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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 EU Vegetable Oil and Proteinmeal Industry (FEDIOL), 85076002321-31.

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

FEDIOL represents the interests of the European vegetable oil and protein meal industry (www.fediol.eu). Its member companies process approximately 55 million tonnes of basic products a year for the food and non-food markets. Oilseed crushing produces vegetable oils and protein meals as co-products. While vegetable oils are used for food and technical uses (pharmaceuticals, paints, detergents, biodiesel, etc.), protein meals are used to meet the increasing global demand for meat and protein.

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 10 national member associations and associated company members, covering more than 180 facilities belonging to ±70 companies in 17 EU countries.

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

Our replies refer to the use of NGTs in plants.

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

FEDIOL member companies are European oilseed crushers, vegetable oil refiners and bottlers. The sector crushes oilseeds, notably rapeseed, sunflower seed, soybeans and linseed into oils and meals and refines those crude oils from crushing and crude tropical oils, notably palm oil, palm kernel oil and coconut oil. In total, approximately 55 million tons of raw materials are processed every year, both of EU origin and imported from third countries.
As per the scope of their activities, FEDIOL member companies do not develop plants derived from NGTs. For the time being, and to the best of their knowledge, these companies, do not process agricultural raw materials or products derived from NGTs.
These companies would however plan to process raw materials or products derived from NGTs in accordance with EU legislation should this framework become more conducive to the use of these techniques and to the commercialization of derived products.

* **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

• As we understand, NGT-products are today considered as GMOs under the EU law (considering ECJ ruling C-528/16). With no NGT-product today formally approved under the EU GMO system, all products obtained through NGTs are therefore considered as EU unauthorized GMOs.
• Hence, no, in order to protect themselves from the unintentional use of NGT-products, FEDIOL member companies have not taken a set of different measures than those already in place to secure their food and feed supplies from the risk of unintentional presence of EU unauthorized GMOs. These measures include:
i. Monitoring GM traits having reached the stage of seed multiplication in third countries and which may bear trade disruption risks in case present in imports. This monitoring is made based on different sources of information like official databases and also includes exchanges with biotech developers.
ii. Having a global perspective of the different sourcing areas, companies then decide to source from geographical areas not expected to have EU unauthorized GMOs. Where possible, FEDIOL companies source from areas where non-authorized events are at early multiplication phase (the surface involved, and the stage of seed multiplication has to be taken into account) or in close loop systems. In these areas, the probability for the non-authorized GM event to show up in shipped supplies is limited. Alternatively, if obliged to source from areas where asynchronous events may be cultivated at commercial scale, contractual arrangements with crop suppliers sourcing from selected growers may be put in place. In these situations, clear traceability systems, possibly with testing at origin, are required
iii. In the case of imported IP supplies (non-GM commodities), commingling between conventional and GM consignments is avoided during bulk transport, handling and storage. A certain system of control is also in place which includes (amongst others) some testing to verify that the measures in place to prevent commingling of IP non-GM consignments with GM consignments are efficient.
• However, compared to “traditional” GMOs, FEDIOL member companies do not have the means today to implement these measures efficiently and to protect themselves from the risk of unintentional presence of NGT-products due to 1) insufficient information available on NGT products being developed globally and 2) having no possibility to control (be it through analytical testing or other mean) whether their raw materials have been obtained through the use of NGTs.
• Should the aforementioned means be available in the future, FEDIOL member companies will, in principle, be able to take additional measures to manage the unintentional use of NGT-products.

* 2 bis. Have you encountered any challenges?

- (●) Yes
- ( ) No

* Please provide details

• There have been attempts by FEDIOL member companies to get oversight on NGT developments outside the EU through monitoring and information sharing. While for transgenic events, global databases exist ([1], [2], [3]), this is not the case for plants obtained through NGTs. Compared to providers of transgenic products (classical GMOs), the number of which is relatively limited, another issue is that there are many players using NGTs to develop new plant varieties [4], not all of them communicating about it (either per choice, as NGTs might be not considered as GMOs in other regions, or because not having a specific communication strategy). With such insufficient information being available, the assessment by FEDIOL member companies of the risk of unintentional presence of NGT product is inevitably affected.

• Routine detection methods and procedures allowing to identify NGT techniques at the origin of a product, are today not yet available, thus 1) not allowing operators to check their assessment of the risk of unintentional presence of NGTs nor 2) to be protected from the risk of fraud.

[1] ISAAA: https://www.isaaa.org/gmapprovaldatabase/default.asp
[2] Biosafety clearing house: https://bch.cbd.int/database/organisms/
[3] Biotrade status: http://www.biotradestatus.com/
[4] Gene Editing and Plant Breeding in Canada. Are Canadian plant breeders utilizing the innovations of gene editing? Survey 17 March 2020. https://saifood.ca/gene-editing-plant-breeding-canada/

*** 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

• FEDIOL covers around 85% of the sector's activity in the EU. FEDIOL is not aware of active initiative in the EU to develop NGTs in the crushing and refining sector. But there are indeed discussions between the sector, researchers, breeders, and farmers, to understand whether plants obtained through NGTS could help address upcoming challenges like the lack of active substances or impact from changed climatic conditions.
• FEDIOL is aware of developments and initiatives outside EU being relevant to the crushing and refining sector:
i. Some NGT products are known to have already reached the market. A vegetable oil derived from a high oleic soybean developed through NGTs is today available on the food market in the United States [5]. This new soybean variety was developed by the plant-based technology company Calyxt, using the Talens techniques [6]. Calyxt recently announced that the acreage of this NGT soybean in the United States increased significantly, having contracted around 40,000 soybean hectares with U.S. farmers in 2020 [7].
ii. There are also company initiatives around NGTs outside the EU involving the crushing and refining sector. Some of FEDIOL member companies are companies operating globally. In other parts of the world, some of these companies have established partnerships with breeding companies around the use of NGTs to deliver innovative products [8] or are involved with other partners into breeding projects using NGTs, some of them being supported at government level [9].

[5] First Commercial Sale of Calyxt High Oleic Soybean Oil on the U.S. Market. 26 February 2019. https://calyxt.com/first-commercial-sale-of-calyxt-high-oleic-soybean-oil-on-the-u-s-market/
[6] Modrzejewski, D., Hartung, F., Sprink, T. et al. What is the available evidence for the application of genome editing as a new tool for plant trait modification and the potential occurrence of associated off-target effects: a systematic map protocol. Environ Evid 7, 18 (2018)
[7] Calyxt Achieves 2020 Soybean Contracted Acreage Goal of 100,000 Acres. 07 February 2020. https://calyxt.com/calyxt-achieves-2020-soybean-contracted-acreage-goal-of-100000-acres-2/
[8] Cargill partnership with Precision Biosciences on healthy canola using gene editing techniques. https://elolife.ag/cargill-announces-ongoing-partnership-with-precision-biosciences-enabling-healthy-canola-oil-products/
[9] Bunge and other industry partners, with Protein Industries Canada, in breeding project using gene editing technology to improve canola protein quality. https://www.proteinindustriescanada.ca/news/supercluster-backing-canola-protein-production

*** 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

Exchanges have taken place between FEDIOL and raw material producer organizations from third countries to raise awareness on the development of the EU legislation around NGTs, and on the need of information along the supply chain to avoid trade disruptions. However, the information available today to FEDIOL member companies is not sufficient to guard against unintentional use of NGT-products.

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

- (●) Yes
- ( ) No

* Please provide details

• In several countries where agricultural raw materials or crude oils are sourced by FEDIOL member companies, the supply chain is not as organized as in the EU and there is no structured organization with which it is possible to discuss. Even if such dialogue is possible, information might not always be available to the raw material producers. Depending on the country at stake, when NGTs are not considered GMOs for example, it may not be required to notify the NGT status during the variety registration process.
• Absence of clarity as to the precise boundaries of the scope of the NGTs considered as GMOs in the EU is adding to the challenge when trying to explain the EU legal framework.
• FEDIOL covers around 85% of the sector's activity in the EU. Small crushing and refining companies which are not members of FEDIOL may not be aware of current EU discussions around NGTs and may have even more limited visibility about NGT developments outside EU.

* **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

• Under the current GMO legislation, FEDIOL companies have the same obligations, whether transgenic events (i.e. classical GMO products) or NGT-products are at stake.
• The same measures are therefore applied by FEDIOL operators: assessment of the risk of unintentional presence, documentary traceability (based on information submitted by suppliers up in the supply chain), testing/detection (to validate the risk assessment and ensure, through statistical evidence, that unauthorized GMOs are absent).
• However, these measures cannot be efficiently implemented in the case of NGT products because of the current lack of information and lack of means to control whether products are derived from NGTs.

* 5 bis. What challenges have you encountered?

The implementation of these measures faces the below challenges when NGTs are at stake:
i. There is limited information available on products developed through NGTs globally (no database)
ii. Coordinated discussion with technology providers is not feasible in practice (too many players, many not even identified)
iii. Awareness raising of raw material producers not always feasible depending on the country at stake
iv. Identification & determination of origin (i.e. whether it is a NGT variety) is not achievable today through routine analytical methods and procedures.

* **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?

European legislation should be implementable and enforceable. With the outcome of the ECJ ruling, this is not the case, leaving business with a considerable legal uncertainty and risk of non-compliance.

* **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

- Yes, FEDIOL company members have experience and knowledge on traceability strategies.
- However, to the best of their knowledge, traceability strategies known by FEDIOL company members are not fully applicable to NGT-products as there is no element (be it of analytic or of any other nature) that operators can verify to check the compliance or efficiency of the strategy.
- Current traceability systems experienced by FEDIOL member companies to forward the identity of a transgenic GMO from its production to the final buyer, combine documentary traceability (starting from the document record on the genetic modification through the variety registration process) and analytical testing (for surveillance purpose). With no legal obligation to highlight the NGT status of the seeds from the beginning (when NGTs are not considered GMOs for example) and as a consequence, when prerequisites for detection (method and reference material) are not available, traceability can only be achieved through documentation. In that case, operators can only rely upon their suppliers. Should analytical traceability become technically possible [10][11], NGT-products could be traced the same way as GMOs.
- FEDIOL company members have experience with other types of traceability strategies, for example implying certification. An example is the sourcing of certified sustainable raw materials or feed safety certifications. Although not of analytical nature, such strategies are also based on precise criteria that can be controlled by operators (through audits) to verify that production and processing are managed in such a way to meet the criteria. It also should be kept in mind that traceability systems, certification schemes, auditing, etc. all imply additional costs to companies, which need to be counterbalanced by creation of an additional value at the end to ensure the economic viability of the products.

[10] Bertheau, Y., 2019. New breeding techniques: detection and identification of the techniques and derived products. In: Reference Module in Food Science, pp. 320-336. Elsevier Science.
[11] Boutigny, A.L., Barranger, A., De Boisséson, C., Blanchard, Y., Rolland, M. 2019. Targeted Next Generation Sequencing to study insert stability in genetically modified plants. Scientific Reports 9, 2308.

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

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

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

/

* What best practices can you share?

/

* Please explain why not

- As said, under the current GMO legislation, the same obligations, which include labelling when required, apply to transgenic events (i.e. classical GMO products) or NGT-products.
- The same measures would therefore be applied by FEDIOL operators.
- This question remains very theoretical in practice. With no NGT-product currently authorized in the EU, it simply means that such presence is not allowed in food and feed. The question of labelling does not arise in the current context.

* 8 bis. What challenges have you encountered?

Challenges encountered are the same as those mentioned on the question of traceability:

i. There is limited information available on products developed through NGTs globally (no database)

ii. Coordinated discussion with technology providers is not feasible in practice (too many players, many not even identified)

iii. Awareness raising of raw material producers not always feasible depending on the country at stake

iv. Identification & determination of origin (NGT or “derived from nature”) is not achievable today through routine analytical methods and procedures.

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

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

* Please describe for the:

- [x] Agri-food sector
- [ ] Industrial sector
- [ ] Medicinal sector

Agri-food sector

• In the agri-food sector, sampling, analysis and interpretation for the implementation of the “zero tolerance” policy for unauthorized GMOs has been harmonized by Regulation 619/2011 (the so-called technical solution for feed)[12]. This Regulation defines 1) appropriate sampling protocols and methods of analysis and 2) provides a technical definition of zero with the level of 0.1% which is considered by the European Reference Laboratory (EU-RL) as the lowest level of GM material where results are found satisfactorily reproducible between official laboratories (when appropriate sampling protocols and methods of analysis for measuring samples are applied). Such instrument (which should ideally cover food and feed) is critical to ensure that national competent authorities and official laboratories have a 1) common approach as regards sampling, analysis and 2) interpretation of analytical results when unauthorized GMOs are detected at very low levels in a product. Different rules for the implementation of the controls (sampling and analysis) and for the interpretation of the analytical results may lead to different conclusions as regards the compliance of a same controlled material depending on where (which Member State) it is controlled, leaving operators exposed to serious legal uncertainty with the risk of disruption for the whole supply chain and the risk to face enormous financial losses should a minute trace of an unauthorized GMO be detected in their imports.[13]

• Without any analytical possibility to trace them, the practical implementation of the zero tolerance for unauthorized GMOs under the current GMO legal framework is even more difficult to address for NGT products.

[12] Regulation 619/2011

[13] Roïz, J. (2014). Limits of the current EU regulatory framework on GMOs: Risk of not authorized GM event-traces in imports. OCL - Oleagineux Corps Gras Lipides. 21. 10.1051/ocl/2014037

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

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B - Information on research on NGTs/NGT-products

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

- ○ Yes
- ◉ No
- ○ Not applicable

* Please explain why not

No/Yes

• In Europe, it is understood that commercial breeding projects close to market development have been stopped and transferred elsewhere following the ECJ ruling [14].
[14] Consequences of the EC-ruling according to Swedish companies and research groups, Swedish Board of Agriculture, 19 December 2018, https://www.upsc.se/documents/News/News_2019/Attachment_1.pdf

• Our member companies are not carrying out NGT-related research in Europe, but some FEDIOL members are companies operating globally. In other parts of the world, some of these companies have established partnerships with breeding companies around the use of NGTs to deliver innovative products or are involved in breeding projects using NGTs, some of them also supported by governments.[8][9]
• Subjects of research include protein quality improvement (i.e. making oilseeds produce high protein meal for downstream use), fatty acid profile improvement (reduction of saturated fatty acids to very low levels).
• These researches correspond to applied research and product development.
• Resources allocated:
[8]: no info
[9]: the project is funded with around $27 million, half coming from the Canadian government and half for the other consortium partners.
• Research locations include Canada, United States.

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

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

* Please specify

• Several players, from public and private sectors, are carrying out NGT related research on oilseeds. Here are some examples.

• Public sector
o PhD thesis: New technologies to replace neonicotinoid pesticides in the control of cabbage stem flea beetle on rapeseed. https://gtr.ukri.org/projects?ref=studentship-2059789
o Research: camelina lines accumulating omega-3 long chain polyunsaturated fatty acids, having undergone CRISPR-Cas9 gene-editing. https://www.rothamsted.ac.uk/articles/gm-camelina-trial-frequently-asked-questions

• Private sector
o Yield10 Bioscience: camelina, canola, soybean. http://ir.yield10bio.com/static-files/944409f9-1c52-4e94-9702-41f99516b6a4
o Bayer-Pairwise: soybean, canola. https://www.businesswire.com/news/home/20180320005803/en/Monsanto-Pairwise-Announce-Collaboration-Accelerate-Innovation-Agriculture
o Cibus: canola, peanut, soybean. https://www.cibus.com/crops.php#pipeline
o Evogene: soybean. https://www.evogene.com/wp-content/uploads/2019/08/Evogene-at-a-glance_corporate-presentation_new-graphics-1.pdf

*

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

• Oilseed production is facing different challenges:

o Agronomic losses caused by insects, diseases/pest, climate change, in a context of reduced possibility to use pesticides/fertilizers/water (at least in the EU).

o The improvement of protein quality: this represents a challenge of competitiveness both for environmental reasons (limitation of nitrogen and phosphorus emissions from farms, by improving digestibility) and technical and economic reasons.

o The improvement of the oil profile: to meet the consumers' needs and regulatory changes

• An acceleration of genetic progress through research on NGTs could bring potential benefits and opportunities by addressing the above challenges in a short-term perspective, in complement to other new approaches (like biocontrol…etc.)

• Ex1: if we take the example of rapeseed production in the EU, planting and yields have declined over the past years. One of the main reasons advanced by growers is the regulatory restrictions or prohibitions on the use of several pesticides (neonicotinoid insecticides in particular). The number of insecticides that can be used on rape has indeed been reduced over the last years: methiocarb, neonicotinoids, pymetrozine are not allowed anymore. In parallel, the production has faced increasing insecticide resistance issues. Insect control becomes increasingly difficult for EU farmers. Current practices to fight against some diseases might also not be considered fully sustainable. Sclerotinia is one of the most harmful disease for the oilseed rape posing global threats to the production of rapeseed, with important yield losses [15]. There is currently no curative fungicide treatment to fight sclerotinia meaning that fungicides have to be applied in prevention. Classical breeding of Sclerotinia-resistant rapeseed cultivar has been unsuccessful so far [16]. In that context, NBTs are an additional tool in the genetic engineering tool box (with advantages in terms of costs, precision, speed of development), that may help breeders to successfully develop much needed new varieties such as new Sclerotinia-resistant varieties [17] or varieties more resistant to insects. The use of NBTs also provide opportunities to breed higher yielding rapeseed varieties (with increased pod strength for example [18]) without additional use of pesticides or fertilizers.

• Ex2: plant-based protein sources are one of the options to respond in a more sustainable manner to the expected increased demand in proteins. Due to their high protein quality and good techno-functional properties [19, 20, 21, 22], rapeseed proteins have the potential to be used as an alternative source of proteins for direct human consumption. However, the use of rapeseed proteins in food is today limited by the presence of antinutritional compounds such as phytates. The reduction or elimination of these phytates, through genetics and/or processes, is facing the challenge of deriving competitive products at the end. Phytate is synthesized by complex pathways involving multiple enzymes. Breeding rapeseed for a low phytate content is therefore challenging as the related gene functions are encoded by several paralogs which may require time-consuming crossing experiments to obtain mutants. In that context, NBTs are also an additional tool in the genetic engineering tool box that may help breeders to develop these new low phytate varieties. Recent work using NGTs (CRISPR-Cas9 mutagenesis) has offered new perspectives for breeding low phytate rapeseed.[23]

[15] Saharan G.S., Mehta N, Sclerotinia Diseases of Crop Plants: Biology, Ecology and Disease Management (2008)
[16] Mei J, et al. Introgression and pyramiding of genetic loci from wild Brassica oleracea into B. napus for improving Sclerotinia resistance of rapeseed. Theor Appl Genet (2020)
[17] Sun Q, et al. CRISPR/Cas9-Mediated Multiplex Genome Editing of the BnWRKY11 and BnWRKY70 Genes in Brassica napus L. Int. J. Mol. Sci. (2018)
[18] Braatz J, et al. CRISPR-Cas9 Targeted Mutagenesis Leads to Simultaneous Modification of Different Homoeologous Gene Copies in Polyploid Oilseed Rape (Brassica napus). Plant Physiology (2017)
[19] Fleddermann M et al. Nutritional evaluation of rapeseed protein compared to soy protein for quality, plasma amino acids, and nitrogen balance e A randomized cross-over intervention study in humans, Clinical Nutrition (2012)
[20] Khattab R.Y., Arntfield S.D. Functional properties of raw and processed canola meal. LWT-Food Sci Technol (2009)
[21] Aluko R.E, McIntosh T. Polypeptide profile and functional properties of defatted meals and protein isolates of canola seeds. J. Sci. Food Agric. (2001)
[22] Yoshie-Stark Y, et al. Chemical composition, functional properties, and bioactivities of rapeseed protein isolates. Food Chem. (2008)
[23] Sashidhar N, et al. Gene editing of three BnITPK genes in tetraploid oilseed rape leads to significant reduction of phytic acid in seeds. Plant Biotechnol J. (2020)

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

- ○ Yes
- ○ No
- ◉ Not applicable

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

- ◉ Yes
- ○ No
- ○ Not applicable

* Please specify which needs/gaps, explain the reasoning and how these needs/gaps could be addressed

- Some of our crops, like linseed, are relatively minor crops compared to other crops like cereals. While presenting interesting potential in terms of possible applications, the marginal surface areas for these types of oilseeds do not always encourage plant breeders to invest in them (given the big investments needed and the limited possibility for them to get return on their investments). Only a limited number of active substances are approved for use on these crops for the same reasons. NGTs are more accessible techniques in terms of costs/time for development. Should a more conducive regulatory environment be implemented in the EU, this may allow local small breeders, more interested in supporting the development of niche markets for their region, to increase their research activities using NGTs to develop new linseed varieties, better addressing the current challenges.
- Along with an appropriate regulatory environment, investments and research would be needed to make the analytical traceability feasible

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

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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

• FEDIOL companies, which are an integral part of the food and feed value chains, recognize the importance of accelerating the transition towards an EU sustainable food system and are conscious of their responsibility in driving change throughout the supply chain by reducing their environmental impacts. Looking at the way the raw materials are produced and enhancing their environmental performance or reduce their impact is one of the key challenges for developing more sustainable food systems. In that context, NGTs which allow an accelerated time for research at a relatively low cost (in comparison to traditional breeding) [24] are one of the important options to address these sustainability challenges.

•[24] Scientific Advice Mechanism (SAM). New Techniques in Agricultural Biotechnology. April, 2017

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

- (●) Yes
- ( ) No

* Please explain

•The benefits are specific to NGTs in the sense that these benefits can be delivered much faster and at a lower cost, compared to conventional breeding techniques.

*** 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

• Society is today making calls for urgent changes in our food systems to address concerns about biodiversity, climate change, environmental impact or health, amongst others. As one of the options to support more sustainable farming, quality products or food safety, NGTs have the potential to enable improvements in farmer livelihoods, sustainability, animal health and welfare, and improving the resilience of global agricultural.

• Concrete examples of benefits/opportunities that may be obtained via NGTs include:

o Changes to the fatty acid profile of oils by reducing the content of SAFA and increasing the share of MUFA or PUFA;

o Increasing the Omega 3 content of oils considering that EU consumers have a deficit in this fatty acid and achieving a more desirable Omega 6:3 balance;

o Being able to maintain or expand productivity on one hectare with reduced input (water/fertilizers/plant

protection products) and targeted responses to persistent oilseed pests, for long-term food security and a better environmental performance.

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

•This would be the case, provided that the use of such tools and derived products are assessed as being safe and counterbalancing any potential risk, and are integrated into transparency processes.

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

- (•) Yes
- ( ) No

* Please explain

- These techniques may be used to achieve the same or similar product traits with greater precision and efficiency, and may not involve the introduction of foreign DNA.
- In 2017, the Scientific Advise Mechanism – High Level Group (SAM-HLG) of the EU made a time/cost comparison between conventional breeding and new breeding technologies and estimated that “generally speaking, the NBT are faster and cheaper than conventional breeding techniques” [24].
- Because these new methods may be more efficient and economical when compared to other plant breeding methods, they are more accessible to public and commercial plant breeders.

* **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

FEDIOL not answering the question. "Yes" selected by default (as answering the field is required) not reflecting FEDIOL position.

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

- (•) Yes
- ( ) No

* Please describe and provide concrete examples/data

FEDIOL not answering the question. "Yes" selected by default (as answering the field is required) not reflecting FEDIOL position.

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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

Challenges raised by NGTs for our sector are linked:

1. To the current unfit and unclear EU regulatory environment surrounding these techniques:

• NGT products should not automatically be regulated as GMOs. EU registration costs for GMOs are high. Having NGTs assimilated to GMOs will in practice prevent researchers and developers with more limited resources to use these techniques and potential benefits for EU agriculture will be very restricted, making the supply chain gradually less competitive and less sustainable, while further eroding the position of the EU as a center of excellence in research in the agri-food sector. With a less productive agriculture, this may also increase dependency on sourcing outside the EU.

• Because of the current negative public perception of GMOs, this would also prevent the uptake of NGT derived products by the market.

• Although all products resulting from any kind of mutagenesis breeding are to be considered GMOs according to the European Court of Justice (case C-528/16), it is not 100% clear which techniques are covered or excluded from the scope of the GMO Directive in practice, which is a source of legal uncertainty.

2. To the impossibility today for operators to control the compliance of imported raw materials through analytical testing, leaving them exposed to the risk of fraud and public distrust.

3. To the gap between the EU and the rest of the world regarding how NGTs are being regulated. In third countries, NGTs are increasingly adopted, plants derived from NGTs have already reached the market. This is exposing operators to the risk of serious problems for commodity trade and risk of supply disruption.

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

- (●) Yes
- ( ) No

* Please explain

•Because most of NGTs lead to plants that are indistinguishable from their traditional breed equivalent with current analytical methodologies, making implementation and enforcement of the EU legislation impossible.

* **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

• As with any new technology, next to promising potentials, NGTs bring risks and uncertainties, which trigger questions and skepticism (as to whether these technologies will live up to their promises and address societal or industrial challenges) from society.

• The integration of the development of NGT products into transparency processes is also very

important for consumer acceptance of these new technologies. The development and implementation of new approaches to the regulation of agricultural biotechnology is therefore needed to ensure consumers and governments of the safety of the food supply, and earn the trust and acceptance of consumers.

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

/

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

- ○ Yes
- ◉ No

* Please explain why not

•�These are challenges/concerns observed for all new technologies, especially those involving the living (the so-called biotechnologies).

*** 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

FEDIOL not answering the question. "Yes" selected by default (as answering the field is required) not reflecting FEDIOL position.

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

- ◉ Yes
- ○ No

* Please describe and provide concrete examples/data

FEDIOL not answering the question. "Yes" selected by default (as answering the field is required) not reflecting FEDIOL position.

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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**

- Food safety is the number one priority of FEDIOL member companies.
- As for any new technology, the most appropriate mechanisms to assess the risks need to be reflected by appropriate competent bodies and established. Current risk assessment frameworks may require adjustments to better capture the specificities of NGTs/NGT products [25]. On this basis, fit-for-purpose mechanisms for appropriate governance and oversight could be developed allowing to balance the potential of NGTs/NGT products (to address current challenges) against the potential risks arising from these new techniques (through their use or misuse).
- Since NGTs can lead to a spectrum of changes (from single nucleotides to the creation of new metabolic pathways), NGTs should not be regulated the same way as GMOs. Risk assessment frameworks should be flexible and the degree of oversight commensurate with the risk. In that context, FEDIOL would support the development of mandatory, flexible, tiered approaches to scientific risk assessment, applied on a case-by-case basis and according to the risk represented by specific products—rather than a one-size fits all risk assessment system broadly applied to the gene-editing process as a whole. The development of such approaches should take into consideration existing frameworks that may have been developed elsewhere in the world.

[25] Draft scientific opinion on the applicability of the EFSA opinion on site-directed nucleases type 3 (SDN-3) for the safety assessment of plants developed using site-directed nucleases type 1 and 2 (SDN-1 and SDN-2) and oligonucleotide-directed mutagenesis (ODM)

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

- ○ Yes
- ◉ No

* Please explain why not

•No, we have no reasons for specific safety concerns beyond those that need to prevail for any technology. In addition, potential risks associated with NGTs should also be balanced against the risk of inaction, in a context where our food systems have to urgently address global challenges such as food security, climate change, environmental impact or health.

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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**

FEDIOL not answering the question.

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

- ◉ Yes
- ○ No

* Please explain

FEDIOL not answering the question. "Yes" selected by default (as answering the field is required) not reflecting FEDIOL position.

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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**

- Development of NGT products should be integrated into transparency processes. Transparency is a key point for consumers, the perceived lack of transparency being one of the issues impacting consumer acceptance of new technologies.
- Information related to the commercialization of NGTs must be accurate, timely, and accessible to all stakeholders for agricultural supply chains and markets to function effectively. This includes information available to farmers on which seed varieties have been produced using NGT and information on the regulatory status of various NBT varieties in major markets.
- However, should all NGT products be labelled as GMOs, this would prevent the uptake of NGT derived products by the market, because of the current negative public perception of GMOs.

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H - Final question

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

- ○ Yes
- ◉ No

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