15 May 2020, Brussels

Stakeholder consultation on new genomic techniques to contribute to a Commission study requested by the Council

Questionnaire

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/CE).

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.

[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.

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].

Stakeholders will be invited to respond to the questionnaire via EUsurvey before the 15th of May 2020 (office closure).

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): European Coordination Via Campesina (ECVC), Transparency Register number: 28920471149-55

- Please mention the sectors of activity/fields of interest of your association: ECVC is a European confederation of national organisations of farmers and agricultural workers. Its main areas of activity/interest are: agriculture and rural development, seed production, livestock production, biodiversity, food security, farmers' rights, etc. More info on: https://www.eurovia.org/about/

- If applicable, please indicate which member associations (national or EU-level), or individual companies/other entities have contributed to this questionnaire: The ECVC currently gathers 31 national and regional farmers, farm workers and rural organizations based in different European countries. ECVC membership list is available online: https://www.eurovia.org/about/members/

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

[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

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

o If yes, please provide details.

o If no, please explain why not.

No, our members do everything that is within their power to not use NGT-products, however, they may use them against their will when they are not labelled as GMOs.

Our members comply with the demands of EU citizens who do not want genetic engineering in their food. By guaranteeing GMO-free production, we allow freedom of choice for all, from the selection, multiplication, cultivation, harvesting, processing, trade and exchange of seeds to the consumer's plate. Trading and processing companies demand GMO-free products. It would be a great competitive advantage if European farmers could produce them. In order to guarantee this in the future, new genetic engineering methods must be regulated by the relevant Community law, as confirmed by the Court of Justice of the European Union in its ruling of 25 July 2018.

This risk is aggravated by a misinterpretation of the Directive 2001/18 by various parties. Some argue that only products containing foreign DNA voluntarily introduced by genetic engineering are affected. Others consider that only products resulting from techniques developed since 2001 are included in the NGTs, whereas the ECJ specified in its judgment of the 25th of July 2018 that these are products resulting from techniques mainly developed since 2001. This includes genetic engineering techniques which, such as transgenesis, started to be developed shortly before 2001. At that time, however, the techniques had not been around for long enough to be able to prove that they were safe e m. Such misinterpretations have led these actors to not evaluate, nor to apply for authorisations for release, nor to label and trace products resulting, for example, from directed mutagenesis or random *in vitro* mutagenesis. he French Conseil d'Etat, in its decision of the 9th of February 2020 (https://www.conseil-etat.fr/ressources/decisions-contentieuses/dernieres-decisions-importantes/conseil-d-etat-7-fevrier-2020-organismes-obtenus-par-mutagenese) identified that products resulting from these techniques do fall under the the scope of Directive 2001/18 and cannot be exempted. ECVC was able to identify Cibus rapeseed and Calyxt soybeans obtained by directed mutagenesis and grown in North America that could be imported into Europe without any traceability, as well as Clearfield rapeseed, chicory made tolerant to herbicides and Convizo Smart beet grown in Europe. There may be others, as well as products contaminated by these various products, unintentionally used by our members and by all those who refuse any use of GMOs.

In general, the safety of NGT has not been evaluated and scientific studies show that these techniques result in unexpected alterations of the genome, both at the intended target and off-target sites. Any of these alterations could result in unexpected toxicity and/or allergenicity. The lack of knowledge also relates to the environmental and cumulative effects that may result from the products of these techniques. The following is an overview of scientific studies on these issues: https://www.gmwatch.org/en/news/latest-news/19223

2. Have your members taken or planned to take measures to protect themselves from unintentional use of NGT-products? *Yes/no/not applicable*

o If yes, please provide details.

Without implementing the Court of Justice ruling, it will be difficult to guarantee GMO-free production - and therefore freedom of choice for the whole economic chain.

The first step should be for the Commission and Member States to invest in research to develop general detection methods. Many scientists have already demonstrated that this is feasible. It should also be ensured that no illegal imports of unauthorised NGT products into Europe take place.

For as long as the ECJ judgment is not applied, looking through suppliers' promotional documents, scientific publications, patents, etc. can help our members identify certain NGT-products that are not labelled, in order to successfully avoid using them. Individual or collective self-production of seeds, plants, breeding animals and other inputs (natural preparations that are not of great concern.) from parents resulting from traditional selections and traditional or natural products are a good way to protect oneself against unintentional use or possible contamination by NGT-products. In Italy, for example, farmers can rely on the law and possibly demand intervention by the public authorities. See: https://www.gazzettaufficiale.it/eli/id/2001/08/09/001G0376/sg

o If no, please explain why not.

o If yes or no, have you encountered any challenges?

If yes, please provide details

The non-implementation of the ECJ's judgment and the lack of public information on the techniques used to obtain the varieties and breeding animals marketed, the lack of labelling and traceability of GM products such as those referred to in the answer to question 1, as well as the lack of public information on the processes used to identify them all make it impossible to totally prevent any unintended use of NGT-products. In addition, these factors undermine the market in organic and guaranteed GMO-free products.

Furthermore, if NGT products were deregulated, farmers who do not use GMOs, which is the vast majority of European farmers, would not be able to protect themselves against the contamination of their crops and would be left to suffer the consequences on their own. The polluter pays principle is being undermined, with enormous economic losses (see production labelled "organic").

3. Are you aware of initiatives in your sector to develop, use, or of plans to use NGTs/NGT-products? *Yes/no/not applicable*

o If yes, please provide details.

Prevention against the unintentional use of NGTs starts with the protection and fundamental maintenance of the existing legislation. As mentioned above, ECVC members do not intentionally use these technologies as they consider them potentially dangerous for their

productions, due to safety concerns and economic reasons. However, beyond ECVC members, an exhaustive search of patent databases and scientific publications should provide a fairly accurate picture of the NGT-products under development or already developed. ECVC has done some very partial research but unfortunately does not have the means to carry out an exhaustive search on its own.

So far, according to publicly available sources, two crops derived from NGT are grown (rapeseed and soybean). In addition, some 50 deregulated GMOs have recently been authorised but not subjected to GMO regulation in the United States. This does not mean that all of them will necessarily be grown and then exported to the EU, although there is a small possibility that this will happen. See: https://www.infogm.org/6994-etats-unis-cinquantaine-nouveaux-ogm-dans-tuyaux.

4. Do you know of any initiatives in your sector to guard against unintentional use of NGT-products? *Yes/no/not applicable*

o If yes, please provide details.

Organic and GMO-free certifications and participatory systems ensure that NGT-products are not used. Conventional farmers relying on GMO-free food can only guarantee that they do not use NGT products if these are regulated, even if they buy GMO-free seed or feed. On-farm self-production of seeds, seedlings, breeding animals and other inputs for plant and animal care and on-farm processing of agricultural products is also a way to guard against unintended uses of NGT products. To give the example of Italy, farms must strictly control the labelling provisions and ensure that the seed laws in force in the State are respected.

o If yes or no, are you aware of any challenges encountered?

If yes, please provide details

All of these initiatives face the challenges outlined in the responses to questions 1 and 2. If NGTs are not regulated by Directive 2001/18, it will be impossible to guarantee a GMO-free production (organic and conventional). We will lose the great competitive advantage that European farmers currently have by being able to produce GMO-free products. This would be a major problem for the existence of a very large number of farms.

5. Are your members taking specific measures to comply with the GMO legislation as regards organisms obtained by NGTs? *Yes/no/not applicable*

o If yes, please describe the measures and their effectiveness including details on the required financial, human resources and technical expertise.

Our members use organic and GMO-free certifications and participatory systems and are developing many collective initiatives to self-produce seeds, seedlings, breeding animals and other inputs on the farm to care for plants and animals and to process agricultural products on the farm without using GMOs or NGT-products.

Currently, no application for NGT product authorisation has been granted in Europe. Therefore, any use of an NGT product is illegal. Currently, NGT products can only enter the

EU market through imports. It is not the responsibility of a sector to guard against the unintended use of NGT products, neither are 'initiatives' to be taken by them; it is the competent authorities in the EU who must prevent illegal imports through effective controls at the European borders. Detection methods are urgently needed, especially for Cibus-Canola and Calyxt-Soy.

o If yes, what best practices can you share?

GMO-free certifications and participatory systems

o If yes or no, what challenges have you encountered?

All of these initiatives face the challenges outlined in the responses to questions 1 and 2, such as the lack of public information on processes to identify and evaluate NGT products, applying for a release authorisation, and the lack of labelling and traceability of products derived, for example, from directed mutagenesis or random *in vitro* mutagenesis.

Please also see question 8 specifically on labelling.

o If no, please explain why not.

6. Has your organisation/your members been adequately supported by national and European authorities to conform to the legislation? *Yes/no/not applicable*

o If yes, please describe what type of support and what best practices you can share?

o If not, what challenges have you encountered?

The national and European authorities have failed to implement the ECJ judgment. Therefore we can't know if unidentified NGT-products, whether imported or produced in Europe, circulate on the market. NGT products that are not approved by the EU should not be imported or grown. There should be zero tolerance, and the authorities should implement the ECJ ruling.

As a first step, methods for the detection of NGT products should be developed. Unfortunately, one gets the impression that neither governments nor the Commission is being held responsible. They are passing the buck back and forth from national to EU level and vice versa, so in the end nobody is bearing the burden.

The main challenges encountered are therefore the lack of labelling and traceability of various NGT-products marketed on European territory, the lack of a coordinated research programme between the European Commission and the Member States to define the regulatory protocols for identifying and distinguishing NGT-products that have not been declared as such, the lack of a public database of existing NGT-derived products and of processes to identify and distinguish them and finally the lack of public and transparent information on the breeding techniques used to obtain plants, breeding animals and micro-organisms marketed and/or disseminated on the European territory, prevent stakeholders from identifying NGT-products in order to comply with the legislation to which they are subject.

7. Does your sector have experience or knowledge on traceability strategies, which could be used for tracing NGT-products? *Yes/no/not applicable*

o If yes, please describe the traceability strategy, including details on the required financial, human resources and technical expertise.

o If no, do you have suggestions on possible traceability strategies and/or methods? *Yes/no*

If yes, please describe.

All operators in the food chain, from farmers to distributors, as well as the competent authorities, have a long experience of documentary and analytical traceability, which has proved its worth in many health crises. This experience has been useful, for example, in the fight against the contamination of food products by undeclared transgenic Chinese rice (http://europa.eu/rapid/press-release_MEMO-06-310_en.htm).

Large retailers, for their part, have the means to "persuade" their suppliers to guarantee NGT-free products: even if "*sometimes the information can be masked*", large retailers "can *demandGMO-free products*" (see Attachment No. 1). The public authorities that finance a very large part of the research that enables the elaboration and then the commercial development of NGT-products have equivalent means of "persuasion", albeit they would have to be willing to use them.

During the "arable crops-seeds" European Civil Dialogue Group of March 6, 2020, Europol representatives made a presentation of the " OPSON seeds", seedlings and intellectual property rights programme, which focuses on the fight against counterfeiting. This programme organises the collection and exchange of information between national services in charge of the fight against fraud. 1500 networked institutions can bounce back at the slightest alert, including the DG Health services in charge of seeds. In response to a question asked by ECVC on the identification of counterfeit NGT-products, which are often presented as indistinguishable from non-counterfeit products because they come from traditional breeding processes, Europol representatives stated that they have never before needed to carry out DNA analysis. Documentation, internet and darknet surveillance have always been sufficient to identify them. According to Europol, it is therefore not impossible to identify and distinguish new GMOs that have not been declared or traced as such. However, Europol does not rule out the possibility of using DNA analysis in the future.

UPOV has established protocols for the identification and differentiation of plant varieties using molecular markers. The Community Plant Variety Office, which manages the collection of European reference varieties in Angers, is very involved in this work. The same methods can easily be used to identify and distinguish GMOs resulting from new genomic techniques. See: https://www.infogm.org/6974-upov-possible-caracteriser-nouveaux-ogm. The results of this UPOV work underline the feasibility of identifying all types of varieties. They are similar to those of ISO. The fact that we are now at the stage of standardization of methods for mutual recognition of procedures demonstrates their technical feasibility and that we are no longer at the stage of proof of concept.

In the following article, Professor Yves Bertheau shows that it is possible to detect NGT-products that would not be declared, because of genomic and epigenomic scars caused

byall in vitro techniques and to the specific signatures linked to the different NGTs, if we give ourselves the means to do so:

Bertheau, Y. (2019). *New Breeding Techniques: detection and identification of the techniques and derived products. In Encyclopedia of Food Chemistry Reference Module in Food Science, L. Melton, F. Shahidi, and P. Varelis, eds. (Oxford: Academic Press)*, pp. 320-336.

The genomic and epigenomic scars and signatures mentioned in this article are only some of the molecular markers used by UPOV and ISO for standardized variety identification.

The Biotech industry confirms that it is scientifically feasible to detect organisms obtained by NGTs. See following article: https://www.stopogm.ch/index.php/themes/nouvelles-techniques-de-modification-genetiques/711-un-expert-scientifique-de-bayer-le-confirme-les-mutations-par-edition-genomique-sont-detectables.

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*

o If yes, please describe the measures and their effectiveness including details on the required financial, human resources and technical expertise.

o If yes, what best practices can you share?

o If no, please explain why not.

Our members refuse to use, produce and market NGT-products because it is impossible to control the risks arising from intentional or unintentional genetic modification by overcoming natural barriers to the multiplication and/or recombination of plants, animals and micro-organisms. Currently in the EU, no NGT products are authorised, and there has not even been an application for authorisation submitted so far, therefore any product labelled NGT on the EU market would be illegal. However, our members may unknowingly and unintentionally use them and therefore have no means of ensuring their compliance with labelling requirements.

o If yes or no, what challenges have you encountered?

Our members are facing the challenges outlined in the responses to questions 1 and 2, such as the lack of public information on processes to identify and evaluate NGT products, applying for a release authorisation, and the lack of labelling and traceability of products derived, for example, from directed mutagenesis or random *in vitro* mutagenesis.

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*

o If yes, please describe for the:

Agri-food sector;

Thanks to the legal work of our members, in its decision of the 9th of February 2020, the French Council of State finally showed that the seed sector and French legislation do not correctly apply the GMO legislation in view of the ECJ judgment and urged the government to take the necessary measures to apply it correctly. These measures should be implemented within 6 and 9 months of the publication of this decision.

The French Government also suggested that breeders indicate the breeding techniques for varieties listed in the catalogue. Unfortunately, this information remains voluntary today. If it were to become mandatory and sufficiently detailed, it could hinder the marketing of undeclared NGT varieties. See https://agriculture.gouv.fr/telecharger/82931?token=20762704ed299a07863a4fc4270ded83 under action 6.4 on page 22.

Between 2011 and 2014, the US company CIBUS has been trying to get approval to grow its herbicide-resistant canola from six national authorities: Finland, Spain, the UK, Sweden, Ireland and Germany. In Germany, the responsible authority, the Federal Agency for Consumer Protection and Food Safety (BVL), stated that GMO techniques did not result in GMOs. The ODM oilseed rape could therefore have been grown in Germany. This cultivation was only prevented by a legal action brought by several organisations. The complainants argued that ODM should be regulated as genetic engineering, implying a cultivation permit or a release authorisation. After the European Court of Justice ruled that organisms produced using new mutagenesis techniques are subject to GMO legislation, the BVL withdrew its ICBUS GMO authorisation for canola (https://www.bvl.bund.de/SharedDocs/Fachmeldungen/06_gentechnik/2018/2018_08_17_Fa_Cibus_Raps_Bescheid.html).

Industrial sector;

Medicinal sector.

Information on research on NGTs/NGT-products:

10. Are your members carrying out NGT-related research in your sector? *Yes/no/not applicable*

o If yes, please specify including subject, type of research, resources allocated, research location.

o If no, please explain why not.

Our member do not carry out any research because the research that is of interest to them isnot funded, including research on identification and traceability of NGT-products, unintended effects of NGTs, assessment of the socio-economic, health, and environmental impacts of marketing NGT-products for agricultural or agro-industrial use,the assessment of the risks related to the dissemination of NGT-products in terms of biosafety, the development of standardised processes and norms for the identification and distinction of

undeclared NGT-products, and the assessment of the impacts of the economic, intellectual property and legal models that ensure their development.

On seed breeding, our members advocate for research that contributes to the agroecological transition through territorial approaches, based on the principles and methods of agroecology recommended during the Regional Symposium on Agroecology for Sustainable Agriculture and Food Systems for Europe and Central Asia. This research shows that agroecology is not compatible with NGTs. The States that participated in this symposium, including the EU, adopted amongst others some specific political recommendations on research, innovation, knowledge sharing and agroecological movements. See page 57: http://www.fao.org/3/a-i7604e.pdf.

11. Are you aware of other NGT-related research in your sector? *Yes/no/not applicable*

o If yes, please specify.

Research is currently being carried out by the Federal Agency for Nature Conservation and the Austrian Environment Agency UBA. See https://www.stopogm.ch/index.php/themes/nouvelles-techniques-de-modification-genetiques/571-reflexions-ethiques-sur-les-nouvelles-techniques-de-modification-genetique and https://www.stopogm.ch/images/stories/STOPOGM/Themes/NBT/New_Plant_Breeding_Techniques_UBA_Vienna_2014_2.pdf

12. Has there been any immediate impact on NGT-related research in your sector following the Court of Justice of the EU ruling[4] on mutagenesis? *Yes/no/not applicable*

o If yes, please describe.

Some political advocacy against this judgment has increased. These activities are sometimes camouflaged under the cover of scientific publications that seek to demonstrate that the ECJ's judgment is wrong, and therefore these biased analyses, which are often legally and scientifically flawed and create confusion with the intention of promoting these techniques, strongly affect us.

It is particularly worrying that a group of scientists is promoting such techniques as scientifically safe, when there is no proof of their safety, whilst there are many scientists who clearly state that there are risks (see Case C-528/16 http://curia.europa.eu/juris/documents.jsf?num=C-528/16), and for which it is fundamental that the EU's precautionary principles are applied. In the field of GMOs, it has been demonstrated in many concrete cases that part of genetic science is driven by the interest of industry, as they are one of the main investors in new genetic technologies. This interest pushes for the deregulation of new genetically modified techniques in plants and to allow their free movement in ecosystems, while the same scientists agree that the use of these techniques is still dangerous for humans and animals due to too many unpredictable off-target events. For this reason, only laboratory experiments should be allowed and subject to strict regulations that include ethical aspects. But the interest of the industry combined with a certain mentality among some scientists is spreading the tendency to consider that plants

are not living organisms like any other. They do not see the risks associated with the release of these products in the field, simply because the risks are not known and researched, and in clear contradiction with the EU's precautionary principle. This dual attitude is the expression of a scientific culture driven by a human interest that focuses on economic interests, which will irreversibly endanger the ecosystems we live in. Reducing the debate to a technical issue, while creating confusion, without including in the debate the potential impact on biosafety diminishes all ethical and societal issues.

See also an article exploring the culture of academic commercialism, its role in the development of powerfully disruptive technologies, and how it might affect the public interest: https://www.thenation.com/article/society/cambridge-analytica-academic/

o If no, please explain why not.

13. Could NGT-related research bring benefits/opportunities to your sector/field of interest? *Yes/no/not applicable*

o If yes, please provide concrete examples/data.

Research is needed to ensure the right to produce and consume GMO-free products, including research on the identification and traceability of NGT-products, the unintended effects of NGTs, the assessment of the socio-economic, health, and environmental impacts of the marketing of NGT-products intended for agriculture or agro-industry, the assessment of the risks related to the dissemination of NGT-products in terms of biosafety, the development of standardised processes and standards for the identification and distinction of undeclared NGT-products, the assessment of the impacts of the economic, intellectual property and legal model that ensures their development.

It is our opinion that biotechnological research in agriculture drains fundamental resources that should instead be put at the service of producers (especially small-scale producers) through the support and participatory development of agroecological techniques, inputs and methodologies. These research programmes must guarantee fairht centrality to farmers, ensuring that there is no appropriation, privatisation and third-party exploitation of biodiversity and/or knowledge, technologies or other types of peasant resources (unlike biotechnology). Similarly, research in agroecology must be locally or regionally linked to the variety of production practices devised and implemented in the farming world: they are specific, appropriate and sustainable, with reduced environmental impact and are generative from a socio-economic point of view. In particular, the family farming sector - and to a lesser extent those of organic and biodynamic agriculture - suffers what is called "research credit", i.e. decades of comparative disadvantage compared with technical and economic resources and political-institutional support for agroindustry and biotechnology.

o If no, please explain why not.

14. Is NGT-related research facing challenges in your sector/field of interest? *Yes/no/not applicable*

o If yes, please provide concrete examples/data.

As far as we know, relevant research, that was cited in the responses to the previous two questions (covering the identification and traceability of NGT-products, the unintended effects of NGTs, the assessment of the socio-economic, health, and environmental impacts of the marketing of NGT-products intended for agriculture or agro-industry, the assessment of the risks related to the dissemination of NGT-products in terms of biosafety, the development of standardised processes and standards for the identification and distinction of undeclared NGT-products, and the assessment of the impacts of the economic, intellectual property and legal model that ensures their development) does not receive any funding. There is generally a clear lack of independent research on the subject. Research is primarily driven by private or small group interests, and there is an acute lack of healthy public debate on the subject.

Every year, the scientific world produces thousands of articles on new genomic technologies, often with conflicting messages. Industry groups interested in these technologies tend to highlight only the results of research in this field motivated by an interest in developing, applying and benefiting from the technology and do not mention research into possible agricultural, environmental and health risks, which is not motivated by private interest. A massive campaign by the biotech industry, using its invested economic resources, has created a situation at EU level that exaggerates the perceived potential and opportunities of NGTs, as opposed to their risks, with the aim of dismantling the EU's precautionary principle. But, as reported in 2016 by the Swiss Federal Ethics Commission for Biotechnology in the Non-Human Field (https://www.ekah.admin.ch/inhalte/ekah-dateien/dokumentation/publikationen/EKAH_Nouvelle_techniques_de_selection_vegetale_2016.pdf) the Swiss Federal Ethics Committee on Non-Human Biotechnology (ECNH) also rejects the criticism that the precautionary principle basically slows down technology and innovation. Instead, it can be argued that the authorisation procedures and regulations applicable to technologies that entail risks stimulate innovation by promoting the development of research into different technologies and solutions.

The risks must be researched using methods that focus on precaution and are free from private interests, otherwise government authorities cannot properly fulfill their obligation to protect health and the environment from the possible risks of genetic engineering and biotechnology. When confronted with GMO products in the approval process, government agencies must be able to critically question the data and results submitted by industry applicants. A mere plausibility check, which simplyreproduces the results submitted by industry, does not guarantee compliance with public protection obligations.

See article exploring the culture of academic commercialism, its role in the development of powerfully disruptive technologies, and how it might affect the public interest: https://www.thenation.com/article/society/cambridge-analytica-academic/

o If no, please explain why not.

15. Have you identified any NGT-related research needs/gaps? *Yes/no/not applicable*

o If yes, please specify which needs/gaps, explain the reasoning and how the needs/gaps could be addressed.

Beyond the lack of research mentioned in the answers to questions 10 and 13 (mainly research covering the identification and traceability of NGT-products, the unintended effects of NGTs, the assessment of the socio-economic, health, and environmental impacts of the marketing of NGT-products intended for agriculture or agro-industry, the assessment of the risks related to the dissemination of NGT-products in terms of biosafety, the development of standardised processes and standards for the identification and distinction of undeclared NGT-products, and the assessment of the impacts of the economic, intellectual property and legal model that ensures their development), there is also a lack of research on the development of sustainable alternatives to NGTs, including collective peasant selections of plants, animals and micro-organisms in situ on the farm, as well as farm-based or local and artisanal food processing. In a context of climate change these systems of farmers' selection are based on local adaptation, as opposed to seeds produced for NGTs, which are based on an agronomic idea in conflict with nature and developed for a model of agricultural production based on monoculture, which destroys biodiversity. ECVC promotes research models based on the principles of agroecology and living things. As stated in question n.10 our members advocate for research that contributes to the agroecological transition through territorial approaches, based on the principles and methods of agroecology recommended during the Regional Symposium on Agroecology for Sustainable Agriculture and Food Systems for Europe and Central Asia. This model of research is not compatible with NGTs. The States that participated in this symposium, including the EU, adopted amongst others some specific political recommendations on research, innovation, knowledge sharing and agroecological movements. See page 57: http://www.fao.org/3/a-i7604e.pdf

Current research has highlighted the errors that occur when integrating NGTs. This can result in the presence of undesirable DNA or RNA residues in the final product, which is a potential risk to health, agriculture and the environment. For example, in the case of genome-modified cattle, unwanted DNA fragments were found in the final organism, including an antibiotic resistance gene. Although evidence is accumulating on the many unintended "off-target" and "on-target" effects of gene editing techniques such as CRISPR (see https://www.gmwatch.org/en/news/latest-news/19280), the concrete implications of these unexpected changes for human or animal health and the environment are still poorly understood and insufficiently studied. The fact that new genomic techniques have only recently been developed and therefore do not have a long history of safe use, provides substantial grounds for further research into the risks they may generate and for maintaining them within the general framework of EU food law (Regulation 192/2002).

See an overview of peer-reviewed papers on risks and unintended effects of NGTs: https://www.gmwatch.org/en/news/latest-news/19223

Information on potential benefits and opportunities of NGTs/NGT-products:

16. Could NGTs/NGT-products bring benefits/opportunities to your sector/field of interest? *Yes/no*

o If yes, please describe and provide concrete examples/data.

o If yes, are these benefits/opportunities specific to NGTs/NGT-products?

o If yes, please explain.

o If no, please explain why not.

We do not see any benefit, and the transposition of the judgment of the Court of Justice is very important to avoid effectively breaking the guarantees of the legislation in terms of GMO-free status and traceability in the supply chain. In this regard, we express great concern about the future loss of confidence of foreign consumers in a GMO-free supply chain should this ruling not be implemented. This would lead to a dramatic loss of markets and value of agricultural products for the growing organic sector, which today amounts to 92 billion euros of global production, 37 of them in the EU (FIBL-IFOAM, 2017). The continuously growing trends in this sector must in no way be jeopardized by the deregulation of NGTs.

Like the promoters of first-generation transgenic GMOs, the promoters of NGTs make multiple promises of plant resistance to all pathogens, to climate change or to meet the needs of food safety by increasing the quantities produced. None of these promises have been fulfilled. More than 90% of the transgenic plants being grown are plants that involve an increased use of herbicides or that produce insecticidal substances themselves. The industrial food system, which pioneers these plants,e produces only 1/4 of the food available on the planet using 3/4 of the land and water resources, while so-called « subsistence » agroecological systems produce 3/4 of the food using only 1/4 of the land and water resources. Like transgenic GMOs, GMOs derived from NTGs have already been placed on the market and have only been genetically modified to tolerate herbicides.

dDiversity, genetic variability, and ensuringf each population of crop plants farm animals, and micro-organisms is able to adapt to thelocal ecosystem, is the only sustainable response to the current acceleration of climate, health and socio-economic changes. However, the economic model of NGT development imposes the generalization of the same very narrow genetic solutions in all territories. NGTs can only modify one or two parameters, such as resistance to one or two pathogens, which are quickly bypassed by the emergence of new pathogens. By generalising ultra-simplified solutions, NGTs destroy the subtle equilibrium of complex agro-ecosystems. The agronomic solutions proposed by NGTs do not focus on agricultural research based on adaptation, but rather on a non-natural genetic orientation (non-natural because of gene engineering, but also because the process is much faster than the natural one, by bypassing the interaction mechanism of the natural selection process) that does not take into account natural life principles, but which rapidly leads to and accelerates conflicts in nature (plants resistant to certain pathologies, causing pathogens to become stronger, herbicide-resistant plants, etc.). In any case, no one should think that NGTs could lead to a reduction of the use of pesticides, because plants selected for their resistance to a certain pathogen that are derived from these techniques and cultivated in an industrial and not adaptive framework will quickly cause these pathogens to mutate and become even more dangerous. Moreover, it will be necessary to use even more dangerous pesticides.

None of these solutions can be sustainable, their obsolescence is programmed from their conception.

The real solutions to reducing pesticide use lie in our production models. For example, in agro-ecological production models, the use of cropping systems designed for their biological complementarities improves the efficiency of nutrient use and pest regulation, thereby improving crop yield stability and reducing or eliminating the use of chemical pesticides in favour of natural formulas. On the model of agro-ecological production there is a very extensive academic literature, but it is in the fields that many real examples can be found.

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*

o If yes, please describe and provide concrete examples/data.

o If yes, under which conditions do you consider this would be the case?

The environmental, economic, social and sustainability impacts of NGTs have not yet been assessed, and many doubts remain. What is most worrying is the issue of off-target changes in the DNA produced by these techniques, which are neither assessed nor taken into consideration by the promoters of NGTs, and which pose a serious biosafety problem if these products are allowed to circulate in ecosystems. Thus, instead of focusing on predicting the untested benefits of NGTs, preference should be given to a variety of solutions in the food and agriculture sector that consider the agri-food system as a whole and are based on hard evidence and a long history of safe use. If we want real solutions, we need to start from the problems and from real research to determine what the best solutions are. Patented homogeneous varieties, which are very expensive, non-reusable and not adapted to local conditions, will almost never produce the desired results.

Furthermore, it is very important to underline that the Declaration of the Rights of Farmers and Others Working in Rural Areas (UNDROP, approved by the United Nations General Assembly on 17 December 2018) clearly protects the right of farmers to freely choose, reseed, maintain, control, protect, develop and sell their seeds, in accordance with Articles 5, 6 and 9 of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the implementation of the UN Convention on Biological Diversity (CBD) and its protocols (Cartagena and Nagoya). UNDROP also commits States to take appropriate measures to support farming seed systems, and to ensure that agricultural research and development directly addresses farmers' needs. These rights, already poorly guaranteed, appear to be further threatened by the development of biotechnology in agriculture.

The promises associated with NGTs and NGT products are crops that resist climate crises, halt biodiversity loss and ensure a competitive EU economy. But the only commercial developments are herbicide-tolerant plants that increase the use of these toxic pesticides.

With these promises, it is suggested that complex societal, political and economic problems can be solved by screwing in the plant genome or by technical intervention via NGTs, respectively. Such a narrow vision risks seeking a simple technical solution to complex problems, maintaining a bad farming system and preventing real solutions. This is a threat to society in general.

The EU's farm-to-fork strategy, with its ambitions for greener and more climate-friendly food production, should focus on breeding models that are not linked to NGTs, and which have the potential to offer a wide range of benefits for agriculture and society in the long term. Overall the strategy should not support technologies, such as NGTs, which fail to address the root causes of the climate crisis resulting, to a large extent, from the large-scale industrial agricultural production model and intensive animal breeding.

18. Do you see particular opportunities for SMEs/small scale operators to access markets with their NGTs/NGT-products? *Yes/no*

o If yes, please describe and provide concrete examples/data.

o If no, please explain why not.

Like the first transgenic GMOs, NTGs will accelerate the concentration of the industry. SMEs do not have sufficient logistics to face the global market, which alone can recover some of the costs of research and development of new NGT-products. The only advantage for an SME that has succeeded in developing an NGT-product that could be profitably exploited commercially is that such a product can be sold to a large company. SMEs that fail, on the other hand, bear the cost of their failure alone. This mechanism allows large companies to outsource a significant part of the research to take advantage of the profits while at the same time transferring the losses to the disadvantage of SMEs, that have to pay for them. See: https://www.gmwatch.org/en/news/latest-news/19239 and https://www.eurovia.org/wp-content/uploads/2020/04/Fact-sheet-EN.pdf.

In order to be able to effectively apply new GMO breeding techniques, breeders need a significant amount of knowledge and resources in molecular genetics and bioinformatics. In addition, they must have appropriate laboratory equipment at their disposal. Small breeders, however, rarely have this expertise and also lack the financial resources and laboratory equipment to work with molecular genetic methods. The laboratories of medium-sized companies also work together, as it is too expensive to have an equipped laboratory. The main obstacles faced by small and medium-sized genetics companies in developing plants with new genetic modification techniques and commercializing them are patents. Having to negotiate with large companies puts small and medium-sized gene companies in a difficult situation, and licensing fees are a significant financial burden. Breeders who have unknowingly used patented plant genetic resources sometimes do not get a license because the patent company refuses to grant them one. In the end, the long process of selection and development of varieties and lines is futile, breeders cannot use them. Thus, it is a great risk for breeders.

19. Do you see benefits/opportunities from patenting or accessing patented NGTs/NGT-products? *Yes/no*

o If yes, please describe and provide concrete examples/data.

o If no, please explain why not.

Patents accelerate the concentration of the seed industry, which reduces the diversity of seed supply and causes seed prices to rise exponentially, see: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3338485.

In addition, the patent system further impedes plant 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.

In addition, the reproduction of seeds, an ancestral right of farmers, is prohibited by patent laws when using patented seeds that are not covered by a plant variety right or when crop contamination occurs. Farmers' rights are thus ignored.

The experience of Canada and the United States raises serious concerns that plant patents limit the availability of seed to farmers and result in higher seed costs without increasing yields. see: Torshizi, Mohammad and Clapp, Jennifer, Price Effects of Common Ownership in the Seed Sector. April 22, 2019. SSRN: http://dx.doi.org/10.2139/ssrn.3338485. See also Annual Review of Resource Economics and Concentration in Seed and Biotech Markets: Extent, Causes, and Impacts- Koen Deconinck, Organisation for Economic Co-Operation and Development (OECD), 2020. 75775 Paris Cedex 16.

Some industries are concerned about patented seeds that may also hinder innovations in the breeding sector and the development of seeds and crops capable of coping with increasingly extreme weather conditions. See:

Clapp, J. 2018. Mega-Mergers on the Menu: Corporate Concentration and the Politics of Sustainability in the Global Food System. Global Environmental Politics 18: 12–33. https://doi.org/10.1162/glep_a_00454

Hendrickson, M., Howard, P.H. & Constance, D. 2019. Power, Food, and Agriculture: Implications for Farmers, Consumers, and Communities. In: Hansen, J., Gibson, J. & Alexander, S. (eds.). Defense of Farmers: The Future of Agriculture in the Shadow of Corporate Power. Lincoln: University of Nebraska Press. p. 13–62. https://doi.org/10.2307/j.ctvgs0crb.7

Howard, P.H. 2015. Intellectual Property and Consolidation in the Seed Industry. Crop Science 55: 2489–2495. https://doi.org/10.2135/cropsci2014.09.0669

Marco, A.C. & Rausser, G.C. 2008. The role of patent rights in mergers: Consolidation in plant biotechnology. American Journal of Agricultural Economics 90: 133–151.

https://doi.org/10.1111/j.1467-8276.2007.01046.x

Solberg, S.O. & Breian, L. 2015. Commercial cultivars and farmers' access to crop diversity: A case study from the Nordic region. Agricultural and Food Science 24:150–163. https://doi.org/10.23986/afsci.48629

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

o If yes, please describe and provide concrete examples/data.

It is not possible to control the risks arising from intentional or unintentional genetic engineering by overcoming natural barriers to the multiplication and/or recombination of plants, animals and micro-organisms. Any use of genetic engineering generates, beyond the claimed modifications, numerous unintentional genetic or epigenetic modifications. If such genetic modifications only involve non-hereditary cells, the risk-benefit balance may justify the decision to accept or reject the risks on a case-by-case basis. However, when these genetic modifications concern hereditary cells, no modelling can predict their fate as they are reproduced, crossed and recombined successively in living organisms, thus modified, nor can it predict the risks they may generate. It is not possible to assess and make decisions on a case-by-case basis since future cases are unknown and cannot be modelled. These risks are borne by farmers and consumers as opposed to the scientists, industry and intellectual property professionals who benefit from them. NGTs will increase the costs of organic and non-GMO quality chains. These negative impacts will be multiplied if NGT-products are not labelled and traced. 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, we don't know if GMOs can be taken out of the environment once released (retrievability). The non-retrievability of NGTs and unknown risks arising from them is conflitctual i with respecting the precautionary principle as guidance for all environmental legislation of the EU. We would lose control of our food production. , these risks and negative impacts are socially unfair and unacceptable and in the most part irreversible and without any sustainable benefits.

It is very important to underline that the Declaration of the Rights of Farmers and Other Persons Working in Rural Areas (UNDROP, approved by the United Nations General Assembly on 17 December 2018) clearly protects the right of farmers to freely choose, reseed, maintain, control, protect, develop and sell their seeds, in accordance with Articles 5, 6 and 9 of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the implementation of the UN Convention on Biological Diversity (CBD) and its protocols (Cartagena and Nagoya). UNDROP also commits States to take appropriate measures to support farming seed systems, and to ensure that agricultural research and development directly addresses farmers' needs. It therefore calls for these aspects to be taken into account, at European and national level, with regard to the development of genetic engineering products.

If yes, are these challenges/concerns specific to NGTs/NGT-products?

o If yes, please explain.

As indicated by the European Court of Justice, these risks are the same as those generated by transgenic GMOs. Please see point 48 of the ruling of the ECJ: http://curia.europa.eu/juris/documents.jsf?num=C-528/16.

As with old GMOs, there is the unclear risk NGTs pose to the environment and the balanced ecosystem. Other specific risks linked to NGTs are gene drives, including gene drive insects with the specific goal of changing whole ecosystems. In addition, they might disseminate in natural populations since they are more likely to reproduce. A large and growing body of research (summarised here https://www.gmwatch.org/en/news/latest-news/19223) shows that NGTs give rise to unexpected alterations in the genome, both at the on-target intended editing site and at off-target sites. The misreading of DNA in a genome-edited plant or animal could impact biodiversity. For example, if the chemistry of a genome-edited plant or animal were changed by the misreading of DNA, it could produce a compound that is toxic to the wildlife that feeds on it. These types of concerns regarding human and ecological safety mean that gene-edited organisms need to be analysed for any on-target effects, and their implications need to be carefully evaluated.

There are also serious risks to health from consumption of products of NGTs, which have not been investigated scientifically. 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, 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).

Regarding human and animal health and animal welfare, the fundamental concern about GMOs, including NGTs, is that genetic engineering can unintentionally interfere with the gene expression of an organism and/or with complex biochemical pathways. 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.

o If no, please explain why not.

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

o If yes, please describe and provide concrete examples/data.

NGTs will exacerbate the already significant loss of consumer confidence in the safety of the food chain.

The business model of genetic engineering requires a return on investment of any innovation on the largest possible market, thus on very large cultivated areas of many different ecosystems in many countries and continents. Plants modified in this way impose an ever-increasing standardization of ecosystems through chemical inputs and the mechanization of these ecosystems, and are therefore unable to adapt to the amplification and acceleration of climate change. NGT-products are intended for industrial monocultures and polluting concentration farms, which are the main factors in the multiplication of health crises. Their production is intended for the agro-industry, which provides a standardized diet of low nutritional value and unsuited to local health and cultural particularities.

Only the economic model of local selections of diverse plants adapted to each local agro-ecosystem can ensure sufficient resilience to the impacts of climate change. The economic

model of NGTs is incompatible with local adaptive selections and relocation of the food chain. Political, financial and legal support for the development of NGTs removes all support for sustainable agro-ecological alternatives and hinders their development.

The scientific community was recently thrown into ethical and regulatory chaos by the claim that a Chinese researcher, He Jiankui, hade used CRISPR to alter the genomes of twin babies in China (see The CRISPR-baby scandal: what's next for human gene-editing: https://www.nature.com/articles/d41586-019-00673-1). A key concern is that CRISPR's effects aren't understood well enough to guarantee the twins' wellbeing.

Gene-editing errors in the genome may be overlooked. This was the case with cattle that were genetically engineered with gene scissors to prevent the growth of horns. DNA originating from genetically engineered bacteria used in the process was unintentionally inserted into their genome. Several years later, researchers found complete DNA sequences conferring antibiotic resistance in the genome of the cattle. This example shows that the process used to genetically engineer organisms has to be the starting point for mandatory risk assessment. Otherwise, side effects caused by the process itself are likely to be overlooked. (See: Norris et al. (2020) Template plasmid integration in germline genome-edited cattle, Nature Biotechnology)

The physical process of genetic engineering raises ethical concerns related to farm animals, regardless of whether cloning is used or not. See: https://office.foeeurope.org/5.4.0-21/web-apps/apps/documenteditor/main/index.html?_dc=5.4.0-21&lang=en&customer=ONLYOFFICE&frameEditorId=iframeEditor#_ftn7. Ethical concerns that have been documented in respect to the genetic engineering of animals include: the treatment of animals solely as instruments for human benefit and interests; infringement of the integrity of the animal by causing fundamental alterations to its DNA and the patenting of genetically engineered animals as technological products.

Genetic engineering of animals can perpetuate poor animal management, particularly in intensive farming operations, compounding existing welfare concerns. For example, gene editing for disease resistance could facilitate the raising of pigs in less hygienic conditions, or cattle without horns could be kept in more crowded enclosures. See Bruce, A. (2017) Genome edited animals: learning from GM crops?: p. 385–398 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5422448/

In addition to welfare issues arising from the introduced trait, welfare issues can arise from any genetic errors created by the gene-editing process, for example those caused by off-target effects. These genetic errors could cause malfunctioning of one or more parts of the cell machinery and lead to health problems in the genetically engineered animal. Importantly, such genetic errors can occur as an unintended consequence of genetic engineering, even if genes (e.g. from a different species) are not inserted into the animal, as might be the case with gene-edited animals. For example, researchers found that gene editing for super-muscly animals resulted in rabbits, pigs and a goat having enlarged tongues and pigs having an extra spinal vertebra, even though no DNA had been inserted.

See p. 273-87, Rodriguez, E. (2017) Ethical issues in genome editing for non-human organisms using CRISPR/Cas9 system. Journal of Clinical Research & Bioethics 8:

https://www.longdom.org/open-access/ethical-issues-in-genome-editing-for-nonhuman-organisms-using-crisprcas9-system-2155-9627-1000300.pdfo If yes, under which conditions do you consider this would be the case?

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

See reply in the field "Please describe and provide concrete examples/data"

o If yes, are these challenges/concerns specific to NGTs/NGT-products?

If yes, please explain.

These risks are the same as those generated by transgenic GMOs. See point 48 of the ruling of the ECJ: http://curia.europa.eu/juris/documents.jsf?num=C-528/16

o If no, please explain why not.

22. Do you see particular challenges for SMEs/small scale operators to access markets with their NGTs/NGT-products? Yes/no

o If yes, please describe and provide concrete examples/data.

Like the first transgenic GMOs, NGTs will accelerate the industry's concentration. SMEs do not have sufficient logistics to face the global market, which alone can offset the research and development costs for new NGT-products. The only advantage for an SME that has succeeded in developing an NTG-product that can be profitably exploited commercially is that it can be sold to a large company. SMEs that fail, on the other hand, bear the cost of their failure alone. This mechanism allows large companies to outsource a significant part of research to take advantage of the profits while at the same time outsourcing the losses at the expense of the SMEs, which have to pay for them. See: https://www.gmwatch.org/en/news/latest-news/19239

SMEs have a limited access to NGTs as most of the groups of patents are controlled by very few agri-food industries in the world, such as Corteya, Bayer or Syngenta (see OECD (2018), Concentration in Seed Markets: Potential Effects and Policy Responses, OECD Publishing, Paris. https://doi.org/10.1787/9789264308367-en). If they want to use NGTs, it costs a lot of money and these industries get all the information on the product. Furthermore, patents on plants limit the availability of seeds for farmers and lead to a higher cost of seeds without increasing yield. It is feared that patented seeds will hinder innovation in the sector of variety selection. Owing to the reduced access to plant prime material, developing seeds able to cope with different and more extreme climate conditions will be complicated.

The economic model behind NGTs places the control of the food chain in the hands of a few transnational corporations more powerful than most states. The globalized segmentation of the various stages of the industrial food chain destroys local food autonomy to the detriment of peoples' food sovereignty and security. The slightest financial, economic, health, social, or geopolitical accident at any stage of the globalized food chain triggers serious food crises.

o If no, please explain why not.

23. Do you see challenges/concerns from patenting or accessing patented NGTs/NGT-products? Yes/no

o If yes, please describe and provide concrete examples/data.

Patents accelerate the concentration of the seed industry, which reduces the diversity of seed supply and causes seed prices to rise exponentially, see: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3338485

Furthermore, in countries such as in North America where patents are widespread, the impact on seed prices is disastrous for farmers. Please see the presentation by Professor Mohammad Torshizi from Alberta University, during a conference organised on February 20th, 2020 in Brussels on the topic of NGT and patents: https://www.eurovia.org/wp-content/uploads/2020/04/M-Torshizi-Presentation-for-ECVC-Feb-20-20.pptx as well as "Price Effects of Common Ownership in the Seed Sector" from April 22nd 2019 by Professeurs Torshizi and Clapp: SSRN: http://dx.doi.org/10.2139/ssrn.3338485

These negative impacts will be multiplied if NGT-products are not labelled and traced. In the absence of an obligation to publish processes that enable products derived from NGTs to be distinguished from other products, an obligation arising from GMO regulations, the scope of a patent on genetic information obtained by NGTs, described in a way that does not enable it to be distinguished from genetic information present in other natural products or resulting from traditional breeding processes, will extend to any product that contains this genetic information and expresses its function, including those not resulting from the patented invention. Small farmers and SMEs will not have the financial means to oppose infringement proceedings which will de facto prohibit them from continuing to use the seeds they have selected and saved without any use of the patented invention.

We would like to recall prior explanations relating to the Declaration on the Rights of Peasants and Other People Working in Rural Areas (UNDROP), The International Treaty on Plant genetic Resources for Food and Agriculture (ITPGRFA) the implementation of the United Nations Convention on Biological Diversity (CBD) and its protocols (Cartagena and Nagoya).

See also document produced by ECVC on the issue of Patents and NGTs: in English: https://www.eurovia.org/wp-content/uploads/2020/04/Fact-sheet-EN.pdf and in French: https://www.eurovia.org/wp-content/uploads/2020/04/FACT-SHEET-FR.pdf.

See also the video of the conference organized by ECVC on this subject: https://www.eurovia.org/report-ecvc-public-conference-new-gmos-seed-patents-and-farmers-rights-to-seeds/

o If no, please explain why not.

Safety of NGTs/NGT-products:

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

As explained in the answer to question 20, the risks of NGTs/NGT-derived products are not foreseeable. They are identical to those of transgenic GMOs and even more if NGT plants produced have different properties from the preceding GMOs, i.e. with different components. Without independent public research, these risks are assessed only by the promoters of NGTs with regard to the payment of their shareholders and not with regard to the public interest. Risk assessment is then only carried out retrospectively, in the event of accidents resulting from the release of these products when they generate large-scale visible damage, such as the spread of pesticide-related diseases associated with transgenic plants, herbicide-tolerant weeds, the appearance of new pathogens occupying destroyed ecological niches, the contamination of wild biodiversity and conventional, GMO-free and organic crops, the destruction of resilient local agro-ecological and food systems, the destruction of domestic and wild biodiversity, and so on.

A risk assessment prior to the delivery of marketing authorisation, the labelling and the traceability offer a certain degree of security. If they are no longer compulsory, it will be impossible to guarantee any security. It will also be difficult to prove the origin of possible damage for the health and biosecurity of ecosystem. NGT plants are new, no systematic risk assessment has been done, but there are enough scientific proofs about the risks linked to NGTs.

25. Do you have specific safety considerations on NGTs/NGT-products? Yes/no

o If yes, please explain.

In the current state of knowledge, these risks can only be controlled in a confined environment. Bringing it out of a confined environment will go against the precautionary principle, a fundamental principle of the EU.

We point out to the European Commission that considering the precautionary principle (see Article 191 of the Treaty on Functioning of the European Union) and public health protection, the criteria for the evaluation of all risks related to NGT (biosafety, health, environmental impact, socio-economic impact, etc.) must be established in a detailed and binding way by the competent authorities, such as the European Food Safety Agency (EFSA), in agreement and with the collaboration of all the actors involved and in compliance with the democratic and transparency rules (representation of stakeholders of the productive sectors and civil society). The burden of proof, moreover, must obligatorily fall on the promoters of the authorization process, i.e. the biotechnology companies, but the experimental tests and the necessary investigations must be carried out by public or otherwise impartial and independent laboratories. We would remind you that the responsibility for authorising the marketing of any chemical or biochemical substance or product lies with the political decision-makers, and that the burden of demonstrating their safety lies with the person requesting its marketing. These responsibilities must never be transferred to the general public or to the users of the commercial product.

o If no, please explain why not.

Ethical aspects of NGTs/NGT-products:

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

From a biological point of view, any release of genetically modified living organisms in violation of natural reproductive barriers (multiplication and recombination) can only generate imbalances to the detriment of all other living organisms, including humans. While natural genetic evolution is relatively slow (on the scale of a human life) and subject to natural selection between each of them, it can only produce organisms that are totally unsuited to the natural environment if the same living organism undergoes multiple genetic modifications in a very short period of time and beyond the control of the laws of evolution and natural selection. This unnatural and quick alteration is bound to cause biological disasters.

According to the Federal Ethics Committee on Non-Human Biotechnology ECNH, this acceleration increases the possibilities that damages may occur as capacities to analyse risks and to introduce adequate authorisation process will be delayed in relation to the production and spread of products (see https://www.ekah.admin.ch/inhalte/ekah-dateien/dokumentation/publikationen/EKAH_Nouvelle_techniques_de_selection_vegetale_2016.pdf).

The invasion of genetically modified organisms amongst indigenous and wild population will profoundly change the nature of our society. Up to now we had little knowledge on species and their relations. We will not be able to change the consequences.

Other ethic question regarding the welfare and the protection of animal are being posed. The corporations are promising to use genetic engineering techniques on domestic animals to produce more meat, more milk with modified ingredients, or simply more milk, cows without horns, virus resistant pigs. The main objective is to make them more adaptable to conditions which are not appropriate to the species. Manipulation of animals may be associated to pains and suffering and it is not acceptable ethically.

The scientist community has recently been in an ethic and regulation turmoil because of a Chinese researcher, He Jiankui who pretended to have used CRISPR to modify the genomes of twin babies in China. The major worry is that the effect of CRISPR are not sufficiently understood to ensure the wellbeing of the twins. The question is part of the issue of the genetic manipulation of the living by men. Research needs marketing of living products, just as genetically modified plants need strict regulations based on the precautionary principle to avoid dangers as in the case of the GM dicamba tolerant plants, in the US:

https://www.theguardian.com/us-news/2020/mar/30/monsanto-crop-system-damage-us-farms-documents

Manipulation of the living poses also the question of patents on plants and animals which are contrary to Ethics. Life belongs to itself, it is not an invention. Patents on seeds is in clear contradiction with the human rights of seeds recognized by the UN Declaration on the Rights of Peasants and Other People Working in Rural Areas in article 19.

27. Do you have specific ethical considerations on NGTs/NGT-products? Yes/no

o If yes, please explain.

Beyond the unacceptable violation of biological balances, any ethical consideration must take into account the socio-economic impacts of the economic, legal and intellectual property model that supports the development of NGTs.

In view of the organic and living nature of GMOs/NGTs, it is clear that after release into the wild there is no way to control or deactivate the modified organisms, which are therefore beyond the control of their creator. While this is worrying in the case of modified plants and animals in the agricultural sector, it is even more so in the case of bacteria, viruses and other micro-organisms that are the subject of research in biotechnology. It should also be remembered that the technology behind NGT products can also be used for destructive purposes, i.e. to eradicate entire living species by means of the gene drive technique (see studies to eradicate anopheles malaria mosquitoes or fungal species): this technology appears to be extremely delicate from an ethical point of view.

It is also unacceptable that private economic actors have the power of choice and action in this field, with the possibility of influencing ecological and social dynamics on a very large scale.

Their research is driven only by the pursuit of profits, outside the political control of the state and the principle of transparency.

From an ethical and political point of view we also reject the partial approach of the technological war against nature. It applies partial and incomplete solutions to complex and systemic problems by privatising the cost of such interventions, extracting profit from technological solutions and individualising the way and approach to solving problems, rather than sharing them by building fair and just solutions in society. This approach, closely linked to the neo-liberal production model, is verifiable not only in agriculture and life sciences, but also in medicine, economics and other fields of science and knowledge. It moves away from tackling the structural problems of society and contributes significantly to the increase in global inequalities: only those who can afford to pay for the solution solve (in the short term) their professional or personal problems.

o If no, please explain why not.

Consumers' right for information/freedom of choice:

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

The right of breeders, farmers, gardeners, bee keepers and consumers to know what they are buying and to choose what they grow, reproduce, raise and eat is a fundamental human right that is superior to the freedom of enterprise. The right of consumers to make an informed choice is also a fundamental element. In the absence of labelling of NGT products

and animal products from animals having consumed GMOs or NGT-products, this right is not respected.

The lies that were circulating in the industries and amongst scientists in relation with the status of some NGTs and other GMO techniques, pretending that we are not dealing with GMO techniques simply because they were not transgenic, obliged some members of ECVC to go to court (in France). The French court asked the European Court of Justice to clarify this point with its decision of July 2018. According to the ECJ, the strategy of the communication campaign of the industry, before the decision of the ECJ, aimed to place these techniques outside of the GMO regulation, in order to avoid risk assessment, traceability, authorisation process and above all labelling, as European consumers would have rejected these products. Labelling is a legitimate, democratic action feared by those who prefer to hide information on what people grow and eat.

Final question

29. Do you have other comments you would like to make? Yes/no

o If yes, please provide your comments here.

The Commission arbitrarily limits 'new genomic techniques' to those which 'have emerged or have been developed since 2001'. In proposing to limit its study to only those techniques developed after 2001, the Commission does not take 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. The very definition of NGT, and consequently the structure of this questionnaire, has been built to influence the decision-making process and stakeholders' responses to this questionnaire. We would like to stress the scientific, political and procedural inaccuracy of this decision.

Furthermore, in the parallel questionnaire addressed to the Member States, the Commission asks if they have adopted measures and new inspection and evaluation techniques to implement the European Court of Justice ruling. In doing so, the Commission is trying to give to Member States the burden of traceability: by transferring the obligation to implement the ECJ ruling, it is also transferring responsibility for its own failures in relation to the non-implementation of the ruling. As early as 2018, the Member States had already asked the Commission to define the measures to be taken to implement the judgment, in particular the specifications of the genetic modification techniques concerned and the standardisation of inspection protocols. It is the Commission's duty to prevent the application of this judgment in a non-harmonised manner in the different Member States: this would be in contradiction with the rules of the single market, which depends exclusively on the Commission. To comply with this, reference should be made to the proposal of the European Committee of Experts on the Traceability of GMOs, which calls for the protocols developed to distinguish and identify transgenic GMOs to be updated so that they can also be applied to NGT. Please consult: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003R1830:FR:HTML

In December 2018, the UN General Assembly adopted the UN Declaration on the Rights of Peasants and Other People Working in Rural Areas, recognized in Article 19 of the Human Right to Seed. This evolution of human rights responds to the fact that seed laws and regulations have often been designed to favour the agricultural industry, while the rights of peasants have been largely neglected. As the Geneva Academy of International Humanitarian Law and Human Rights states: « *It was in particular to meet these challenges that the United Nations adopted this Declaration. The implementation of the Declaration represents a unique opportunity to rebalance the lack of support for farmers' seed systems...This rebalancing is essential for the protection of the lives and livelihoods of hundreds of millions of farmers, as well as for the benefit of all for the conservation of biodiversity.* »

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 a:

- comprehensive case-by-case risk assessment;

- 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;

- 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;

- Implementation of the precautionary principle.