these laws ensures transparency - and thus having ensured free choice for consumers, farmers, breeders, and food processors.

In opposing and protecting against the unintentional use of products obtained through genetic modification techniques, we believe that a system that is absolutely essential for clarity and transparency towards the consumer derives from a label able to tell the truth and to reveal to the consumer every detail about the way of production and the territory of origin. Slow Food has developed the 'narrative label' and it contains few but fundamental information on everything the consumer has the right to know even in relation to any genetic manipulation of the variety or animal breed. Only this transparency guarantees the possibility of exercising a free choice, which is the right of every consumer, and avoid any unintentional consumption. The free movement of goods at European level must be able to guarantee the consumer's right to make an informed choice. Only true, fair and complete labelling guarantees the truth for the consumer and the possibility that the choice is made on the basis of genuine knowledge of the origin of the products and the production methods.

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

- Yes
 No

* Please provide details

Transparency and traceability are preconditions for the implementation of the EU's GMO laws (directive 2001 /18, regulations 1829 and 1830/2003) as well as the strict application of regulation 611/2011. The implementation of these laws ensures transparency - and thus having ensured free choice for consumers, farmers, breeders, and food processors.

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

Please also see question 8 specifically on labelling

- Yes
 No
 Not applicable

* Please explain why not

Our members are firmly convinced of the political vision behind our association which in no way envisages an engineered agriculture, both from a genetic and technical point of view. Our association has been and still is against any form of genetic modification from the very beginning and believes that the policy of spreading hybrid seeds is also at the root of a wrong path that breaks the link between genetics and territory and deprives every farmer of sovereignty over his own seeds and his own agriculture. All these issues are strongly linked to models of industrialised agricultural development that do not respect natural resources, especially non-renewable ones.

Our association continues to support the opportunity for genetically engineered organisms (GMOs and NGTs) to remain confined to the same legislation and to be restricted through the precautionary principle in terms of adoption and dissemination. No loosening of control measures against these organisms that pose a serious risk to biodiversity and make no real contribution to agricultural production is acceptable for Slow Food.

- * 5 bis. What challenges have you encountered?

No loosening of control measures against these organisms that pose a serious risk to biodiversity and make no real contribution to agricultural production is acceptable for Slow Food.

- * **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

- * Do you have suggestions on possible traceability strategies and/or methods?

- Yes
- No

- * Please describe

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-authorized 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-authorized NGTs 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 crops 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?

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.

*

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

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, such as those practised and promoted by our Association.

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 unanswered questions related to risks of NGT and in general to GMO-plants.

*** 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

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

- Yes
- No
- Not applicable

* Please explain why not

Research that would provide benefits to our Association 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 licencing 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

* **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 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 fulfil 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

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.

Our association fights genetic engineering techniques on a number of cultural but also extremely technical bases. The release in cultivation of genetic engineered organisms (NGTs), in fact, still poses a series of uncertain aspects; the improvements underlined by multinationals and research centres, mainly focused on disease resistance, are not sufficiently evaluated 'in time' and 'in space'. In detail, for the first aspect, attention has never been paid to assessing the stability of genome modification determined by genetic engineering. Stability means confirmation that the laboratory result is stable over the years (in time), with no regression to the original forms that would cause substantial damage to farmers. As far as the evaluation 'in space' is concerned, it is known that any plant finding must undergo a period of serious evaluation in different growing environments because environmental pressure plays an important role. From the biological point of view, in fact, the environment determines a non-secondary influence in the expression of genetic traits and the genetic improvement activity carried out in a laboratory, operated exclusively through the manipulation of a few genes, does not allow sufficient guarantees to be acquired.

Beyond these critical aspects highlighted by genetic engineering techniques, the whole context of extreme uncertainty determined by the risk of biodiversity contamination that could be irremediably lost in the long run remains valid and unresolved by the scientific research activity.

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

The sustainability of NGT has not been yet assessed, thus using products or organisms that haven't been assessed in regards to environmental, economic or social impacts is not supported by Slow Food.

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 crisis, 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 editing 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 systemic problems, perpetuating a harmful system of agriculture and preventing real solutions.

* **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

Slow Food does not believe there are any benefits for SME/small scale operators to develop NGT and NGT products.

* **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.

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**

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 to our Association..

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.

Our 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

These challenges are specific to NGT products since, without proper regulation, these would be difficult to detect and identify, without labelling.

*** 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 that NGT pose to the environment and the balanced ecosystem, in addition to the fact that GMO and NGT, once released into the environment, cannot be retracted.
- 2) The fact 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 unprecedented risk to the environment and ecosystems specific to NGT. In addition, they might disseminate in natural populations since they are more likely to reproduce.

Concerns on human health:

The fundamental concern regarding GMOs, including NGT is that genetic engineering can unintentionally interfere with the gene expression of an organism and/or with complex biochemical pathways within an organism. Consequently, the biological and biochemical characteristics of the organism might be changed in a way that impacts human and animal health and/or the environment.

There are serious risks to health from consumption of products of NGTs, which have not been investigated scientifically. Risks include unexpected toxicity and/or allergenicity of food products and food crops produced with these techniques. Many animal feeding studies with first-generation transgenic GM crops showed unexpected toxicity and/or allergenicity from these novel foods It is likely that the same unexpected risks also arise from NGT.

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 !

Despite claims of increased “precision” relative to the old techniques of genetic engineering, an increasing number of peer-reviewed papers has demonstrated the potential of these new techniques to also produce numerous unintended and unpredictable ‘off-target’, as well as ‘on-target’ effects.

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

These challenge arise if NGT are NOT regulated under GMO law.

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

- Yes
 No

- * Please explain why not

Many of these challenges are the same as "old" GMOs.

- * **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

The sustainability of NGT has not been yet assessed, thus using products or organisms that haven't been assessed in regards to environmental, economic or social impacts is not supported by Slow Food.

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

- Yes
 No

- * Please describe and provide concrete examples/data

The sustainability of NGT has not been yet assessed, thus using products or organisms that haven't been assessed in regards to environmental, economic or social impacts is not supported by Slow Food.

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E - Safety of NGTs/NGT-products

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

The safety of NGT has not been yet assessed, thus using products or organisms that haven't been assessed in regards to environmental, economic or social impacts is not supported by Slow Food.

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

- Yes
 No

* Please explain

The safety of NGT has not been yet assessed, thus using products or organisms that haven't been assessed in regards to environmental, economic or social impacts is not supported by Slow Food.

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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**

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 the loss biodiversity which our long-term food security depends on.

This experience shows that values being displayed by biotech corporations are often: profit-driven, irresponsible, cooperation, competition, control. Slow Food defends values such as environmental justice & protection, health protection, solidarity, equality, freedom of choice for farmers and citizens.

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.

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.

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.

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

- Yes
 No

* Please explain

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 the loss biodiversity which our long-term food security depends on.

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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 Functioning 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.

Latest EU surveys on GMOs

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

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

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

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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

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 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)

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