Contribution ID: cc5ff9e8-d793-48a8-9723-c85d71477a7b
Date: 15/05/2020 14:59:53

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

European Environmental Bureau (EEB)

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

Environmental sustainability

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

We are an environmental CSO and do not conduct research or other activities related to NGTs

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

* **3. Are you aware of initiatives in your sector to develop, use, or of plans to use NGTs/NGT-products?**
  - Yes
  - No
  - (•) Not applicable

* **4. Do you know of any initiatives in your sector to guard against unintentional use of NGT-products?**
  - Yes
  - No
  - (•) Not applicable

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

Please also see question 8 specifically on labelling

- Yes
- No

- (●) Not applicable

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

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

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

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

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

The EEB does not have expertise in this area, but we support the position of other NGOs such as Friends of the Earth Europe, BirdLife Europe, Testbiotech, Health and Environment Alliance, EURO-COOP, Pesticide Action Network Europe, Food & Water Europe and more.

* **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

* **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

From the point of an environmental organisation, there is no need to increase NGT-related research as the proven benefits are absent and

* **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

The EEB does not have expertise in this area, but we support the position of other NGOs such as Friends of the Earth Europe, BirdLife Europe, Testbiotech, Health and Environment Alliance, EURO-COOP, Pesticide Action Network Europe, Food & Water Europe and more.

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

- ◉ Yes
- ○ No
- ○ Not applicable

* Please provide concrete examples/data

There is a general challenge of NGT-related research being driven by commercial motivations while failing to prioritise the fundamental precautionary principle. Too little of the research is driven by public interest but rather by private/economic interests..

Additionally, researchers themselves might have conflict of interest in NGT research. This bias in research results, thus jeopardising the impartiality and objectivity of NGT-related research. This is exemplified by a number of recent statements in favour of NGTs made by scientific institutions, such as the statement by the Vlaams Instituut voor Biotechnologie (1) (VIB) signed by researchers from hundred scientific institutions and research centers, the statement by the European Academies of Science Advisory Council (2)(EASAC) just recently circulated in the EU Parliament, the statement by the Group of Chief Scientific Advisors (3)(SAM) as well as the report by the German Leopoldina (4). On a closer look, several of the authors and experts behind those reports applied for patents or are involved in the development for specific applications (see for example Testbiotech's report on the issue: https://www.testbiotech.org/content/vertrauen-in-die-wissenschaft).

The lack of independent research on possible risks for environment and health, creates a situation where perceived potential and opportunities of NGTs might be exaggerated compared to risks. This goes against the GMO-directive 2001/18 which stipulates that "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 such 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.
It is essential that any research done on NGTs in public research institutions is driven by a motivation to further broad societal interests (environment, health, crop resilience) rather than specific profit interests of individuals or companies. The precautionary principle must be the central guiding principle for all such research to minimise the risk of severe unintended consequences of the application of NGTs.

We believe that the focus of the research is on developing and applying new technology while the focus should be on protecting human and animal health from NGT-related risks, as well as examining possible negative environmental impacts.

References:
(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

The EEB does not have expertise in this area, but we support the position of other NGOs such as Friends of the Earth Europe, BirdLife Europe, Testbiotech, Health and Environment Alliance, EURO-COOP, Pesticide Action Network Europe, Food & Water Europe and more.

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 EEB does not have expertise in this area, but we support the position of other NGOs such as Friends of the Earth Europe, BirdLife Europe, Testbiotech, Health and Environment Alliance, EURO-COOP, Pesticide Action Network Europe, Food & Water Europe and more.

*** 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 describe and provide concrete examples/data

NGTs may provide some benefits to the future sustainability of agriculture, however the EEB does not believe this technology is either sufficient or essential to achieve sustainable food systems. NGTs are targeting single traits to address single challenges and are unlikely to be able to catch up with the complexity and interconnectedness of agricultural challenges to the environment and human health. What is needed is a systemic change of the entire food system as concluded by the Commission's European Green Deal and numerous reports, for example IPES-Food (1).
One example of the limited scope of NGT-based solutions is the use of CRISPR/Cas to boost the muscle mass of cattle and pigs (2). While this is desirable for the producer who can produce more meat, it comes with significant animal welfare implications. And it does not address GHG emissions, biodiversity degradation and human rights violations associated with deforestation caused by the production of feed imported from abroad. It doesn't solve problems with nutrient overload in air and water nor questions of animal welfare. It also does not address the extremely inefficient feed-to-food ratio of these animals which makes meat and dairy some of the most problematic food items in terms of global land use change and food availability. All of these issues can only be addressed meaningfully through a comprehensive and integrated food system approach changing production, consumption and everything in between.

References:
(1): http://www.ipes-food.org/pages/CommonFoodPolicy
(2): https://www.testbiotech.org/en/limits-to-biotech/super-muscly-pigs

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

In the context of a system-wide approach, addressing environmental sustainability and human health in an integrated and long-term oriented manner, NGTs could potentially be used to solve certain issues that are hard to solve by other means. Cattle that produce less methane, for example, might be desirable in a food system where livestock production has transitioned into extensive pasture-based production as part of mixed farming systems, provided that all precautionary measures have been taken in the development.
Potential benefits can only be realised if the development and application of the technology are strictly regulated to ensure transparency as well as safety for environment and health, undergoing mandatory approval process, risk assessment and labelling before any market approval is issued. It is crucial that the industry-driven (non-legal) so-called "innovation principle" does not undermine the (legal) precautionary principle and legal requirements to protect people and the environment.

* Are these benefits/opportunities specific to NGTs/NGT-products?

- ○ Yes
- ◉ No

* Please explain why not

Not based on current knowledge. The only benefit specific to NGTs is the capacity to create new crop varieties or animal breeds faster than through conventional breeding. However, many benefits that can be achieved through breeding or NGTs can also be achieved through other means. Currently we are not aware of striking examples showing unique benefits which cannot be achieved through conventional breeding and /or alternative means.

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

- ○ Yes

- [x] No

* Please explain why not

The EEB does not have expertise in this area, but we support the position of other NGOs such as Friends of the Earth Europe, BirdLife Europe, Testbiotech, Health and Environment Alliance, EURO-COOP, Pesticide Action Network Europe, Food & Water Europe and more.

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

- [ ] Yes
- [x] No

* Please explain why not

The EEB does not have expertise in this area, but we support the position of other NGOs such as Friends of the Earth Europe, BirdLife Europe, Testbiotech, Health and Environment Alliance, EURO-COOP, Pesticide Action Network Europe, Food & Water Europe and more.

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?**

- [x] Yes
- [ ] No

* Please describe and provide concrete examples/data

The EEB does not have expertise in this area, but we support the position of other NGOs such as Friends of the Earth Europe, BirdLife Europe, Testbiotech, Health and Environment Alliance, EURO-COOP, Pesticide Action Network Europe, Food & Water Europe and more.

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

- [x] Yes
- [ ] No

* Please explain

The EEB does not have expertise in this area, but we support the position of other NGOs such as Friends of the Earth Europe, BirdLife Europe, Testbiotech, Health and Environment Alliance, EURO-COOP, Pesticide Action Network Europe, Food & Water Europe and more.

*

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

Concerns related to nature conservation, protection of the environment, human and animal health:

(1) Agronomic resilience and NGTs
Agricultural systems need to be increasingly resilient to extreme weather exacerbated by climate change (IPCC, 2019: Climate Change and Land) and to pests, diseases and parasites (considering the Commission' s ambitions of reducing pesticide use). For this, agrobiodiversity can be a good solution for adaptation to many of these stressors. And genetic engineering has led to more, not less, use of agro-chemicals since its adoption. It is far from certain whether NGTs will change this trend.
Evidence from research and practice suggests that a food production system that is able to adapt to a changing climate, needs an approach based among others on short supply chains, soil improvement, crop genetic diversity and locally adapted varieties that respect farmers' and breeders' rights. Classical breeding programmes have already made substantial advances in this respect, while evidence that simple traits brought in through genetic engineering contribute to drought-tolerance, for instance, is lacking.
Finally, current trends of commercialisation of seeds by multinational companies might challenge the autonomy and economic resilience of farmers, as it risks making the farmers dependent on these companies for their livelihood.

(2) Improvements provided by NGTs risk being too little too late as an isolated solution and risk diverting attention away from real solutions
As explained in question 17 and below, the great uncertainty about potential unintended consequences of NGTs will require a strong precautionary approach to the licensing of NGTs for use in agriculture. Such a process of careful risk assessments based on credible and thorough scientific studies and followed by cautious legislation takes a long time. But we need to begin addressing the health and environmental problems caused by agriculture immediately. Additionally, single NGT-applications are unlikely to be able to address all the changes needed within each type of plant and animal so the usefulness of resulting products will be inadequate when finally developed and released. Therefore we run the risk of being late with an inadequate answer if we mainly count on NGTs to solve our challenges in agriculture.

(3) Four concerns that must be addressed by risk assessments
- Changes in plant ingredients such as oil, protein, starch or other biologically active ingredients (such as plant estrogens or vitamins) can have unintended effects on mammalian wildlife species, birds and insects as well as their related food webs.
- Changes in plant composition can also affect communication and interactions with organisms which do not feed on them but are associated in other ways, e.g. cooperation (such as beneficial insects, e.g. predators or pollinators), or symbionts (such as the plant's microbiome) or organisms that attack the plants (so-called 'pest' insects).
- The risk of gene flows from plants where enhanced fitness is intended by the trait (e.g. increased drought tolerance, resistance to pest infestation or to plant diseases caused by viruses or fungi) to natural populations in surrounding habitats. Risk assessment also has to take into account effects that may unintentionally enhance fitness in unexpected ways.
- Genetically engineered organisms' ability to spread in the environment. If this cannot be ruled out, the uncertainties would in many cases be so great that they would outweigh other considerations and render risk assessment inconclusive. Therefore, organisms derived from NGT applications able to persist and

propagate in the environment should undergo especially detailed environmental risk assessment.

See for example the cases of inedible carmelina, the 'Monarch Fly', hornless cattle and more here: https://www.testbiotech.org/en/limits-to-biotech

Concerns related to consumer interest:

One of the promises of the European Green Deal is to increase transparency and consumer information in the food system. To achieve this, current GMO legal provisions (including labelling, mandatory approval process and risk assessment) must continue to apply to NGT-products. These standards must not be questioned by free trade agreements.
See question 28 for more.

Concerns related to ethical questions:

There are multiple ethical concerns related to NGTs for which reason there is an entire question about this. See our full answer in question 26.

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

In the situation where NGTs are not regulated under the current GMO directive. Under such circumstances, there are risks that the precautionary approach would not be applied adequately.

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

- ○ Yes
- ◉ No

* Please explain why not

Many of the concerns apply to all GM technologies, but NGTs are particularly worrying because they can surpass many previous technical barriers to GM and especially if it is not regulated under the GMO Directive.

*** 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 EEB does not have expertise in this area, but we support the position of other NGOs such as Friends of the Earth Europe, BirdLife Europe, Testbiotech, Health and Environment Alliance, EURO-COOP, Pesticide Action Network Europe, Food & Water Europe and more.

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

- ◉ Yes
- ○ No

* Please describe and provide concrete examples/data

The EEB does not have expertise in this area, but we support the position of other NGOs such as Friends of the Earth Europe, BirdLife Europe, Testbiotech, Health and Environment Alliance, EURO-COOP, Pesticide Action Network Europe, Food & Water Europe and more.

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**

Given the risks highlighted in response to question 21, the EEB finds that NGTs can only be considered safe in a limited set of organisms subject to thorough risk assessment and regulation. Under any other circumstances, NGTs cannot be considered safe. We believe the precautionary principle should always be applied.

Answer to question 21:

Concerns related to nature conservation, protection of the environment, human and animal health:

(1) Agronomic resilience and NGTs
Agricultural systems need to be increasingly resilient to extreme weather exacerbated by climate change (IPCC, 2019: Climate Change and Land) and to pests, diseases and parasites (considering the Commission' s ambitions of reducing pesticide use). For this, agrobiodiversity can be a good solution for adaptation to many of these stressors. And genetic engineering has led to more, not less, use of agro-chemicals since its adoption. It is far from certain whether NGTs will change this trend.
Evidence from research and practice suggests that a food production system that is able to adapt to a changing climate, needs an approach based among others on short supply chains, soil improvement, crop genetic diversity and locally adapted varieties that respect farmers' and breeders' rights. Classical breeding programmes have already made substantial advances in this respect, while evidence that simple traits brought in through genetic engineering contribute to drought-tolerance, for instance, is lacking.
Finally, current trends of commercialisation of seeds by multinational companies might challenge the autonomy and economic resilience of farmers, as it risks making the farmers dependent on these companies for their livelihood.

(2) Improvements provided by NGTs risk being too little too late as an isolated solution and risk diverting attention away from real solutions
As explained in question 17 and below, the great uncertainty about potential unintended consequences of NGTs will require a strong precautionary approach to the licensing of NGTs for use in agriculture. Such a process of careful risk assessments based on credible and thorough scientific studies and followed by cautious legislation takes a long time. But we need to begin addressing the health and environmental problems caused by agriculture immediately. Additionally, single NGT-applications are unlikely to be able to address all the changes needed within each type of plant and animal so the usefulness of resulting products will be inadequate when finally developed and released. Therefore we run the risk of being late with an inadequate answer if we mainly count on NGTs to solve our challenges in agriculture.

(3) Four concerns that must be addressed by risk assessments
- Changes in plant ingredients such as oil, protein, starch or other biologically active ingredients (such as plant estrogens or vitamins) can have unintended effects on mammalian wildlife species, birds and insects as well as their related food webs.
- Changes in plant composition can also affect communication and interactions with organisms which do not feed on them but are associated in other ways, e.g. cooperation (such as beneficial insects, e.g. predators or pollinators), or symbionts (such as the plant's microbiome) or organisms that attack the plants (so-called 'pest' insects).
- The risk of gene flows from plants where enhanced fitness is intended by the trait (e.g. increased drought tolerance, resistance to pest infestation or to plant diseases caused by viruses or fungi) to natural populations in surrounding habitats. Risk assessment also has to take into account effects that may unintentionally enhance fitness in unexpected ways.
- Genetically engineered organisms' ability to spread in the environment. If this cannot be ruled out, the uncertainties would in many cases be so great that they would outweigh other considerations and render risk assessment inconclusive. Therefore, organisms derived from NGT applications able to persist and propagate in the environment should undergo especially detailed environmental risk assessment.

See for example the cases of inedible carmelina, the 'Monarch Fly', hornless cattle and more here: https://www.testbiotech.org/en/limits-to-biotech

Concerns related to consumer interest:

One of the promises of the European Green Deal is to increase transparency and consumer information in the food system. To achieve this, current GMO legal provisions (including labelling, mandatory approval process and risk assessment) must continue to apply to NGT-products. These standards must not be questioned by free trade agreements.
See question 28 for more.

Concerns related to ethical questions:

There are multiple ethical concerns related to NGTs for which reason there is an entire question about this. See our full answer in question 26.

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

- (●) Yes
- ( ) No

* Please explain

The EEB does not have expertise in this area, but we support the position of other NGOs such as Friends of the Earth Europe, BirdLife Europe, Testbiotech, Health and Environment Alliance, EURO-COOP, Pesticide Action Network Europe, Food & Water Europe and more.

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**

It is crucial to evaluate the desirability of NGTs and GTs in general as an option, based on potential benefits and risks. NGTs are inherently characterised by uncertainties and sometimes unintended consequences that are hard to predict or even to detect. Their interaction with the environment and human health are inherently difficult to map, as elaborated in question 21. Furthermore, as discussed in question 17, NGTs are unlikely to be an adequate answer to the multiple environmental and health challenges posed by our current food system. This requires profound system change. Lastly, the targeted and accelerated changes made possible by NGTs have implications for a larger discussion about what can be considered 'natural' in the world, not the least if genetic material spreads from GMOs to wild populations and this calls for a wider public debate. For these reasons it is clear that NGTs are an approach with limited potential and considerable uncertainty about associated risks. Based on this, it is of paramount ethical importance that any development and application of NGTs is used only to a limited extent and under specific circumstances. NGTs must contribute to broad societal benefits (and not to narrow commercial interests) and be subject to thorough regulation and risk assessments based on the precautionary principle.
It is also of ethical relevance to have a public debate about intellectual properties within the field. From an ethical perspective, it is inherently questionable to commercialise and patent common goods such as the genetic diversity of our nature and the conditions of this market should be subject to broad public and political debate.
The issue of non-retrievability of GMO entails that every decision of releasing NGT-organisms/products into the environment under the ethical question of "can we expect the generations following to live with the consequences". This is related to the precautionary principle. Having the precautionary principle as one of the core principles for EU-environmental law, it must be applied here too when looking at the problem of lacking traceability and potentially lacking retrievability.

Finally, a major ethical issue relates to animal welfare and protection. There are already several publications reporting on NGTs applied to livestock animals. These include applications that can be used on farm animals in order to produce more meat, milk with changed composition, hornless cows, virus-resistant pigs and animals that are adapted to climate change. Interests in marketing these animals can lead to serious conflicts with well-established social and ethical standards and with the values of European society.

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

- (●) Yes
- ( ) No

* Please explain

It is crucial to evaluate the desirability of NGTs and GTs in general as an option, based on potential benefits and risks. NGTs are inherently characterised by uncertainties and sometimes unintended consequences that are hard to predict or even to detect. Their interaction with the environment and human health are inherently difficult to map, as elaborated in question 21. Furthermore, as discussed in question 17, NGTs are unlikely to be an adequate answer to the multiple environmental and health challenges posed by our current food system. This requires profound system change. Lastly, the targeted and accelerated changes made possible by NGTs have implications for a larger discussion about what can be considered 'natural' in the world, not the least if genetic material spreads from GMOs to wild populations and this calls for a wider public debate. For these reasons it is clear that NGTs are an approach with limited potential and considerable uncertainty about associated risks. Based on this, it is of paramount ethical importance that any development and application of NGTs is used only to a limited extent and under specific circumstances. NGTs must contribute

to broad societal benefits (and not to narrow commercial interests) and be subject to thorough regulation and risk assessments based on the precautionary principle.
It is also of ethical relevance to have a public debate about intellectual properties within the field. From an ethical perspective, it is inherently questionable to commercialise and patent common goods such as the genetic diversity of our nature and the conditions of this market should be subject to broad public and political debate.
The issue of non-retrievability of GMO entails that every decision of releasing NGT-organisms/products into the environment under the ethical question of "can we expect the generations following to live with the consequences". This is related to the precautionary principle. Having the precautionary principle as one of the core principles for EU-environmental law, it must be applied here too when looking at the problem of lacking traceability and potentially lacking retrievability.

Finally, a major ethical issue relates to animal welfare and protection. There are already several publications reporting on NGTs applied to livestock animals. These include applications that can be used on farm animals in order to produce more meat, milk with changed composition, hornless cows, virus-resistant pigs and animals that are adapted to climate change. Interests in marketing these animals can lead to serious conflicts with well-established social and ethical standards and with the values of European society.

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**

Labelling should be mandatory and measures should be taken to protect non-GM production of seeds, food and feed in order to enable freedom of choice for breeders, farmers and consumers. Current EU legislation provides for freedom of choice. One of the promises of the European Green Deal is to increase transparency and consumer information in the food system. To achieve this, current GMO legal provisions (including labelling, mandatory approval process and risk assessment) must continue to apply to NGT-products. These standards must not be questioned by free trade agreements.

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 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