

# 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

Arche Noah - Association for the conservation and development of crop diversity (Austria) Transparency Registry number: 50668704394-89

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

Plant genetic resources conservation and management, biodiversity, agriculture,

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

Bese Természetvédelmi Egyesület - Bese Nature Conservation Society representing the Hungarian Magház (Seedhouse) Network (Hungary); Hrvatski savez udruga ekoloških proizvođača - Croatian Organic Farmers' Alliance (Croatia); Froesamlerne – Danish Seed Savers (Denmark); Maadjas – Estonian Seed Savers (Estonia); Peliti – Greek Seed Savers' Organisation (Greece); Latvijas Permakultūras biedrību – Latvian Permaculture Association

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)

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\* 1. Are your members developing, using, or planning to use NGTs/NGT-products?

- Yes  
 No  
 Not applicable

\* Please explain why not

The represented organisations conserve and develop crop diversity, for example through the ex-situ conservation in community seed banks, in-situ conservation by network members in their fields and gardens, the exchange and distribution of seeds and plants, and the development of new, locally-adapted varieties and populations in on-farm breeding projects. Seed savers thereby play an important role in the conservation of plant genetic diversity. According to the FAO, “75 percent of plant genetic diversity has been lost as farmers worldwide have left their multiple local varieties and landraces for genetically uniform, high-yielding varieties”. At the same time, as set out by the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES) this diversity represents our toolbox to deal with future threats, such as pests, pathogens and climatic stresses, which owing to climate change are likely to increase in frequency and intensity.

First, the represented organisations do not use (or intend to use) NGT-products on ethical grounds. We respect the integrity and complexity of nature and living organisms. We are also highly concerned about the under-researched risks that NGTs pose to the organism, human health, and the wider ecosystem, as well as the potentially devastating consequences of NGT-products in the context of gene drives or biological warfare.

Second, experience to date has shown that the breeding of highly uniform and specialised, patented “super-varieties” leads to a loss in plant genetic diversity. Rather, the focus must be on creating sustainable and resilient agriculture, especially through the cultivation of greater diversity, both in terms of the genetic variation within a variety as well as the diversity of varieties and species that are cultivated. In response to the climate and biodiversity crises – and for the EU to meet its international commitments in these areas – policy-makers should instead support truly innovative, participatory and decentralised plant breeding approaches and organic breeding activities that develop locally-adapted plants, taking account of the integrity and complexity of the plant and its ecosystem.

Sources:

FAO, WHAT IS HAPPENING TO AGROBIODIVERSITY? (2020): <http://www.fao.org/3/y5609e/y5609e02.htm>

IPBES, Summary for Policymakers of the IPBES Global Assessment Report on Biodiversity and Ecosystem Services (2020): <https://ipbes.net/sites/default/files/2020-02>

[/ipbes\\_global\\_assessment\\_report\\_summary\\_for\\_policymakers\\_en.pdf](https://ipbes.net/sites/default/files/2020-02/ipbes_global_assessment_report_summary_for_policymakers_en.pdf)

IPCC, Special Report (2019): Special Report on Climate Change and Land, Summary for Policymakers <https://www.ipcc.ch/srccl/chapter/summary-for-policymakers/>

**\* 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

NGT-products fall under the provisions in Directive 2001/18/EC, and we expect the European Commission and national authorities to ensure the Directive is fully enforced, including with respect to imports. The onus should NOT lie with seed savers 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, and would therefore represent a significant threat to the conservation and development of plant genetic diversity and the achievement of the EU and Member States’ 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

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

- Yes
- No

\* 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

The organisations do not use NGT-products.

\* 5 bis. What challenges have you encountered?

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

\* What challenges have you encountered?

The organisations do not use NGTs or NGT-products. However, there is a clear and urgent need for national and European authorities to develop and apply detection methods that can be used to ensure Directive 2001 /18/EC is fully enforced, including with respect to imports.

\* 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

Directive 1830/2003 provides an existing framework for the traceability of authorised NGT-products. We do not identify a need for a new tracing strategy.

There is a separate issue regarding the traceability of non-authorised NGT-products that are placed on the market illegally or arise through contamination. But this issue is not new, and there are positive experiences in relation to the “old” GMOs on which can be drawn. However, as we raise in other answers, there is an urgent need for the European Commission and national authorities to develop effective detection methods. The necessary advances in detection technologies are entirely possible. It is a question of political will to realise them.

**\* 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 organisations do not use NGTs or NGT-products.

**\* 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

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**\* 10. Are your members carrying out NGT-related research in your sector?**

- Yes
- No
- Not applicable

\* Please explain why not

We are convinced that participatory and organic research approaches are already delivering important solutions to the complex challenges of today, including those arising because of the climate crisis. However, these are still lacking in adequate funding – in contrary to NGT, where a lot of investment has led to very little in terms of relevant outcomes.

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

- Yes
- No
- Not applicable

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

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

- Yes
- No
- Not applicable

**\* Please explain why not**

We do not carry out NGT-related research. However, the ruling provided much needed legal clarity. We now need effective enforcement of the ruling.

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

- Yes
- No
- Not applicable

**\* Please explain why not**

NGT-related research in relation to plant breeding is a diversion of attention and resources from truly innovative, participatory and decentralised plant breeding approaches and organic breeding activities that develop locally-adapted plants, recognising the complexity and integrity of both the plant and the ecosystem. Experience to date has shown that the breeding of highly uniform and specialised, patented "super-varieties" leads to a loss in plant genetic diversity. At the same time, this diversity represents our toolbox to deal with future threats, such as pests, pathogens and climatic stresses, which owing to climate change are likely to increase in frequency and intensity.

However, as we raise in other answers, there is an urgent need for the European Commission and national authorities to develop effective detection methods in relation to unauthorised NGT-products, and to ensure sufficient, truly independent research into the possible unexpected, unwanted effects of the genetic engineering of plants with NGTs, including long-term effects and the impact on the interaction of the plant with its environment.

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

- Yes
- No
- Not applicable

**\* 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 an urgent need to develop techniques that can be used to detect NGT-products to ensure Directive 2001/18 and Directive 1830/2003 can be enforced effectively, including with respect to imports. To date there has also been insufficient independent research in relation to the risks posed by NGT-products, both in relation to human health and the wider environment.

The largest research gap is, however, in relation to funding for truly innovative, participatory and decentralised plant breeding approaches and organic breeding activities that develop locally-adapted plants, recognising the complexity and integrity of both the plant and the ecosystem. These provide the key to sustainable and resilient agriculture that can deal with future threats, such as pests, pathogens and climatic stresses, which owing to climate are likely to increase in frequency and intensity. This gap is particularly striking given the overwhelming public support for more ecological agriculture and the rejection of GMOs.

*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**

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**\* 16. Could NGTs/NGT-products bring benefits/opportunities to your sector/field of interest?**

- Yes
- No

\* Please explain why not



The conservation and sustainable use of plant genetic diversity in agriculture is central to ensuring we can meet future challenges, such as climatic changes and new pests and diseases. This conservation and sustainable use can only be provided for a framework that guarantees farmers and breeders rights to seeds, and fosters diversity of seed companies producing locally-adapted seeds, including those appropriate for organic cultivation.

NGT-products are not compatible with this framework. First, they reflect a breeding approach that seeks to provide “specialised” solutions based on the tinkering with individual genes. This approach may work with relatively simple traits, such as herbicide resistance. But does not offer solutions to the more complex traits, such as drought resistance, that will be required to ensure we can produce sufficient and diverse food in the face of climate change. Second, NGT-products cannot be viewed in isolation from the economic structures in which they exist. Both NGTs and NGT-products are highly patented, with large seed companies controlling the vast majority of patents. As a result, the NGTs are not “democratic” methods, as the patent holders control access, but also serve to restrict access to plant genetic material, particularly for those smaller companies that cannot afford (or do not wish on ethical grounds to apply for) plant patents, the cornerstone of all innovation in plant breeding.

Sources:

Wember, Dr. Quirin (2018): Der Dürresommer 2018 – Brennende Argumente der Gentechniklobby  
[http://www.dreschflegel-verein.de/\\_pdf/2018-der-duerresommer-brennende-argumente-der-gentechniklobby.pdf](http://www.dreschflegel-verein.de/_pdf/2018-der-duerresommer-brennende-argumente-der-gentechniklobby.pdf)

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.

**\* 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

While noting that NGTs can be valuable tools for gene research under the conditions pertaining to contained use under Directive 2009/41, we do not see a value in NGT-products in agriculture or food production to society in general. The conservation and sustainable use of plant genetic diversity in agriculture is central to ensuring we can meet future challenges, such as climatic changes and new pests and diseases. This conservation and sustainable use can only be provided for a framework that guarantees farmers and breeders rights to seeds, and fosters diversity of seed companies producing locally-adapted seeds, including those appropriate for organic cultivation.

NGT-products are not compatible with this framework. First, they reflect a breeding approach that seeks to provide “specialised” solutions based on the tinkering with individual genes. This approach may work with relatively simple traits, such as herbicide resistance. But does not offer solutions to the more complex traits, such as drought resistance, that will be required to ensure we can produce sufficient and diverse food in the face of climate change. Second, NGT-products cannot be viewed in isolation from the economic structures in which they exist. Both NGTs and NGT-products are highly patented, with large seed companies controlling the vast majority of patents. As a result, the NGTs are not “democratic” methods, as the patent holders control access, but also serve to restrict access to plant genetic material, particularly for those smaller companies that cannot afford (or do not wish on ethical grounds to apply for) plant patents, the cornerstone of all innovation in plant breeding.

There is insufficient, independent research impact of NGTs/NGT-products on the organisms, human health, and the environment for any credible claims to be made in this respect.

Further, the EU Environmental Agency showed in its report “Late lessons from early warnings” that ignoring the precautionary principle can bring short-term private profits, but to profound social and economic burdens on society, and no profound benefits.

Sources:

Wember, Dr. Quirin (2018): Der Dürresommer 2018 – Brennende Argumente der Gentechniklobby  
[http://www.dreschflegel-verein.de/\\_pdf/2018-der-duerresommer-brennende-argumente-der-gentechniklobby.pdf](http://www.dreschflegel-verein.de/_pdf/2018-der-duerresommer-brennende-argumente-der-gentechniklobby.pdf)

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.

EU Environmental Agency (2002): Late lessons from early warnings [https://www.eea.europa.eu/publications/environmental\\_issue\\_report\\_2001\\_22](https://www.eea.europa.eu/publications/environmental_issue_report_2001_22)

**\* 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

Both NGTs and NGT-products are highly patented, with large seed companies controlling the vast majority of patents. At the latest at the point of commercialisation, small scale operators using NGTs will therefore have to enter into negotiations with the patent holder. These negotiations themselves represent a barrier to market entry to small operators, in addition to potential licence fees.

In addition, the patenting of NGT-products blocks access to genetic material for other breeders. The full and free use and exchange of plant genetic diversity has been the cornerstone of innovation in plant breeding for generations. Small operators are particularly negatively impacted by plant patents, as they do not have legal teams to research which varieties and material are already affected by patents. The more patents are granted: (i) the smaller the pool of traits accessible to small operators for their breeding work and (ii) the greater the legal uncertainty in relation to the use of new genetic material, hindering innovation in the sector.

Sources:

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.

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

- Yes  
 No

\* Please explain why not

The full and free use and exchange of plant genetic diversity has been the cornerstone of innovation in plant breeding for generations. The patenting of seeds, plants, their harvest and their products blocks access to genetic material and accelerates the concentration in the seed market. The more patents are granted: (i) the smaller the pool of traits accessible to small operators for their breeding work and (ii) the greater the legal uncertainty in relation to the use of new genetic material, hindering innovation in the sector. In sum, patents pose a fundamental risk to both the conservation of plant genetic diversity, its traditional use in local communities (which have cared for genetic diversity for generations), and to innovation in plant breeding.

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

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

- Yes  
 No

\* Please describe and provide concrete examples/data

The risk of contamination by NGT-products poses a direct threat to the conservation of the existing stock of plant genetic diversity. As seen in the case of Teosinte and GM maize in Spain, there is not only a risk of cross-contamination with other crops, but also with crop wild relatives, which are form very important part of local genetic biodiversity and can be the basis for new breeding activities – see, for example, the Horizon 2020 Project Farmers' Pride: <http://www.farmerspride.eu>).

In the case of a de-regulation or lighter-touch regulation of NGT-products, it would no longer be possible to contain the risk of cross-contamination. This would put organic farmers and the GMO-free sector out of business, and deny consumers freedom of choice.

The issue of cross-contamination is particularly acute (i) where there is small-scale agriculture and (ii) for organic plant breeders. The first instance was central to the Austrian government's decision to implement to prohibit the cultivation of GMOs in line with Directive 2015/412. Under Article 3 (3) (1) the Gentechnik-Anbauverbots-Rahmengesetz, the prohibition on GMO cultivation is justified with reference to „die Tatsache, dass Koexistenzmaßnahmen aufgrund der landwirtschaftlichen Strukturen nur mit unverhältnismäßigen Aufwand realisierbar oder mit unverhältnismäßigen Kosten verbunden sind“. We also note in this context that small farms play a disproportionately large role in the conservation and sustainable use of plant genetic diversity. In the second instance, in some locations the work of organic plant breeders and GM-free seed producers is no longer possible, for example in relation to corn, as the risk of contamination can no longer be managed. At the same time, the EU has committed to increasing the supply of plant propagating material under the Regulation 2018/848 and a rise in the share of organic agriculture is necessary if the EU is to meet its commitments regarding biodiversity conservation and emissions reduction under the CBD and Paris Agreement respectively.

Finally, as described in previous responses, patents on NGT-products threaten the conservation of genetic diversity, its traditional use in local communities, and innovation in plant breeding.

Sources:

Binimelis, Rosa (2008): Coexistence of Plants and Coexistence of Farmers: Is an Individual Choice Possible? <https://link.springer.com/article/10.1007/s10806-008-9099-4>

IFOAM EU (2017): Socio-Economic Impacts of GMOs on European Agriculture [http://www.ifoam-eu.org/sites/default/files/ifoam\\_eu\\_project\\_keeping\\_gmos\\_socioeconomic\\_study\\_final.pdf](http://www.ifoam-eu.org/sites/default/files/ifoam_eu_project_keeping_gmos_socioeconomic_study_final.pdf)

Jarvis et al. (2008): A global perspective of the richness and evenness of traditional crop-variety diversity maintained by farming communities. Proceedings of the National Academy of Sciences of the United States of America, 105(14):5326-5331

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

- Yes  
 No

\* Please explain why not

They apply to all 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

The intended changes achieved by NGTs can be potentially devastating for society and the environment, considering their potential use in gene drives and biological warfare. But even in less sinister contexts, the potential of NGT-products in agriculture is highest in relation to relatively genetically simple traits, such as herbicide resistance or discolouration – traits which do not contribute to a more sustainable, diverse and resilient agriculture. The important but genetically complex traits that we will need to cope with climate change, such as drought resistance or adaption to longer periods of snow cover, cannot be achieved through NGTs. Instead, we need a truly innovative, participatory and decentralised plant breeding approaches and other organic plant breeding activities that develop locally-adapted plants, taking account of the integrity and complexity of the plant and its ecosystem. The protracted discussion over the regulatory status of NGTs/NGT-products, even after the ECJ ruling, is a dangerous distraction.

The unintended consequences of NGTs on the genome (both on-target and off-target effects), the organism as a whole, and the wider ecosystem can be wide-reaching, and are currently under-researched. The precautionary principle must therefore prevail, and the ruling of the European Court of Justice fully enforced. The EU Environmental Agency showed in its report „Late lessons from early warnings“ ([https://www.eea.europa.eu/publications/environmental\\_issue\\_report\\_2001\\_22](https://www.eea.europa.eu/publications/environmental_issue_report_2001_22)) that ignoring the precautionary principle can lead to short-term private profits, but to profound social and economic burdens on society, and no profound benefits. These lessons must be applied to the question of NGTs/NGT-products.

Further, the promotion of highly uniform and specialised, patented "super-varieties" – for example through the favouring of NGTs, but also through restrictive laws regarding the marketing of seeds and plant propagating material – leads to a loss in plant genetic diversity. But it is this genetic diversity that represents our toolbox to deal with future threats, such as pests, pathogens and climatic stresses , which owing to climate change are likely to increase in frequency and intensity.

Finally, NGTs/NGT-products cannot be viewed in isolation from the economic structures in which they exist. All of the current conservation and breeding activities of the seed savers community are GMO-free; some larger organisations such as Arche Noah have organic certification. In several cases, the marketing of amateur varieties, seeds, and in future organic heterogeneous material is an important source of income. A lack of clear rules, GMO labelling and effective traceability would have profound negative economic impacts on this sector (as well as other GMO-free sectors) and devastate public trust, which expect to exchange GMO-free seeds. Directive 2001/18/EC must therefore be fully applied and enforced with respect to NGT-products. In addition, the high level of patents in relation both to NGTs and NGT-products will foster further concentration in the seed market, including increasing monopolisation of the genetic diversity that is the cornerstone of all innovation in plant breeding. Ultimately, this concentration poses a risk to our future food security.

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

If Directive 2001/18/EC and other GMO legislation is not fully applied and enforced to NGTs and NGT-products.

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

- Yes  
 No

\* Please explain why not

They apply to all 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

Both NGTs and NGT-products are highly patented, with large seed companies controlling the vast majority of patents. At the latest at the point of commercialisation, small scale operators using NGTs will therefore have to enter into negotiations with the patent holder. These negotiations themselves represent a barrier to market entry to small operators, in addition to potential licence fees.

Further, the patenting of NGT-products blocks access to genetic material for other breeders. Small operators are particularly negatively impacted by plant patents, as they do not have legal teams to research which varieties and material are already affected by patents. The more patents are granted: (i) the smaller the pool of traits accessible to small operators for their breeding work and (ii) the greater the legal uncertainty in relation to the use of new genetic material, hindering innovation in the sector.

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

- Yes  
 No

\* Please describe and provide concrete examples/data

As already described, the full and free use and exchange of plant genetic diversity has been the cornerstone of innovation in plant breeding for generations. The patenting of seeds, plants, their harvest and their products blocks access to genetic material and accelerates the concentration in the seed market. The more patents are granted: (i) the smaller the pool of traits accessible to small operators for their breeding work and (ii) the greater the legal uncertainty in relation to the use of new genetic material, hindering innovation in the sector. In sum, plant patents pose a fundamental risk to both the conservation of plant genetic diversity, its traditional use in local communities, and to innovation in plant breeding.

*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**

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

The scientific facts demonstrate that all NGTs/NGT-products should be regulated at least as stringently as it is currently required under EU GMO legislation. In addition, there has been insufficient, independent research into the risks of NGTs/NGT-products. It is the responsibility of the European Commission and national authorities to fund this research and, in the case of concrete applications, establish a framework under applicants pay for truly independent research, create a strong, independent scientific basis for its decision-making, with a fair distribution of the costs between those who wish to work with NGTs and the tax payer. (As we note in response to question 15, the more pressing research gap is in relation to funding for truly innovative, participatory and decentralised plant breeding approaches and organic breeding activities

that develop locally-adapted plants, recognising the complexity and integrity of both the plant and the ecosystem. These provide the key to sustainable and resilient agriculture that can deal with future threats, such as pests, pathogens and climatic stresses, which owing to climate change are likely to increase in frequency and intensity. This gap is particularly striking given the overwhelming public support for more ecological agriculture and the rejection of GMOs.

Nevertheless, we identify safety risks in relation to unintended changes caused by the intervention, both to the genome (the so-called “on target” and “off target” effects) and to the organism as whole . We also identify safety issues in relation to the impact of the release of an NGT-product into the environment, for example on the interaction between plants and pollinators and on microbiomes. In sum, the safety of NGT-products cannot be limited to the organism itself, but must also take account of the impacts that a release would have on the wider ecosystem.

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

- Yes  
 No

\* Please explain

Once an NGT-product is released into the environment, there is a risk of its uncontrolled spread, for example through crossing. This process is irreversible. It is therefore paramount that the precautionary principle prevails, as is foreseen in the current regulatory framework. We are highly concerned about the potentially devastating consequences of the use of NGT-products in gene drives and biological warfare.

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## F - Ethical aspects of NGTs/NGT-products

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

NGT-products do not respect the integrity and complexity of nature and living organisms. Further, if released into the environment, NGT-products can have irreversible consequences for the whole ecosystem. We note again that plant genetic diversity is our toolbox to deal with future threats, such as pests, pathogens and climatic stresses, which owing to climate change are likely to increase in frequency and intensity – and that the release of GMOs into the environment directly (owing to the risk of cross-contamination) and indirectly (by creating unfair costs for those who work to conserve and sustainably use plant genetic diversity in a GMO-free context as well as via the pressures generated by plant patents, as described in questions 18.19 and 22-23) threatens this diversity. It is undeniable that these are deeply ethical issues. It is therefore paramount that alongside risk assessment, seed savers, breeders, farmers and consumers are 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.

We also note that the EU and its Member States have made commitments in relation to the conservation of plant genetic diversity under both the UN Convention on Biological Diversity, and the Member States have made additional commitments under the International Treaty on Plant Genetic Resources for Food and Agriculture.

We also note the ethical responsibility of the EU and national governments to take account of the impact of

NGT-products not only on the balance sheets of seed companies, but also on the health of their citizens and the environment in which they live, and therefore to put the precautionary principle at the centre of its approach. For example, the EU Environmental Agency showed in its report „Late lessons from early warnings“ that ignoring the precautionary principle can lead to short-term private profits, but to profound social and economic burdens on society, and no profound benefits. Ignoring these lessons in relation to the NGTs/NGT-products is not acceptable from an ethical standpoint.

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

- Yes  
 No

**\* Please explain**

In addition to the points made under question 26, we are highly concerned about the potentially devastating consequences of the use of NGT-products in both gene drives and biological warfare. It is therefore imperative that decision-makers act in line with the precautionary principle, prioritising the health of their citizens and the environment in which they live – for current generations and those to come.

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## G - Consumers' right for information/freedom of choice

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**\* 28. What is your view on the labelling of NGT-products? Please substantiate your reply**

Labelling is, and should continue to be, required as per the current regulatory framework for GMOs. No distinction should be made between the labelling of “old” GMOs and NGTs. A single label important to ensure simple, clear information for food growers and producers along the whole value chain and for consumers, particularly in light of the large range of NGTs and their potential applications. Creating a parallel labelling regime would be a duplication of resource and the inefficient use of taxpayer money.

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## H - Final question

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

- Yes  
 No



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## **Contact**

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