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

Fields marked with * are mandatory.

Questionnaire on new genomic techniques to contribute to the study requested by the Council

Discussed and finalised in the Ad-hoc Stakeholder meeting on 10 February 2020

Background

The Council has requested [1] the Commission to submit, by 30 April 2021, "a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law" (*i.e.* Directive 2001/18/EC, Regulation (EC) 1829/2003, Regulation (EC) 1830/2003 and Directive 2009/41/EC).

To respond to this Council's request, the Commission is collecting contributions from the stakeholders through the questionnaire below. The study covers all new genomic techniques that have been developed after 2001.

Instructions

For the purpose of the study, the following definition for new genomic techniques (NGTs) is used: techniques that are capable of altering the genetic material of an organism and which have emerged or have been developed since 2001 [2].

Unless specified otherwise, the term "NGT-products" used in the questionnaire covers plants, animals, micro-organisms and derived food and feed products obtained by NGTs for agri-food, medicinal and industrial applications and for research.

Please substantiate your replies with explanations, data and source of information as well as with practical examples, whenever possible. If a reply to a specific question only applies to specific NGTs/organisms, please indicate this in the reply.

Please indicate which information should be treated as confidential in order to protect the commercial

interests of a natural or legal person. Personal data, if any, will be protected pursuant to Regulation (EU) 2018/1725 [3].

[1] Council Decision (EU) 2019/1904, OJ L 293 14.11.2019, p. 103-104, https://eur-lex.europa.eu/eli/dec/2019/1904/oj
[2] Examples of techniques include: 1) Genome editing techniques such as CRISPR, TALEN, Zinc-finger nucleases, mega nucleases techniques, prime editing etc. These techniques can lead to mutagenesis and some of them also to cisgenesis, intragenesis or transgenesis. 2) Mutagenesis techniques such as oligonucleotide directed mutagenesis (ODM). 3) Epigenetic techniques such RdDM. Conversely, techniques already in use prior to 2001, such as Agrobacterium mediated techniques or gene gun, are not considered NGTs.
[3] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295, 21.11.2018, p. 39–98

Guidelines

Please note that the survey accepts a maximum of 5000 characters (with spaces) per reply field. You might be able to type more than 5000 characters, but then the text will not be accepted when you submit the questionnaire. You will also receive a warning message in red colour below the affected field.

You have the option to upload supporting documentation in the end of each section. You can upload multiple files, up to the size of 1 MB. However, note that any uploaded document cannot substitute your replies, which must still be given in a complete manner within the reply fields allocated for each question.

You can share the link from the invitation email with another colleague if you want to split the filling-out process or contribute from different locations; however, remember that all contributions feed into the same single questionnaire.

You can save the draft questionnaire and edit it before the final submission.

You can find additional information and help here: https://ec.europa.eu/eusurvey/home/helpparticipants

Participants have until 15 May 2020 (close of business) to submit the questionnaire via EUsurvey.

QUESTIONNAIRE

Please provide the full name and acronym of the EU-level association that you are representing, as well as your Transparency Registry number (if you are registered)

If the name of the association is not in English, please provide an English translation in a parenthesis

The Fédération Européenne des Fabricants d'Aliments Composés (FEFAC), 77105321408-83

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

Compound feed and premix manufacturing for food producing animals

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

Answers provided on behalf of 22 National Member Associations of manufacturers of premixtures and compound feed for food producing animals in 22 EU Member States (see www.fefac.eu)

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

All replies refer to NGTs at large as applied to plants only. We assume that presently authorised GMOs have all been obtained by techniques available before 2001 and not all NGTs fall under the scope of the GMO legislation in accordance with ECJ ruling.

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

• NGTs (e.g. precision targeted mutagenesis) falling under the scope of the GMO legislation: These have not been placed on the EU market yet. Thus we do not use products produced by NGTs that would fall under the scope of GM legislation. We also expect that our 3rd countries trade partners do not supply us with crops produced by NGTs falling under GM legislation.
• We are not aware of placing on the EU market of NGT products not falling under the scope of the GM legislation
• In the future we will likely use NGTs providing the legal framework - is clarified, conditions of use are proportionate, workable, not discriminatory for operators and providing the technique is accepted by feed & food chain partners, including consumers.

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

- ○ Yes
- ◉ No
- ○ Not applicable

* Please explain why not

• At the moment our members do not take specific measure since, to the best of our knowledge, no NGTs product is placed on the EU market at the moment and the methods to control the presence of NGT products are not available at the moment.
• In the future we will protect our feed materials purchases against illegal placing on the EU market for feed use of NGT-products via outreach activities, including risk assessments, as we do currently for non-EU authorised GMOs, within the limitations created by the absence of clear guidance/rules in the EU on which NGTs may be legally placed on the EU market, the inconsistency of legal status worldwide and the lack of appropriate analytical methods (JRC 2019).
• A prerequisite for an efficient protection system to work is for operators to get access to relevant information to perform their own assessment, e.g. a worldwide catalogue of NGTs per producing country. Maintaining such a catalogue fully and timely updated is nevertheless extremely challenging.

* 2 bis. Have you encountered any challenges?

- (●) Yes
- ( ) No

* Please provide details

• In case there would be a demand for feed not containing legally permitted NGT- products, we would take inspiration of systems in place that have been created for “non-GM” chains. In principle these may also apply to NGTs; however a clear limitation is that compliance with rules on “non-GM” chains depends on identification of presence of GM material by analytical method, which is currently not possible for NGT-products. A clear legislative guidance would therefore be needed to avoid misleading product standards & claims.
• A clear prerequisite for operators of the downstream part of the chain to control unintentional use of NGT-products, whether legal or not, is the availability of internationally validated analytical methods.

*** 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

We are aware of research (*Dominik Modrzejewski et al, 2019) being performed worldwide to develop crops with specific improved agronomic and nutritional traits obtained by NGTs. However, we cannot provide much detail as this is still at a development phase at plant breeding sector level (see also answer to question 13).

*** 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

We are aware of initiatives coordinated by International grain traders coalition to monitor commercial and legal developments of NGT-crops meant for use in food and/or feed.

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

- (●) Yes
- ( ) No

* Please provide details

Please see Q21

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

Please also see question 8 specifically on labelling

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

* Please explain why not

• As indicated in the answer to the first question we are not aware of the illegal placing on the EU market for feed use of NGTs that would fall under the scope of GM legislation.
• Compound feed manufacturers are in close dialogue with their suppliers to avoid that non-EU approved GMOs are placed on the EU market.

* 5 bis. What challenges have you encountered?

What is feasible for “classical” GMOs obtained by transgenesis where validated analytical methods are available is challenging for NGTs products which are not distinguishable from products that have been obtained from conventional breeding methods.

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

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

* What challenges have you encountered?

• There has been for more than a decade a legal uncertainty on how to consider NGTs among the EU institutions. Nowadays, despite the ECJ Ruling, there is still no clarity and little visibility for operators as to what NGT-product falls under the GMO legislation and we understand that a number of competent authorities are in a similar position than we are.
• In addition, operators lack tools to detect / identify NGT products now and have not been given any perspective as to the availability of these tools in the future.

* **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

• Identity preservation systems are commonly implemented in the feed and food sector, in particular for non-GM chains or organic. In the first case, this involves the ability at each stage of the chain to verify by analytical means that products do not contain GMOs. In the second case, this depends on certification systems.
• Since NGTs products are indistinguishable from other products obtained by conventional breeding techniques, traceability systems would have to be based on paper trail. This might be possible to achieve but only for small volumes In addition, the costs of establishing and running reliable traceability systems should not be underestimated.

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

Yes
No
Not applicable

* Please explain why not

• As indicated in the answer to the first question we are not aware of the placing on the EU market for feed use of NGTs products that would fall under the scope of GM legislation.

* 8 bis. What challenges have you encountered?

absence of analytical methods

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

Yes
No
Not applicable

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

The maximum file size is 1 MB

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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

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

- ○ Yes
- ○ No
- ◉ Not applicable

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

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

- ○ Yes
- ○ No
- ◉ Not applicable

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

- ◉ Yes
- ○ No
- ○ Not applicable

* Please provide concrete examples/data

• Better crops may provide benefits for animal nutrition by improved nutritional value of crops (amino acid profiles, specific nutrients), reduction of contaminants and antinutritional factors, resistance to moulds hence lower mycotoxins content, etc..
• In research there are already improved crops that could bring benefits to our sector (farmers, feed and the food industry):
a) Agronomic value: soybean tolerant to drought could help boosting EU protein production along the objectives of the EU Protein plan that would help improve market access to high protein feed materials (SBM, sunflower meal etc)
b) Feed quality:
i) Soybean and camelina with improved fatty acid compositions (Jiang and Henry 2017) - Could allow more precise feeding of animals;
ii) Reduction of environmental emissions: less phytic acid in oilseed cake (Niharika Sashidhar et al., 2020) increasing phosphorous digestibility in animal feed and thus reduce phosphorous emissions to the benefit of the environment
• More resilient, more sustainable plant varieties with or without specific nutritional quality traits will directly benefit the European compound feed industry and the EU livestock sector and subsequently the agri-food supply chain.

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

- ◉ Yes
- ○ No
- ○ Not applicable

* Please provide concrete examples/data

A too heavy EU regulatory burden the EU may lead to discrimination against European Universities and research centres in comparison with other countries. Exchange of materials and study collaboration may be limited/challenging. This could halt the EU progress in plant breeding research as investors would move to more favourable regulatory environments. New plant varieties can deliver on multiple agendas – including stimulating growth, productivity and improving the competitiveness in EU (also towards global trade) and lead to better strategies to cope with food security and climate challenges.

* **15. Have you identified any NGT-related research needs/gaps?**

- ○ Yes
- ○ No
- ◉ Not applicable

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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 describe and provide concrete examples/data

• Nutritionally improved crops may allow formulation of better balanced feed, meaning better animal welfare, improved feed conversion ratio, less environmental emissions (GHG, ammonia, phosphorous), improved nitrogen use efficiency, i.e. less crude protein needed and therefore lower dependency on Third Countries for the EU supply in proteins. They also contribute to higher livestock productivity.
• Crops with less contaminants allow better animal health and welfare and avoids wasting crop resources due to non-compliance with EU food/feed safety standards (mycotoxins).

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

- ◉ Yes
- ○ No

* Please explain

please see above

* **17. Could NGTs/NGT-products bring benefits/opportunities to society in general such as for the environment, human, animal and plant health, consumers, animal welfare, as well as social and economic benefits?**

- ◉ Yes

No

* Please describe and provide concrete examples/data

• EU society strives for more sustainable local products with lesser use of pesticides, fertilizers. NGTs have the potential to meet the societal demand as improved crops can better respond to pests and climate/soil conditions. In addition crops could be grown locally even in areas where this wasn't possible previously due to environmental constraints and conditions, e.g drought).
• We need better crops with better yields in order to respond to an increased global demand for agriculture products due to growing population and increasing living standards (EU production of vegetable proteins for feed use, increased land use efficiency)
• Lower contaminants in crops mean higher animal health and welfare
• From our perspective, the NGTs could help increase agricultural productivity in a sustainable way and thus benefit the whole society. By enabling NGTs to deploy their full potential we believe they can contribute to many of the Sustainable Developments Goals including food security (Aerni, 2019) and climate change. In addition NGTs, in comparison to traditional breeding techniques, allow all of those mentioned benefits deliver in relatively shorter timeframe resulting in lower costs to move these varieties to the market (SAM, 2017).

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

in more friendly EU legislative environment

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

Yes
No

* Please explain

please see above

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

Yes
No

* Please describe and provide concrete examples/data

• As far as we understand, the NGT technique in itself brings many savings for a plant breeding company and is therefore favourable for SMEs. The main cost for market access is regulatory requirements in the country where the NGT-product is to be marketed.
• In countries where legal requirements are no more demanding than for conventional breeding technologies (which is the case in many Third Countries), market access might be even easier for SMEs for NGT-products than for conventional products.
• On the other hand, for countries with a very demanding legislative framework as is the case in the EU for e. g. GMOs, SMEs are no more likely to access the market for NGT-products than for GMO-products.

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

Yes

- (●) No

* Please explain why not

Not relevant for FEFAC

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

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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

• On the global market, competitiveness remains a key challenge, having regards to persistent discrepancies between the EU and third countries in terms of standards. Different regulations worldwide, as could be the case for NGTs, usually increase feeding costs, as they limit market choices and thus the production cost of animal products in the EU,
• A level playing field should be kept whenever it is possible. In that regards the European farmers should have access to plant breeding innovation in order to be able to compete with farmers outside Europe.
• Traceability of NGTs products is a key challenge in the absence of analytical tools.

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

- (●) Yes
- ( ) No

* Please explain

please see above

* **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

• We do not see specific challenges / concerns related to NGT-products themselves compared to products obtained by conventional breeding techniques. However, we do see challenges/concerns in the unharmonised way this technique may be regulated globally.
• ECJ ruling (the case C-528/16 of 25 July 2018) says NGTs are falling under the scope of the EU GMO Directive 2001/18/EC. Should this approach be maintained in the future, it is likely that the regulatory hurdles will lead to the same result as for GMOs, i.e. no “European” GMO authorised and barely any GMO cultivation in the EU. Availability of NGTs plants is a key element to preserve the competitiveness of the European farmers and food chain operators.
• Any difference in legal requirements and their implementation would jeopardise the access of EU operators to the global market. Any need to implement Identity Preservation systems to avoid illegal placing on the market for feed use of NGTs would place EU operators at a significant economic disadvantage vs. third country operators.
• Due to the absence of analytical means to differentiate NGT-products from conventional products (no clear detection methodology exists, JRC 2019), the exposure to fraud is potentially huge, unless very costly traceability and product segregation systems are put in place with low or no direct benefits for environment, animals, consumers or citizens.
• Third countries supplying countries having to comply with EU requirements might lose interest to export to the EU, since additional cost would be required in view of the need to develop a strict separated production and logistic channels for raw materials in the whole supply chain. All in all this could lead to trade isolation of the EU or the Third countries could lodge Specific Trade Concerns (STC) under WTO rules.

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

please see above

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

- (●) Yes
- ( ) No

* Please explain

please see above

* **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

• NGT-products provide opportunities to SMEs, unless the legal requirements become so demanding (as for GMOs) that they will create an unsurmountable market entry barrier, as it is today for conventional breeding companies who had to renounce to GM technology as they could not afford the legislative costs, putting them at economic disadvantage vs. larger seed companies.

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

- ( ) Yes

◉ No

* Please explain why not

Not relevant for FEFAC

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E - Safety of NGTs/NGT-products

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

• The safety of a product is not a matter of stakeholders' opinion but deserves a scientific response based on risk assessment.
• FEFAC is expecting from breeding companies that they place safe products on the market, i.e. that they perform a risk assessment of the variety they place on the market. Such risk assessment is needed, whether the variety is obtained by conventional breeding techniques or by NGTS.
• In practice we do not expect that NGT products, being not distinguishable from products from conventionally obtained plant varieties, will present a significantly different risk profile. The opinion of the scientific community should remain the reference on this matter and international scientific consensus should be sought (Codex Alimentarius)

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

◉ Yes
○ No

* Please explain

We believe that can NGTs products may contribute to overall safety of crops eg reduction of occurrence of mycotoxins.

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

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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**

• We do not see why NGTs would carry more ethical aspects than conventional breeding methods. If there is a specific demand for non-NGT products, this will be met, although at a price. It could in fact be seen as un-ethical not to take benefit of an innovative, effective technique to address future challenges and contribute to Sustainable Developments Goals (e.g. Climate changes, food security).
• The potential costs of not using a new technology should be also acknowledged (EASAC, 2020).

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

- ○ Yes
- ◉ No

* Please explain why not

please see Q26

Please upload any supporting documentation for this section here

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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**

We understand that the majority of crop breeding programmes using NGTs are not distinguishable from conventional breeding methods (SAM, 2018; WTO, 2018; ENGL, 2019). We do not see a necessity to require the labelling of NGTs, bearing in mind that there might still be a scope for investigating a harmonised NGT-free products labelling system to meet a potential demand.

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

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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

The answers provided above reflects the state of our knowledge at the time they were provided. In particular, many answers Yes or No were prompted by the present situation which is that there is no NGT product on the market for feed use. These short answers might be different in the future. We have therefore aimed to provide more elements anticipating on possible future market developments in the detailed answers.

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

The maximum file size is 1 MB

Contact

SANTE-NGT-STUDY@ec.europa.eu

Q3

Dominik Modrzejewski et al, 2019: What is the available evidence for the range of applications of genome-editing as a new tool for plant trait modification and the potential occurrence of associated off-target effects: a systematic map, Available at: https://environmentalevidencejournal.biomedcentral.com/articles/10.1186/s13750-019-0171-5

Q2

JRC, 2019: Detection of food and feed plant products obtained by new mutagenesis techniques, Available at: https://gmo-crl.jrc.ec.europa.eu/doc/JRC116289-GE-report-ENGL.pdf

Q13

Jiang and Henry 2017: Significant enhancement of fatty acid composition in seeds of the allohexaploid, Camelina sativa, using CRISPR/Cas9 gene editing, Available at: https://onlinelibrary.wiley.com/doi/pdf/10.1111/pbi.12663

Niharika Sashidhar et al., 2020: Gene editing of three BnITPK genes in tetraploid oilseed rape leads to significant reduction of phytic acid in seeds, Available at: https://onlinelibrary.wiley.com/doi/pdf/10.1111/pbi.13380

Q17

SAM, 2017: New techniques in Agricultural Biotechnology, Available at: https://ec.europa.eu/research/sam/pdf/topics/explanatory_note_new_techniques_agricultural_biotechnology.pdf

Aerni, 2019: Politicizing the Precautionary Principle: Why Disregarding Facts Should Not Pass for Farsightedness, Available at: https://www.frontiersin.org/articles/10.3389/fpls.2019.01053/full

Q21

JRC, 2019: Detection of food and feed plant products obtained by new mutagenesis techniques, Available at: https://gmo-crl.jrc.ec.europa.eu/doc/JRC116289-GE-report-ENGL.pdf

Q26

EASAC, 2020: The regulation of genome-edited plants in the European Union, Available at: https://easac.eu/fileadmin/PDF_s/reports_statements/Genome_Editing/EASAC_Genome-Edited_Plants_Web.pdf