

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 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

FIAN International e.V.

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

FIAN International is an international human rights organization promoting the human right to food and nutrition. Our work areas include agriculture, land governance, biodiversity, farmers' rights, nutrition, food systems. For more information see: www.fian.org.

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

This questionnaire has been filled in by FIAN's International Secretariat, which is based in Heidelberg, Germany, taking into account the work of the entire organization, including FIAN's European sections. A list of national FIAN sections is available at: www.fian.org/en/fian-international.

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

FIAN considers that the use of biotechnologies, including NGTs and NGT products, requires a thorough and independent assessment of potential risks related to health, environmental, social, economic and human rights impacts, according to relevant principles and standards of international law. Techniques, products or organisms that have not been assessed and/or which are not adequately regulated must not be used in application of the precautionary principle. New biotechnologies need to be effectively regulated according to EU law, as confirmed by the decision of the Court of Justice of the European Union of 25 July 2018.

* 2. Have your members taken or planned to take measures to protect themselves from unintentional use of NGT-products?

- Yes
 No
 Not applicable

* Please provide details

Protecting people, including peasant farmers' and consumers' rights, from the risk of unintentionally using or consuming NGT products as well as the risks linked to such use requires the application of the EU's GMO legislation (Directive 2001/18), as required by the decision of the Court of Justice of the European Union of 25 July 2018. This includes clear labelling. The EU and its member states are further required to ensure that no illegal import of NGT from other countries takes place.

* 2 bis. Have you encountered any challenges?

- Yes
- No

* Please provide details

Protecting people, including peasant farmers' and consumers' rights, from the risk of unintentionally using or consuming NGT products as well as the risks linked to such use requires the application of the EU's GMO legislation (Directive 2001/18), as required by the decision of the Court of Justice of the European Union of 25 July 2018. This includes clear labelling. The EU and its member states are further required to ensure that no illegal import of NGT from other countries takes place.

* **3. Are you aware of initiatives in your sector to develop, use, or of plans to use NGTs/NGT-products?**

- Yes
- No
- Not applicable

* Please provide details

FIAN considers that the application of the EU's GMO legislation (Directive 2001/18), as required by the decision of the Court of Justice of the European Union of 25 July 2018, as well as the application of relevant standards of international law is a condition sine qua non for the use of any biotechnologies, including NGT and NGT products.

* **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

FIAN considers that the application of the EU's GMO legislation (Directive 2001/18), as required by the decision of the Court of Justice of the European Union of 25 July 2018, as well as the application of relevant standards of international law is a condition sine qua non for the use of any biotechnologies, including NGT and NGT products.

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

- Yes
- No

* Please provide details

If NGT and NGT products are not regulated according to the EU Directive 2001/18, it will be difficult, if not impossible, to guarantee GM-free production (organic and conventional). This would have severe adverse impacts on human rights, including the rights of peasants to decide on the crops and species that they wish to grow (UN Declaration on the Rights of Peasants and Other People Working in Rural Areas, art. 19.5) as well as the rights of EU citizens to choose what they eat. In addition, it could lead to economic difficulties for food producers, in particular peasant farmers.

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

Please also see question 8 specifically on labelling

- Yes
 No
 Not applicable

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

- Yes
 No
 Not applicable

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

- Yes
 No
 Not applicable

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

Traceability is an important element 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 hidden GMOs. 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. 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. Similar or comparable approaches should be applied with regards to NGTs, in particular to impede the import of any non-authorized NGTs (such as Calyxt High Oleic Soybean and Cibus SU Canola) into the EU. An EU wide coordination approach would be most effective in this regard. While the identification of NGTs and NGT products may require DNA testing (e.g. using molecular markers, see: www.infogm.org/6974-upov-possible-characteriser-nouveaux-ogm), the response of Europol officials to a question asked by the European Coordination Via Campesina during a meeting of the Civil Dialogue Group of DG AGRI on 6 March 2020, indicates that documentation, investigation as well as surveillance of the internet and the darknet have proven to be effective means to identify illegal GMOs, including NGTs and NGT products.

*

8. Are your members taking specific measures for NGT-products to ensure the compliance with the labelling requirements of the GMO legislation?

- Yes
- No
- Not applicable

- * Please describe the measures and their effectiveness including details on the required financial, human resources and technical expertise

FIAN International supports peasant small and medium scale food producers' organizations who do not want to use of NGTs and NGT products as a way to protect their rights and economic interests. FIAN further considers that the rigid application of the precautionary principle as well as strong and effective regulation is necessary given the great difficulties to assess and manage the risks deriving from biotechnologies. Adequate labelling is one critical element in the context of the current EU GMO legislation and needs to be applied to NGT and NGT products, in conformity with the legislation as well as the decision of the Court of Justice of the European Union of 25 July 2018. Without application of strict traceability and labelling, NGTs and NGT products could contaminate non-GMO products, causing severe detrimental economic impact for the breeding, farming, food processing and retailing sectors, as well as health and human rights impacts on citizens.

- * What best practices can you share?

Effective implementation of farmers' rights and application of the precautionary principle.

- * 8 bis. What challenges have you encountered?

Lack of implementation of farmers' rights and the precautionary principle

*** 9. Do you have other experience or knowledge that you can share on the application of the GMO legislation, including experimental releases (such as field trials or clinical trials), concerning NGTs/NGT-products ?**

- Yes
- No
- Not applicable

- * Please describe for the:

- Agri-food sector
- Industrial sector
- Medicinal sector

Agri-food sector

The work of peasant organizations and civil society organizations have contributed enormously to implementing the EU GMO legislation. Pressure put on responsible EU member state authorities have led to important guidance as well as the correction of cases of non-application of the EU GMO legislation. Recent examples include:

1. A ruling of the French State Council (Conseil d'État) of 9 February 2020, which demonstrated that the seed sector and French legislation did not correctly apply the GMO legislation as required by the decision of the Court of Justice of the European Union of 25 July 2018. The Council ordered the government to take the

necessary measures to apply it correctly. These measures need to be implemented within 6 and 9 months of the publication of this decision.

2. Legal action by several German public interest civil society organizations prevented the cultivation of a herbicide-resistant variety of canola of the US company CIBUS, which had been authorized by the German Federal Agency for Consumer Protection and Food Safety (BVL). After the European Court of Justice ruled that organisms produced using new mutagenesis techniques are subject to GMO legislation, the BVL withdrew its CIBUS GMO authorization for canola.

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

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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 specify including subject, type of research, resources allocated, research location**

FIAN supports organizations of small and medium scale food producers as well as consumer groups in their efforts to guarantee the full respect of human rights and environmental law in the context of biotechnologies and its use. This includes research and developing of proposals for the most effective ways of ensuring strict application of the precautionary principle as well as effective regulation. FIAN further supports the realization of small-scale food producers' right to decide on the crops and species that they wish to grow (UN Declaration on the Rights of Peasants and Other People Working in Rural Areas, art. 19.5) as well as the full respect, protection and promotion of their right to seeds (UN Declaration on the Rights of Peasants and Other People Working in Rural Areas, art. 19), including to maintain their peasant seed systems (UN Declaration on the Rights of Peasants and Other People Working in Rural Areas, art. 19.6 and 20.2). These are critical and effective means to guarantee the conservation and sustainable use of biodiversity as well as ensuring the adaptation to climate change.

*** 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 describe**

We have observed an intensification of lobby activities of the industrial agriculture sector to avoid the implementation of the ruling, which are sometimes disguised as research initiatives. FIAN recognizes the need for further research and the need for broad public discussion on the use or non-use of GMOs including NGTs and NGT products, but underlines that this needs to be done while upholding the principles and standards of international human rights and environmental law.

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

- Yes
- No
- Not applicable

* Please provide concrete examples/data

FIAN acknowledges the need for further research on NGTs and NGT products as a basis for a broad public debate on the use of biotechnologies. In order to ensure the respect, protection and fulfilment of human rights, in particular the right to food and nutrition as well as peasants' rights, as well as environmental law, research should be conducted on the following issues:

- (1) the identification and traceability of NGT products,
- (2) the unintended effects of NGTs,
- (3) the assessment of the socio-economic, health, human rights and environmental impacts of the marketing of NGT products intended for agriculture or agro-industry,
- (4) the assessment of the risks linked to the dissemination of NGT products in terms of biosafety,
- (5) the development of standardised processes and standards for the identification and distinction of undeclared NGT products,
- (6) the assessment of the impacts, in particular on small and medium scale food producers of the economic model, intellectual property regime and legal framework that allows their development.

FIAN further stresses the need to increase public funding for research that supports the needs and rights of small and medium scale food producers, such as the implementation of their rights to seeds/farmers' rights (recognized by the International Treaty on Plant Genetic Resources for Food and Agriculture as well as the UN Declaration on the Rights of Peasants and Other People Working in Rural Areas) as well as peasant seed systems.

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

- Yes
- No
- Not applicable

* Please provide concrete examples/data

FIAN has observed that substantial research is funded and conducted by groups that are interested in the marketing and use of NGTs. This raises serious concerns about conflicts of interest and the reliability of research outcomes. Research needs further to be guided by human rights and environmental law principles and standards, in particular the precautionary principle. Critical issues, such as the ones outlined in response to question 13, are underfunded. FIAN underlines the provisions of recital Nr. 21 of the EU GMO-directive 2001/18, which states: "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."

FIAN further considers that research needs to inform a broad public debate on the risks and potential

opportunities linked to the use of NGT products, as a basis for democratic decision-making for the public interest.

*** 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

As indicated in response to question 13, FIAN considers that there is a lack of independent research on critical issues, such as:

- (1) the identification and traceability of NGT products,
- (2) the unintended effects of NGTs,
- (3) the assessment of the socio-economic, health, human rights and environmental impacts of the marketing of NGT products intended for agriculture or agro-industry,
- (4) the assessment of the risks linked to the dissemination of NGT products in terms of biosafety,
- (5) the development of standardised processes and standards for the identification and distinction of undeclared NGT products,
- (6) the assessment of the impacts, in particular on small and medium scale food producers of the economic model, intellectual property regime and legal framework that allows their development.

In addition, there is a lack of public research on the development of sustainable alternatives to GMOs, including NGT and NGT products. FIAN stresses the need to increase public funding for research that supports the needs and rights of small and medium scale food producers, such as on-farm/in situ plant, animal and micro-organism selection by peasants, as well as on-farm or local and artisanal food processing. In a context of climate change and rapid decline of biodiversity, peasant seed and management systems ensure local adaptation, resilience and sustainability. Such research should be guided by the need to implement peasants' rights to seeds and biodiversity (recognized by the International Treaty on Plant Genetic Resources for Food and Agriculture as well as the UN Declaration on the Rights of Peasants and Other People Working in Rural Areas).

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

FIAN acknowledges that NGT and NGT products are promoted as bringing several benefits. Such potential benefits need to be carefully assessed and weighed against risks. Application of human rights and environmental law, in particular the precautionary principle as well as implementation of the EU GMO legislation and the Court of Justice of the European Union of 25 July 2018 are crucial to protect farmers and consumers from potential harmful impacts linked to the use of NGT and NGT products. It is critical to protect peasants' rights as enshrined in the UN Declaration on the Rights of Peasants and Other People Living in Rural Areas, in particular peasants' right to seeds (art. 19). Farmers' rights over seeds are further recognized by the International Treaty on Plant Genetic Resources for Food and Agriculture (especially articles 5, 6 and 9) FIAN further emphasizes the important contribution made by peasants and indigenous peoples to the conservation, sustainable use, and further development of biodiversity, which is recognized by scientific research and the Convention on Biological Diversity. This contribution is based on their farming and seed selection practices, which need therefore to be effectively protected. The diversity and genetic variability of peasant seed systems as well as ensuring that populations of crops, plants, animals and micro-organisms can adapt to local ecosystems as well changes in agro-ecological conditions, including climate change) are critical features that provide effective responses to the current rapid decline in biodiversity and climate change, as well as guaranteeing peasants' livelihoods.

*** 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

All claims for potential benefits of NGT and NGT products need to be carefully assessed and weighed against the risks that could arise for human rights, health and the environment. Application of human rights and environmental law, in particular the precautionary principle as well as implementation of the EU GMO legislation and the Court of Justice of the European Union of 25 July 2018 are crucial to protect farmers and consumers from potential harmful impacts linked to the use of NGT and NGT products. The world and the EU are currently facing important challenges, including climate change, the rapid loss of biodiversity and socio-economic challenges. The response to these challenges need to be based on the human rights framework and the application of relevant norms of environmental law. The contribution of peasant farmers and indigenous peoples to the conservation, sustainable use and further development of biodiversity is recognized by scientific research and the Convention on Biological Diversity. Their knowledge, innovation and practices provide an effective and accessible means to respond to the challenges faced by humanity today. Any use of NGT or NGT products can only be considered if the rights and interests of peasant farmers as well as consumers are respected, protected and guaranteed. Arguments by promoters of NGT and NGT products suggest that complex societal, political, environmental and economic challenges can be solved by technical interventions. This is an extremely narrow view that can represent a threat, rather than an opportunity for society in general.

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

- Yes
 No

* Please explain why not

FIAN would like to point out that the global and regional seed markets are highly concentrated, and are controlled by a small number of large corporations. The use of NGTs and NGT products entails the risk of further increasing market concentration, taking into account in particular the high costs of research and development of NGTs. Such costs are difficult to bear for SMEs. In addition, protection of NGT and NGT through patents and other intellectual property rights will make it difficult for SMEs to take advantage from NGT. FIAN would like to stress that any potential benefits from the use of NGTs and NGT products for specific sectors need to be assessed very carefully and weighed against the risks that could arise for human rights, health and the environment. Application of human rights and environmental law, in particular the precautionary principle as well as implementation of the EU GMO legislation and the Court of Justice of the European Union of 25 July 2018 are crucial.

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

- Yes
 No

* Please explain why not

FIAN would like to stress the important role that patents and other forms of intellectual property rights have played in leading to an extremely concentrated seed sector. Such concentration reduces the diversity of available seeds and can lead to increases in seed prices. Patents and other forms of intellectual property rights also limits breeding companies' free access to and use of plant genetic material, because the possibility of patenting plant material developed with new methods of genetic modification leads to the granting of even more patents. As a result, the global patent situation will become more and more complex and ambiguous for breeders. The unknown use of patented material, which may occur in such a situation, may lead to legal action for patent infringement, as well as potentially serious financial implications, which are particularly difficult for small breeders to afford.

Patents and other forms of intellectual property rights further lead to a limitation of the rights to seeds of peasants and indigenous peoples, as recognized by the UN Declaration on the Rights of Peasants and Other People Living in Rural Areas as well as the International Treaty on Plant Genetic Resources for Food and Agriculture. The EU's and EU Member States' human rights obligations require them to ensure the full respect, protection and fulfilment of peasants' rights over seeds.

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

FIAN underlines that the use of NGT and NGT products could entail serious adverse consequences for human rights and the environment. Therefore their authorization needs to be very carefully assessed and

any potential benefits carefully weighed against such adverse impacts, taking into account human rights, environmental law as well as EU legislation. FIAN would like to highlight particularly the threats that NGTs and related intellectual property rights issues are likely to have on small and medium scale food producers, in particular their rights to seeds as recognized by the UN Declaration on the Rights of Peasants and Other People Working in Rural Areas (particularly art. 19) as well as the International Treaty on Plant Genetic Resources for Food and Agriculture (in particular arts 5, 6 and 9).

In addition, we would like to recall that EU law guarantee consumers' rights, which include their right to information (Art 169 TFEU). This requires the strict implementation of EU GMO legislation, including adequate labelling of NGT products. A large majority of European citizens reject the use and consumption of GMOs, of which NGT products are part.

FIAN would also like to highlight the risk that the authorization of NGTs and NGT products presents for the non-GMO agricultural sector, in particular the organic agriculture sector, whose market share in the EU has been constantly rising, and which constitutes an important market for small and medium scale food producers. NGTs will likely increase the costs of organic and non-GMO quality chains. These negative impacts will be multiplied if NGT-products are not adequately labelled and traced. In case of contamination, breeders, farmers and processors, as well as the commercial sector will not be able to claim for their loss and will be left alone. If this posed risks to health, it would be impossible to withdraw them from the food chain. Indeed, it is not shown that GMOs can be taken out of the environment once released (retrievability). The non-retrievability of NGTs and unknown risks arising from them is conflictual with the precautionary principle as guidance for all environmental legislation of the EU.

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

- Yes
 No

* Please explain

As specified by decision of the Court of Justice of the European Union of 25 July 2018, NGTs and NGT products need to be considered as GMOs. However, each specific genetic engineering technique entails specific risks that need specific assessment and evaluation.

*** 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

FIAN considers that NGTs and NGT products entail serious risks for the environment and human rights.

Environmental concerns:

- 1) as with old GMO there is the risk NGT pose to the environment and the balanced ecosystem, plus the question if the GMO can be taken back out of the environment once released (retrievability)
- 2) The fact of non-retrievability of NGT and unknown risks conflicts with the precautionary principle, which is a fundamental principle of international environmental law and serves as guidance for all environmental legislation of the EU.
- 3) Gene drives present particular threats, including the extinction of entire species and the altering of ecosystems. (see: https://www.fian.org/fileadmin/media/publications_2018/Letters_and_statements)

/A_human_rights_analysis_of_gene_drives_final_EN_updated.pdf) This poses an unprecedented risk to the environment and ecosystems.

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 processes 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. 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 yet been sufficiently investigated. 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 (summarised in the book, *GMO Myths and Truths*, 4th edition, by C. Robinson, M. Antoniou and J. Fagan; also in these reviews <http://www.enveurope.com/content/27/1/4/abstract> ; and <http://sth.sagepub.com/content/early/2015/08/05/0162243915598381>). There is a risk that similar effects could arise from NGT products. Such risks need to be carefully assessed and weighed against any potential benefits of NGTs.

FIAN would like to stress that the EU general food law (178/2002) establishes that citizens need to have access to safe and wholesome food of highest standards, and requires a high level of protection of human life and consumers' interests in relation to food. The EU treaties further establish consumer rights, including adequate labelling as a precondition for the right to information for consumers (Art 169 TFEU). Only the strict implementation of EU GMO legislation can ensure this core right of consumers.

Concerns on human rights of peasant farmers

NGTs and related intellectual property rights regimes are likely to have adverse impacts on small and medium scale food producers, in particular their rights to seeds as recognized by the UN Declaration on the Rights of Peasants and Other People Working in Rural Areas (particularly art. 19) as well as the International Treaty on Plant Genetic Resources for Food and Agriculture (in particular arts 5, 6 and 9). These rights as well as peasant seed systems are critical for the protection of their livelihoods, the conservation and sustainable use of biodiversity as well as the adaptation to climate change.

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

The risks would be further increase in case of inadequate regulation and/or non-application of relevant legislation.

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

- Yes
 No

* Please explain

As specified by decision of the Court of Justice of the European Union of 25 July 2018, NGTs and NGT products need to be considered as GMOs. However, each specific genetic engineering technique entails specific risks that need specific assessment and evaluation.

*** 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

FIAN would like to point out that the global and regional seed markets are highly concentrated, and are controlled by a small number of large corporations. The use of NGTs and NGT products entails the risk of further increasing market concentration, taking into account in particular the high costs of research and development of NGTs. Such costs are difficult to bear for SMEs. In addition, protection of NGT and NGT through patents and other intellectual property rights will make it difficult for SMEs to take advantage from NGT. FIAN would like to stress that any potential benefits from the use of NGTs and NGT products for specific sectors need to be assessed very carefully and weighed against the risks that could arise for human rights, health and the environment. Application of human rights and environmental law, in particular the precautionary principle as well as implementation of the EU GMO legislation and the Court of Justice of the European Union of 25 July 2018 are crucial.

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

- Yes
 No

* Please describe and provide concrete examples/data

FIAN would like to stress the important role that patents and other forms of intellectual property rights have played in leading to an extremely concentrated seed sector. Such concentration reduced the diversity of available seeds and can lead to increases in seed prices. Patents and other forms of intellectual property rights also limits breeding companies' free access to and use of plant genetic material, because the possibility of patenting plant material developed with new methods of genetic modification leads to the granting of even more patents. As a result, the global patent situation will become more and more complex and ambiguous for breeders. The unknown use of patented material, which may occur in such a situation, may lead to legal action for patent infringement, as well as potentially serious financial implications, which are particularly difficult for small breeders to afford.

Patents and other forms of intellectual property rights further lead to a limitation of the rights to seeds of peasants and indigenous peoples, as recognized by the UN Declaration on the Rights of Peasants and Other People Living in Rural Areas as well as the International Treaty on Plant Genetic Resources for Food and Agriculture. The EU's and EU Member States' human rights obligations require them to ensure the full respect, protection and fulfilment of peasants' rights over seeds.

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

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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**

As a human rights organization, FIAN cannot assess the safety of NGTs and NGT products from a scientific standpoint. We would like to reiterate, however, that the possible authorization of NGTs and NGT process depends on a thorough assessment of potential risks, applying the highest human rights and environmental law standards, including the precautionary principle. The results of such assessments need to be weighed against any potential benefits of the use of NGTs and NGT products. According to the principle of the primacy of human rights, the full respect, protection and fulfilment of human rights needs to be placed above any economic interests by a specific business sector.

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

- Yes
 No

* Please explain

As a human rights organization, FIAN cannot assess the safety of NGTs and NGT products from a scientific standpoint. We would like to reiterate, however, that the possible authorization of NGTs and NGT process depends on a thorough assessment of potential risks, applying the highest human rights and environmental law standards, including the precautionary principle. The results of such assessments need to be weighed against any potential benefits of the use of NGTs and NGT products. According to the principle of the primacy of human rights, the full respect, protection and fulfilment of human rights needs to be placed above any economic interests by a specific business sector.

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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**

FIAN considers that NGTs and NGT products raise serious ethical concerns. Such concerns need to be carefully evaluated before taking any decision on the authorization of such products in the EU. The international human rights and environmental law framework provide concrete guidance on how to assess and deal with concerns that regard human and environmental wellbeing.

Particular concerns arise from the use of NGTs and NGT products regarding irreversible alteration of ecosystems, unknown impacts on human and animal health as well as the impairment of the human rights of peasant farmers, in particular their rights to seeds, as recognized by the UN Declaration on the Rights of Peasants and Other People Living in Rural Areas as well as the International Treaty on Plant Genetic Resources for Food and Agriculture.

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

- Yes
 No

* Please explain

Particular concerns that arise from the use of NGTs and NGT products concern irreversible alteration of ecosystems, unknown impacts on human and animal health as well as the impairment of the human rights of peasant farmers, in particular their rights to seeds, as recognized by the UN Declaration on the Rights of Peasants and Other People Living in Rural Areas as well as the International Treaty on Plant Genetic Resources for Food and Agriculture.

Gene drives present particular threats, including the extinction of entire species and the altering of ecosystems. (see: https://www.fian.org/fileadmin/media/publications_2018/Letters_and_statements/A_human_rights_analysis_of_gene_drives_final_EN_updated.pdf) This poses an unprecedented risk to the environment and ecosystems. It should be noted that such technologies could also be used for the production of biological weapons, representing huge threats to humanity as a whole.

FIAN emphasizes the need and the EU's obligation to comply with its obligations under international human rights law as well as international environmental law when addressing the issue of NGTs and NGT products.

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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

FIAN would like to emphasize the need to respect, protect and fulfil the rights of farmers, breeders, gardeners, bee keepers and consumers as recognized by human rights. This includes their right to choose what food they produce and how, as well as to decide what to eat. These rights need to be placed above any economic interests of particular business sectors, according to the principle of the supremacy of human rights.

Traceability and adequate labelling are critical elements in the context of the current EU GMO legislation and needs to be applied to NGT and NGT products, in conformity with the legislation as well as the decision of the Court of Justice of the European Union of 25 July 2018. Without application of strict traceability and labelling, NGTs and NGT products could contaminate non-GMO products, causing severe detrimental economic impact for the breeding, farming, food processing and retailing sectors, as well as health and human rights impacts on citizens.

We would like to recall that the EU's 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.“

Article 18 of the same Regulation further 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.“

In addition, Article 169 of the Treaty on the Functioning of the EU ensures the consumer's right to information.

FIAN would like to highlight that while traceability and labelling are important elements to address the risks deriving from NGTs and NGT products, they are not sufficient to address all such risks. Effective measures need to be taken, for instance, to prevent contamination of non-GMO/NGT crops and animals.

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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

FIAN would like to emphasize that the use of terms such as “NGT/NGT-products” must not obfuscate the fact that such products need to be considered as GMOs, as clarified by the Decision of the Court of Justice of the European Union of 25 July 2018.

FIAN would also underline that a limitation of “new genomic techniques” to those which “have emerged or have been developed since 2001” in the EC’s study, would result in the Commission not taking into account GMOs not resulting from transgenesis developed some years before 2001 and which should not be excluded from the scope of Directive 2001/18/EC. We would like to stress the scientific, political and procedural inaccuracy of this decision.

FIAN would further like to highlight the need for the EU and EU Member states to comply with their obligations under international human rights law as well as international environmental law when assessing the use of NGTs and NGT products. FIAN would particularly highlight the obligation to respect the rights of small and medium scale food producers, as explicitly recognized in the UN Declaration on the Right of Peasants and Other People Working in Rural Areas. This concerns particularly their rights to seeds and biodiversity (articles 19 and 20). Farmers’ rights over seeds have further been recognized by the International Treaty on Plant Genetic Resources for Food and Agriculture.

With regard to NGTs, the only way to ensure that these techniques do not threaten farmers' rights to seeds is for NGT-derived organisms to be regulated, as indicated by the European Court of Justice (ECJ), as GMOs under the current legislative framework, which requires:

- comprehensive case-by-case risk assessments;
- methods for detecting, identifying, and quantifying the GMO provided by the producers, and publicly available in an EU database;
- documentation to track the GMOs and NGTs as well as GMO and NGT products at all stages of the supply chain;
- Adequate labelling of GMO and NGT products for the consumers and their freedom of choice at all stages of the supply chain;
- post-market monitoring and the right to suspend an authorisation;
- GMO location register;
- Liability in case of damage;
- Strict implementation of the precautionary principle.

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