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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

FoodDrinkEurope (Transparency Registry Number: 75818824519-45)

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

FoodDrinkEurope represents Europe’s food and drink industry, Europe’s largest manufacturing sector in terms of turnover, employment and value added.

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

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

The term New Genomic Techniques (NGTs) as defined for this study is rather broad. We recognize that NGTs can be used in a number of applications. Nevertheless, the content provided by FoodDrinkEurope in this questionnaire focuses on applications of NGTs for plant crops and NGT-derived plant varieties only. For other specific applications such as yeast, please refer to our sector member COFALEC's position in this topic, sent as attachment.

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 provide details

Our answer relates only to NGT-derived plant varieties.

We think that the current regulatory framework does not guarantee favourable conditions at the moment. FoodDrinkEurope members believe that NGTs can provide a valuable potential to improve different traits of crops, plant raw materials and ingredients. Some members are looking into the possibility of using NGT-derived plant varieties, but currently not exploiting these. In the context of the Green Deal objectives for more sustainable food systems and increased pressure to reduce pesticide use, these technologies, if permitted under reasonable regulatory conditions, could be extremely helpful to build resilient and sustainable food systems.
Food Business operators (FBOs) work closely with farmers, agronomists, commodity traders, and varied specialists of the agri-food chain and related sciences and there is thus big awareness of the increasing agronomical difficulties in producing crops and food and the financial risks involved. NGT-products could potentially bring benefits to the food systems as a whole.

In what NGTs are concerned, Europe finds itself in a threefold lockdown situation:
• Detection and analytical methods - Some NGTs (SDN 1 and SDN 2) cannot be controlled and differentiated from their essentially identical counterparts produced by conventional plant breeding methods. Some NGTs can introduce single nucleotide changes without integrating foreign DNA and thereby generate organisms with intended phenotypes. Consequently, such organisms and products thereof might be indistinguishable from naturally occurring or conventionally bred counterparts with established analytical

tools. The modifications can entirely resemble random mutations regardless of being spontaneous or induced chemically or via irradiation.(1)
Validation of an event-specific detection method and its implementation for market control will only be feasible for genome-edited plant products carrying a known DNA alteration that has been shown to be unique. Under the current circumstances, market control will fail to detect unknown genome-edited plant products.(2)

• Market – In view of the current regulatory framework, there are no authorized NGT-derived plants available on the European market to drive further development and use.

• Categorization - the ruling by the ECJ shifts all NGTs and the products derived hereof generally towards the GMO legislation and its measures for compliance. It does not follow a differentiated risk-orientated approach as recommended by most of the scientific panels. Moreover, with the present perception of GMOs by consumers, and the general labelling requirement, it leaves products derived from NGTs in a de facto blockage situation.

The former conditions signal a clear message to researchers, venture capital and investors, innovators, business operators from the different sectors in Europe: don't develop, plan to use or explore the possibility of using. The financial and reputational risk to do so is high.
Meanwhile, other countries worldwide have released the regulatory lockdown on at least parts of NGTs which opens their markets, research institutions and businesses to develop, use, or plan to use NGTs/NGT-products. They have made the conditions possible to unlock their potential.

Food and drink companies express high concern that some NGTs cannot be controlled with common testing procedures and hence it cannot be guaranteed that they have not been used. In this situation, suppliers cannot really ensure their FBO customers they are providing non-GMO (conventional) material according to the current regulatory framework, but paradoxically cannot ensure the absence of NGTs either. This is the present day-to-day conundrum raw material suppliers and FBOs are facing. In this regard there is no legal certainty for all parts of the food chain.

(1) Grohmann, et al., 2019. Detection and Identification of Genome Editing in Plants: Challenges and Opportunities | https://doi.org/10.3389/fpls.2019.00236

(2) European Network of GMO Laboratories (ENGL), Detection of food and feed plant products obtained by new mutagenesis techniques, 26 March 2019 (JRC116289)

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

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

* Please provide details

Our answer relates only to NGT-derived plant varieties.

The food and drink sector has set up the respective quality control and testing procedures in place on all the raw materials inputs to guarantee non-GM status. Companies deploy many resources and testing capabilities to avoid cross contamination, hence the importance of the tolerance threshold for unintentional presence.

Many FBOs have monitoring plans set up to detect the presence of unintentional GM material. These controls are targeted to the GMOs authorized in Europe and performed by Polymerase Chain Reaction (PCR). Considering that the detection of NGTs-derived products is currently unclear, these monitoring plans are not adapted to such products. As long as the European Commission cannot clarify how to detect the above mentioned NGTs-products, it is extremely difficult for FBOs to take specific and coordinated measures to protect themselves from unintentional use of these NGT-derived plant varieties. The challenges for analytical methods and the detection of genome-edited events (altered DNA sequence) in the context of market control and under the current circumstances have been raised as well in the JRC report of March 2019 (3). The report also points out that several issues with regard to the detection, identification and quantification of genome-edited products are currently based on theoretical considerations only and lack any experimental evidence. Therefore, they will require further consideration.
Presently, FBOs routinely check GM status for plant ingredients and raw material inputs which following the ECJ ruling would include the application of NGTs. In addition, when crops from NGT begin to be commercialised outside the EU in coming years, it is expected that companies would need to include these crops and materials produced from them in their regular GMO traceability and control systems bearing in mind that as of today, market control will fail to detect unknown genome-edited plant products; i.e. presence of NGT material (SDN 1, SDN 2). In this regard the Food and drink sector faces the same problems as the food control authorities in the Member States.

(3) European Network of GMO Laboratories (ENGL), Detection of food and feed plant products obtained by new mutagenesis techniques, 26 March 2019 (JRC116289)

* 2 bis. Have you encountered any challenges?

- ○ Yes
- ◉ No

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

- ◉ Yes
- ○ No
- ○ Not applicable

* Please provide details

Our answer relates to applications of NGTs for plant crops and NGT-derived plant varieties only, provided regulatory certainty and an innovation-friendly environment are in place to meet the strategies and goals embedded in Europe's Green Deal and the big tasks expected by the wider agri-food sectors. This requires a differentiated risk-orientated approach in the regulation of NGT´s.

European food and drink companies produce conventionally derived food products to meet customer needs and expectations, given their concerns towards GMOs. The ECJ ruling means that all NGTs-derived products are equally considered to be GMOs which consequently require authorization and labelling. Due to this undifferentiated categorization lockdown, FBOs are not be able to accept raw materials derived from NGTs under the present scenario, which is a pity in view of the increased pressures on agri-food systems due to climate change and the immediate need for resilient and sustainable food systems.

Comprehensive traceability systems are the standard in the food and drink industries as required by the General Food Law Regulation, but these are not yet adapted to site-directed nucleases (SDNs) technologies. Tailored analytical methods are required for the enforcement. Without this, the intention of use or plans for investment are shadowed at a longer term.
Moreover, the dimensions of global food supply chains and inherent global trade needs to be considered. For example, in the USA, soybean oil containing 20% less saturated fatty acids produced by gene editing has been commercialised (Calyno) for use in foods. Then again, if this healthier oil were used in food products made in Europe, these would need to be labelled as GM-product.

* **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

Our answer relates only to NGT-derived plant varieties.

Food supply chains are intrinsically and tightly connected and so are the controls on plant food ingredients and raw materials. Food and drink businesses operating in Europe and worldwide routinely check as standard practice the GM of ingredients sourced and used to safeguard against the unintentional use of GM.

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

- ( ) Yes
- (●) No

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

Please also see question 8 specifically on labelling

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

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

Our answer relates only to NGT-derived plant varieties.

In regard to the existing quality control, testing procedures and monitoring plans set up to detect the content of unintentional GM material and the existing difficulties to detect at least some of NGTs-derived products (see answer Q1), FBOs and their raw material suppliers are hindered in their capabilities in controlling information on the use of these NGTs. On top of this difficult situation, in practice FBOs and suppliers of crop plants and food ingredients from different sources cannot as of today detect some NGTs thorough analysis.

Furthermore, there is also lack of clarity for the time being regarding which organisms produced by NGTs are included within the GMO legislation, and which ones are not. The final ruling of the French Conseil D' Etat (February 2020)(4) based on the European Court of Justice's decision on mutagenesis breeding resolved that random mutagenesis in vitro consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagens' are not exempted an have to be considered as creating GMOs. The French decree may clarify the situation for France, but it unfortunately could bring along fragmentation of the European single market.
Due to cost of application and labelling requirement, commercial production will not be interesting with the current interpretation of the GMO legislation for NGTs. If legislation is not adapted, commercial production will take place outside of EU. At the same time, the European food and drink sector will still be faced with the above-mentioned control problems with regard to imported bulk commodities.

Activities in the research/developments of NGTs and NGT-products are done in line with current GMO legislation.
Other companies for example are currently using GM-derived enzymes and are testing the safety and suitability of the GM-derived enzymes, but compliance to GM regulations is put on the enzyme supplier.
A further example on overarching measures to comply with the GMO legislation is the dairy sector whose traceability and general rules of traceability are well established under the animal origin legislation.

(4) https://www.conseil-etat.fr/ressources/decisions-contentieuses/dernieres-decisions-importantes/conseil-d-etat-7-fevrier-2020-organismes-obtenus-par-mutagenese

* What best practices can you share?

Please refer to the answer above.

* 5 bis. What challenges have you encountered?

Please refer to the answer above.

* **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?

Our answer relates to applications of NGTs for plant crops and NGT-derived plant varieties only.

In Q1 we presented the threefold lockdown situation Europe finds itself in (detection and analytical methods, market, and categorization). Support from the European Authorities would ease up this lockdown. Guidance on how to operate under this situation would be welcome. For both food and drink business operators and control authorities it is a real conflictive situation at many levels to have regulations in place after the ECJ ruling which cannot be controlled and enforced because of missing analytical methods. Clarification is missing as well on the definitions of 'conventionally used mutagenesis techniques' and of 'newer mutagenesis techniques'.

Our members report that research and development activities receive good support in some Member States. Different levels of support by national initiatives increase the uncertainty and fragmentation to develop and assess new technologies and their products.

* **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

Our answer relates only to NGT-derived plant varieties only.

Traceability is already an obligation embedded in the General Food Law Regulation requiring that also GMOs are traced throughout the supply chain. Small DNA changes originated by NGTs are not possible to control as of today since there is no standard methodology available to detect such modifications. This does not mean it might not change in the future. Analytical methods are constantly improving and becoming more precise.
In the absence of analytical approaches for some NGTs, FBOs rely on their own range of traceability systems available, e.g. paper trails and digital records, contractual agreements, and auditing. Existing traceability methods could be used and adapted for NGTs. Nevertheless, this poses clear limitations, particularly to ensure compliance, for both FBOs and control authorities: whereas GM maize can be detected, as there is a method and a threshold available, the same is not true for other NBT-derived products.
The lockdown caused by the lack of analytical methods could not guarantee an effective and reliable system of full traceability with the corresponding compliance and information flow on new products from new technologies. Reliance on records, certification schemes, audits and agreements between suppliers and FBOS would have to be the norm. Thus, traceability needs to build on trust and supply chains need to be segregated.

* **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

As explained below.

* What best practices can you share?

As explained below.

* Please explain why not

Our answer relates only to NGT-derived plant varieties.

In spite of FBO's well established quality control systems, testing procedures and extensive monitoring plans set up to detect the content of unintentional GM material, the existing difficulties to detect and control some NGTs-derived products due to the current regulatory framework prevail (see answer Q1, Q2 and Q5). The fact of the matter is that with lack of a reliable analytical approach, commercial production of food products with NGTs-products will not be economically attractive to FBOs under current interpretation of the GMO legislation for NGTs, and the labelling requirements.
Due to the impossibility of analysing for compliance, the whole supply chain and control authorities in Member States would face the problem that current legal provisions are not practical.
At this point in time, there are no commercialised NGT crops, e.g. maize, wheat, peas and potatoes, confirmed as such that will be subject to EU GMO labelling obligations and therefore no specific measures are currently required.

* 8 bis. What challenges have you encountered?

As explained above.

* **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

Our answer relates to NGT-derived plant varieties only.

We would like to highlight the waste of human, material and economic resources that producers, buying raw material and all NGTs-products to be considered as GM, would inevitably encounter when they would need to comply with labelling obligations, but lack of a method to detect them.
For producers (of plant crops, young plants, or seed producers) doing contract production, the conclusion is that production will not be possible due to cost of approval and labelling demands.

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

The maximum file size is 1 MB

B - Information on research on NGTs/NGT-products

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

- ○ Yes
- ◉ No
- ○ Not applicable

* Please explain why not

Our answer relates to applications of NGTs for plant crops and NGT-derived plant varieties only.

Our members are not extensively conducting NGT-related research. The current regulatory framework does not encourage research and innovation (R&I). At a wider agri-food chain scale, we understand that following research is being carried out:
- reduction of use of pesticides during cultivation of the crop (on the field).
- bioactive compounds in plants can be made more functional and easier to extract through the use of NGT.
- reduction of anti-nutritional components through the use of NGT e.g. glycoalkaloids in potatoes.

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

- ◉ Yes
- ○ No
- ○ Not applicable

* Please specify

Our answer relates to applications of NGTs for plant crops and NGT-derived plant varieties only.

On a global level we are aware of experimental work (and even commercial activity) on key agricultural crops. In Europe, there are several NGT-related research projects running with public funding and European Union funding.
Here we emphasize again the importance of providing favourable conditions to unlock the potential of NGTs (see elements in answer Q1). In the IPCC (2019a) land report (5), the innovation and resilience potential of new genomic techniques for Sustainable Food Systems is acknowledged. Genetic improvements for tolerance to heat and drought are recognised as options for adaptation of food systems to climate change.

(5) IPCC Special Report on climate change, desertification, land degradation, sustainable land management, food security, and greenhouse gas fluxes in terrestrial ecosystems, https://www.ipcc.ch/srccl/

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

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

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

* Please describe

Our answer relates to applications of NGTs for plant crops and NGT-derived plant varieties only.

Even in the absence of data and information, it is obvious that the current regulatory framework is a strong deterrent to any research that our members may have undertaken, or wished to undertake, to identify more precise data and figures on the advantages that undoubtedly the application of NGTs may grant. More dramatic is the missed opportunity on the benefits such crops may have in relation to food security, environment, or nutrition. These opportunities will be taken outside of Europe.

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

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

* Please provide concrete examples/data

Please see answer to question 16 and 17

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

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

* Please provide concrete examples/data

Our answer relates to applications of NGTs for plant crops and NGT-derived plant varieties only.

As indicated previously, the current legislation stagnation discourages the support and development of research in innovative NGT-products in Europe. Without an outlook of bringing into the market, promising research development remain in the background, many of these funded by the European R&I programmes.

*** 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

We believe the global food and drink industry is facing significant food security challenges ahead (with population growth, climate change, land degradation and biodiversity loss) and that NGT may be able to provide some solutions (e.g. higher yielding more resilient crops requiring less fertiliser).

Food and drink manufacturers are generally processors of raw materials and usually don't engage in the development of any new variety or microbial culture. We nevertheless are in continuous contact with our partners of the wider food supply chain and perceive the need to loosen the lockdown the current legislation puts on research & innovations that never reach the market.
Given the current situation with increasing population, climate change and the need to develop biodiversity it is essential that the agricultural and forestry sector can use different technologies to develop the crops that are then processed by FBOs. NGTs can support traditional breeding with increased possibilities to change specific properties in plants.

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

The maximum file size is 1 MB

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

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

Our answer relates to applications of NGTs for plant crops and NGT-derived plant varieties only.

In its scientific opinion 'Towards a sustainable food system', the EU's Scientific Advice Mechanism (SAM) states (6):
"The food system is already undergoing major transformations that will affect sustainability. Climate change will affect production, processing, distribution and storage of food. Moreover, the current European food system is deeply intertwined with global food systems."
NGTs could be a much-needed way to protect plant crops and animals from pests and diseases and to improve the sustainability of the food system. Among these, CRISPR technology has been documented to offer advantages such as improved yields, lower pesticide and herbicide usage, decreased tillage, and reduced fossil fuel use (7).

FoodDrinkEurope members see the immense challenge of increasing demand for high-quality food, feed and bio-based goods while using limited resources and producing less emissions. Many sectors and their raw material suppliers are already suffering from climate change and more extreme weather conditions on agricultural land in Europe and worldwide.

The ability to adapt and mitigate climate change through R&I are key to meet the goals of the Farm to Fork Strategy and the European Green Deal.
We raise again attention to the IPCC report on climate change that underscores the need for further breeding innovation to mitigate its effects such as resistance to water and heat stress and resistance to changing pest and disease risks.

(6) Towards a Sustainable Food System - Group of Chief Scientific Advisors https://ec.europa.eu/info/sites/info/files/research_and_innovation/groups/sam/scientific_opinion_-_sustainable_food_system_march_2020.pdf

(7) Baulcombe, D., Dunwell, J., Jones, J., Pickett, J., & Puigdomenech, P. (2014). GM science update. A report to the council for science and technology. Retrieved from https://www.gov.uk/government/publications/genetic-modification-gm-technologies
National Academies of Sciences, Engineering, and Medicine. 2016. Genetically Engineered Crops: Experiences and Prospects. Washington, DC: The National Academies Press. https://doi.org/10.17226/23395.

(8) IPCC Special Report on climate change, desertification, land degradation, sustainable land management, food security, and greenhouse gas fluxes in terrestrial ecosystems, https://www.ipcc.ch/srccl/

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

- (●) Yes
- ( ) No

* Please explain

As by the answer 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

Our answer relates to applications of NGTs for plant crops and NGT-derived plant varieties only.

Disease and insect resistance
Bacterial blight-resistance in rice [R. Oliva et al. Broad-spectrum resistance to bacterial blight in rice using genome editing, Nat. Biotechnol. 37 (2019) 1344–1350. doi:10.1038/s41587-019-0267-z.]
Viticulture is a highly conservative branch where growers and producers favour the maintenance of existing, highly popular grape varieties. However, crossbreeding for new disease-resistant varieties (that will not need to be sprayed as much) takes well over a decade and the final new variety will most likely be different from the original variety also in other aspects. New techniques for site-directed mutagenesis (e.g. CRISPR/Cas or other) will enable the introduction of disease- and pathogen resistance while maintaining original grape varieties.
Late blight resistance in potato
Agronomic traits
Abiotic stress tolerance
Drought-tolerant maize
Salt-tolerant rice
Pod shatter-resistant oilseed rape
Food quality/food health traits
Non-transgenic, CRISPR/Cas9-developed wheat with much reduced immunoreactivity for people with coeliac disease [Sánchez-León S et al (2018). Low-gluten, non-transgenic wheat engineered with CRISPR /Cas9. Plant Biotechnology Journal, 16: 902-910.]
Recovering lost, wild tomato quality traits by de novo domestication of wild tomato [Zsögön A et al (2018). De novo domestication of wild tomato using genome editing. Nature Biotechnology, doi:10.1038/nbt.4272.]
Root chickory producing more and healthier inulin food fibre as well as medicinal terpenes (http://chicproject.eu)
High-amylose starch potato suitable for industrial applications [Andersson M et al, 2018. Genome editing in potato via CRISPR-Cas9 ribonucleoprotein delivery. Physiologica Plantarum doi: 10.1111/ppl.12731]
Vitamin A-enriched rice [O.X. Dong, et al, Marker-free carotenoid-enriched rice generated through targeted gene insertion using CRISPR-Cas9, Nat. Commun. 11 (2020) 1178. doi:10.1038/s41467-020-14981-y.]
Waxy maize [H. Gao et al, Superior field performance of waxy corn engineered using CRISPR–Cas9, Nat. Biotechnol. (2020). doi:10.1038/s41587-020-0444-0.]
Specific hydrolysis of proteins which could have benefits for people who are allergic to proteins.

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

To be successful in bringing these benefits, an interconnected agricultural food supply chain must work together to develop and implement new approaches to a differentiated regulation of agricultural biotechnology that assures consumers and governments of the safety of the food supply, earns the trust and acceptance of consumers, and sets up coherent regulatory frameworks globally.

In the context of the EU's Green Deal and Farm to Fork Strategy, this can only be achieved through a supportive policy which is truly holistic, co-ordinated, harmonised, co-owned, inclusive and based on science. This policy must be continuously evaluated against its objectives and should include incentives for both consumers and businesses (9).

(9) FoodDrinkEurope preliminary contribution to EU 'Farm to Fork' Strategy on Sustainable Food (March 2020): https://www.fooddrinkeurope.eu/uploads/publications_documents /FoodDrinkEurope_preliminary_contribution_to_F2F_Strategy_on_Sustainable_Food_%28March_2020%29.pdf

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

- (●) Yes
- ( ) No

* Please explain

As in the field 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

Our answer relates to NGT-derived plant varieties only.

If regulated according to the GMO legal framework, businesses might probably avoid the associated business and consumer acceptance risks of marketing crops developed by the technology.

Given a situation where NGTs are regulated as crops developed by traditional breeding methods, it opens up big opportunities for SME/small scale operators to go into the market with NGT products. On the other hand, if NGTs were to be regulated as GMOs, this will create difficulties for SMEs to work with this NGTs-products (e.g. associated costs, economic disadvantage compared to other regions of the world, lack of attractiveness of the finished product due to consumer perception towards GMOs). See Q22.
Nevertheless, an assessment of NGTs must be flexible, applied on a case-by-case basis, and proportionate to the risk and the specific modification brought to the variety.

Another consideration is that if all NGT products needs to undergo approval similar to Novel Food, this would require many resources to access markets in time, ability and financial possibilities, which might be challenging for many SMEs.Our answer relates to NGT-derived plant varieties only.
If regulated according to the GMO legal framework, businesses might probably avoid the associated business and consumer acceptance risks of marketing crops developed by the technology.

Given a situation where NGTs are regulated as crops developed by traditional breeding methods, it opens up big opportunities for SME/small scale operators to go into the market with NGT products. On the other hand, if NGTs were to be regulated as GMOs, this will create difficulties for SMEs to work with this NGTs-products (e.g. associated costs, economic disadvantage compared to other regions of the world, lack of attractiveness of the finished product due to consumer perception towards GMOs). See Q22.
Nevertheless, an assessment of NGTs must be flexible, applied on a case-by-case basis, and proportionate to the risk and the specific modification brought to the variety.

Another consideration is that if all NGT products needs to undergo approval similar to Novel Food, this would require many resources to access markets in time, ability and financial possibilities, which might be challenging for many SMEs.

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

Our answer relates to applications of NGTs for plant crops and NGT-derived plant varieties only.

NGT- derived plant varieties will normally be covered by existing legislation on breeder’s rights. The discussion about the possibility to make patents on this technology and GMO has been there for a long time. The basic reason for our very old system with patents is that especially small entrepreneurs should be able to put substantial investment into new development and have a chance to get financial return. Larger companies normally have access to a bigger market and thus are less dependent on patents if they are not very costly. Limitations on the possibility to make patents will reduce development efforts especially among SME/small scale operators. If there is a worry about access to new development this could be handled by compulsory licensing.

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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

Our answer relates to NGT-derived plant varieties only.

Public perception of these products could be similar to that of GMOs, which could trigger consumer rejection of the technology despite all its advantages. This would reduce the incentive for business operators to apply the technology and use products obtained by it.
The development of NGTs and NGT-products needs assurance of safety, information sharing, a focus on consumer benefits (consumer-facing products, sustainability, etc.) and aligning regulatory frameworks between trading partners.

Genetic engineering (including gene editing) are paramount innovations for production agriculture and its applications. It has and will continue to show the potential to enable improvements in farmer livelihoods, sustainability, animal health and welfare, and the resilience of global agricultural supply chains.
Nevertheless, we cannot ignore the existing debate as to how these new techniques should be regulated and if some of them should be subject to existing genetic engineering regulations.
We consider that some NGTs (SDN 1 and SDN 2) should not be regulated within the GMO framework, but a way for regulation needs to be found taking the safety of the products as the baseline. In overall, an assessment of NGTs must be flexible, applied on a case-by-case basis, and proportionate to the risk and the specific modification brought to the variety.

Further challenges:
- Lack of technology to analyse will put companies and society into a situation where it will be unknown if imported products on the market are produced with this technology.
- If European producers do not have access to NGTs there will be a competitive disadvantage on export markets and eventually also on EU market due to lack of detection possibility.
- A situation where EU is regulating NGTs according to the GMO-directive while other parts of the world do not, will potentially create a big challenge for the EU market and an uneven playing field at global food supply and trade level.

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

- (●) Yes
- ( ) No

* Please explain

As explained 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

Our answer relates to NGT-derived plant varieties only.

It is important to first acknowledge that safety cannot be established with absolute certainty. Through centuries of experience, we have learnt to handle uncertainties e.g. with food products, and we have learnt that a science-based approach is by far the best way to achieve the highest degree of safety. Thus, we support a risk-based assessment for NGTs.
It is also important to acknowledge that refraining from applying the GMO risk assessment and risk management to the products of NGT does not mean that these will be unregulated. In addition to this, all newly developed varieties still need to go through thorough testing (Value for Cultivation and Use (VCU) of agricultural crops and Distinctness, Uniformity and Stability (DUS) (10)) and have to be approved before they can be released on the market.
There may very well be concerns related to a specific product. But these concerns are strictly related to the trait itself and have nothing to do with the specific technique that was used when the genetic material was modified in the breeding process.
Taking in account consumer concerns regarding GM foods, a UK survey has shown that the resistance towards GM food is based on a mixture of rational and affective responses. Acceptance of GM food also has social, cultural and affective contexts, and depends on e.g. beliefs about the value of science.
As addressed in Q17, it is crucial that stakeholders, national authorities and the Commission work together at all steps to develop and implement new approaches to a differentiated regulation of agricultural biotechnology that assures consumers of the safety of the food supply, earns the trust and acceptance of consumers, and sets up coherent regulatory frameworks in Europe and globally. Indeed, in case NGT-products have to be labelled as GMOs, consumers will not accept them and it will be difficult for them to value these products, despite all the technical advantages NGTs can bring from a scientific and economic point of view. See also Q16.

(10) Value for Cultivation and Use (VCU) of agricultural crops and Distinctness, Uniformity and Stability (DUS)

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

As explained above.

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

- (●) Yes
- ( ) No

* Please explain

As explained 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

Our answer relates to NGT-derived plant varieties only.

Challenges for SMEs could be massive due to costs of regulatory hurdles and the uncertainty about consumer acceptance in certain markets (assuming labelling requirements are implemented)
The major concern for SMEs/small scale operators is the following: if all the products of NGTs will be regulated as GMOs, it will be impossible for SMEs/small scale operators to work towards the market in Europe. The procedure for risk assessment and risk management will simply be too costly compared to the value created and with an uncertain outcome. It is therefore expected that SMEs/small scale operators will, whenever possible, direct their R&D activities towards markets outside of Europe. This is a major problem as Europe represents a large market and it may be detrimental to SMEs/small scale operators to not have access to this market.

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

See also answer to Q19 above.
Our answer relates to applications of NGTs for plant crops and NGT-derived plant varieties only, Misuse of patents will be difficult to monitor because the change in the genome is not detectable by standard methods.

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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**

Our answer relates to applications of NGTs for plant crops and NGT-derived plant varieties only.

There is nothing inherently unsafe about these technologies. But each case needs to be reviewed, and without question, safety needs to be assessed.
Safety assurance and information-sharing requirements are key to establish consumer acceptance. We view these conditions as prerequisites for the commercial implementation in the agri-food chain of plant varieties made with gene editing techniques, resulting in targeted mutagenesis in such a way that a comparable result could have been achieved by methods considered having a history of safe use.
Ultimately, the development of NGTs and NGT products needs assurance of safety, information sharing, a focus on consumer benefits (consumer-facing products, sustainability, etc.) and aligning regulatory frameworks between trading partners.

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

- ○ Yes
- ◉ No

* Please explain why not

Our answer relates to applications of NGTs for plant crops and NGT-derived plant varieties only.

In principle these products would be as safe as conventional, provided that the safety has been comprehensively assessed, the products have been authorised, and a tailored regulatory framework, other than the GMO framework, has been developed if appropriate. (Please refer to Q24 as well)

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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**

Our answer relates to applications of NGTs for plant crops and NGT-derived plant varieties only. References in Q27 apply here as well.

Food safety is of paramount importance to FoodDrinkEurope members, who remain committed to ensure that all products meet the highest safety standards, from farm to fork.

Status quo and its implications for precaution and harm
There is an ethical dimension to the safety discussion as operators should refrain from doing harm. This principle has been enshrined in EU legislation through the General Food Law and the environmental liability directive. In this context it is important to keep in mind that maintaining status quo is not necessarily the optimum way of refraining from doing harm. A regulatory situation that prevents the use of improved technologies may in fact cause more harm than a regulatory situation that promotes application of these technologies. This is in particular the case when improved technologies can be applied for environmental and /or health benefits. As we have mentioned in Q20, an assessment of NGTs must be flexible, applied on a case-by-case basis, and proportionate to the risk and the specific modification brought to the variety.

Because NGTs and NGT products have a real potential to contribute to a more sustainable agriculture and food production and thereby contribute to helping achieve important sustainable development goals, it would be unethical to hinder the use of some NGTs and NGT products if left within the GMO legislation. The approach towards regulating NGTs should be proportionate.
We believe that using new techniques to keep up with consumer demands and food security is highly ethical. Furthermore, using these techniques to continue reducing the environmental impact of agriculture should also be considered ethical. Or rather: not using these techniques would be unethical.

Climate change is of serious concern. If temperature rises are not contained, the consequences for future generations will be unpredictable. This should weigh heavily in an ethical assessment. Plant breeding innovation alone cannot solve the climate challenge, but the situation today is so serious that all available technologies should be employed unless there are substantial arguments not to do so. Accelerated variety development would be a strength in a situation with rapid climate change, both for adaptation to and mitigation of climate change.

There have been substantial concerns over the years on the products of gene technologies. For ethical reasons, it is important that these concerns are taken into account. However, there are also several other ethical concerns related to the policy approach towards NGT products in Europe, related to the recommendations from relevant scientific bodies such as the EU Scientific Advice Mechanism.

A regulatory situation that prevents, slows down or delays the development and marketing of plant varieties that have been developed using NGTs that do not create specific risks and carry substantial environmental, health and/or economic benefits, is ethically questionable.

Use of NGT products in third countries
Developing countries have a lot to gain with the use of NGTs and NGT products, and many look at Europe for the way they would want to regulate modern breeding technologies. Europe should take this into consideration and promote policies that allow the responsible use and marketing of NGTs.

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

- (●) Yes
- ( ) No

* Please explain

Our answer relates to applications of NGTs for plant crops and NGT-derived plant varieties only.

Ethics of not applying improved technologies
Ethical questions are not limited to NGTs/NGT-products, but always relevant in R&I on whether or not to use a technology, but must also consider the consequences of not using a technology – and what the benefits are of a given product for a pursued goal (environmental, preventive health, societal, land-use, farm-level economic etc).
We therefore agree with the statement from EASAC (12) “that the potential costs of not using a new technology, or being slow in adoption, must be acknowledged. There is no time to lose in resolving the problems for food and nutrition security in Europe.“

This is also addressed by the Danish ethics Council which concluded in its “Statement on GMO and ethics in a new era” (13) that “it also raises the question of whether it is ethically problematic if the legislation obstructs the development and marketing of GMOs, e.g. those with positive effects, if they are not deemed more risky than similar conventional varieties.”

Freedom of choice
Freedom of choice is an important principle with strong ethical implications. There are consumers that demand labelling of GM products in order to actively choose not to buy these. It cannot be overlooked though that there are also consumers who will actively choose to buy GM products, as well as the products of NGTs, as these might be associated with reduced environmental impact (14), improved farmer economy (15), and higher nutritional quality (16).

It is equally ethically problematic that farmers who want access to improved seeds are denied this. Farmers are constantly struggling to deliver high-quality products in sufficient quantity while protecting their crops against insects, diseases and unfavourable weather conditions, and at the same time minimising the impact on the environment. It is therefore imperative to give farmers access to crop varieties that have been genetically improved for, amongst others, heat stress tolerance, salt stress tolerance, improved phosphorous and nitrogen uptake, improved water use, or to resist pests and pathogens.

Equal access to technology
It is ethically problematic from the point of view of equal access to technology. Should the products of NGT be subject to the provisions of the GMO legislation, this would result in SMEs/small scale operators being excluded from using the technology for the European market, and thus work actively against a particular segment on the market.(17)

(12) EASAC: The regulation of genome-edited plants in the European Union https://easac.eu/publications /details/the-regulation-of-genome-edited-plants-in-the-european-union/

(13) http://www.etiskraad.dk/~/media/Etisk-Raad/en/Publications /DCE_Statement_on_GMO_and_ethics_in_a_new_era_2019.pdf?la=da

(14) Brookes, G. and Barfoot, P. (2018) Environmental impacts of genetically modified (GM) crop use 1996–2016: impacts on pesticide use and carbon emissions. GM Crops Food 9, 109–139

(15) Brookes, G. and Barfoot, P. (2017) GM Crops: Global Socio-economic and Environmental Impacts 1996–2015, PG Economics

(16) De Steur, H. et al. (2017) The socioeconomics of genetically modified biofortified crops: a systematic

review and meta-analysis. Ann. N. Y. Acad. Sci. 1390, 14–33

(17) Rommens, C.M. (2010) Barriers and paths to market for genetically engineered crops. Plant Biotechnol. J. 8, 101–111

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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**

Our answer relates to applications of NGTs for plant crops and NGT-derived plant varieties only.

We are in favour of consumers receiving the information they request and are entitled to.
NGT products could be indistinguishable from plants or animals that can be obtained by traditional breeding techniques. In such cases we consider it inappropriate to apply GMO labelling according to Regulation 1829 /2003. Labelling would amount to a de facto blockage, due to the current negative public opinion perception of NGTs. However, it will be important that consumers understand the benefits of NGT and where they have been applied, so alternative means to transparent consumer information should be considered.

When plant varieties come from targeted, site-specific mutagenesis, there should not be more consumer information than for varieties stemming for random mutagenesis (chemicals, gamma irradiation) that have been placed on the market for the last 50 years. To the opposite, when the modifications are more important, consumers information could be considered on a case by case basis. Globally the approach should be product-based rather than technology-based.
As of today, products which have undergone a significant genome change have a labelling requirement. For this matter, the rule should apply to all methods of genome modification. As soon as a major change is induced in the genome, the variety is labelled; regardless of whether the method is traditional or new. As further steps in the safety assessment and evaluation, all newly developed varieties still need to go through thorough testing (Value for Cultivation and Use (VCU) of agricultural crops and Distinctness, Uniformity and Stability (DUS), and have to be approved before they can be released on the market. Lastly, it will prove difficult to explain to consumers about technologies and NGT, consequently uniform and transparent (and simple) labelling must be implemented in every member state. The Food Information to Consumers Regulation still is implemented differently in member states, hence we are concerned that some Member States make separate labelling systems to inform about NGTs.

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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 term New Genomic Techniques (NGTs) as defined for this study is rather broad. We recognize that NGTs can be used in a number of applications. Nevertheless, the content provided by FoodDrinkEurope relates to applications of NGTs for plant crops and NGT-derived plant varieties only. For other specific applications such as yeast, please refer to our sector member COFALEC's position to this topic, sent as attachment
As last remarks to this contribution:
It is important to provide clarification to crucial concepts and definitions in the legal texts. Examples are the GMO definition itself, mutagenesis, and long history of safe use.
It is important to work towards international harmonisation of key regulatory requirements, to reduce international trade obstacles.

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31794c35-10fd-41f2-b6c7-d54d997fbd0f/Cofalec_position_paper_on_NGTs_15_May_2020.pdf

Contact

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COFALEC position on NEW GENOMIC TECHNIQUES, May 15th 2020

COFALEC (https://www.cofalec.com/) is the Confederation of yeast producers that represents the European Union yeast industry in Europe (Transparency Registry Number: 2073390649-79).
Yeast is a natural living micro-organism used in traditional fermented products (bread, wine, beer) and more recently in human and animal health (probiotics) but also in biofuel industry (e.g. ethanol production), agriculture (biocontrol, bio-stimulant and fertilizers), etc.…

Implementation and enforcement of the GMO legislation with regard to new genomic techniques (NGTs)

COFALEC members are developing, using, or planning to use NGTs/NGT-products. Industrial Biotechnology is innovating constantly and dynamically. In doing so we use all technologies of interest and relevance to our research and development activities. Many of these technologies were developed after 2001 – Therefore COFALEC members are planning to use NGTs. Given the regulatory context prevailing in the EU, we do not use these techniques for food commercial products, but for research purposes only.
COFALEC members comply with relevant legislation, and this compliance includes microorganisms (and products thereof). An approach based on the characteristics of organisms instead of the technologies used to develop it, would make authorization and compliance much easier and robust. The technology-based approach of the Directive makes it challenging to even determine whether an organism would fall within the scope or not.
Regarding traceability strategies, which could be used for tracing NGT-products, microorganisms that have been modified in a way that does not distinguish them from nature-sourced counterparts or classical mutagenesis can only be subject to documentary traceability, as analytical traceability will not be possible. Microorganisms that have been modified in ways that are analogous to transgenesis could also be subject to documentary traceability. In addition to this, there would be the possibility to perform an analytical traceability, based on the microorganism's single genetic characteristics that were described by the applicant when applying for authorization for deliberate release. The latter option would however require significant resources and technology at control laboratories.

Research on NGTs/NGT-products

COFALEC members are companies operating in the field of industrial biotechnology. This is a constantly innovating sector, in which we use the latest available set of tools to perform our R&D. Since NGTs are defined as post-2001 technologies, it is clear that we have been using many of these in our research. For IP reasons our members cannot disclose the subject, type of research and resources allocated. One can simply assume that this concerns all fields of application of industrial biotechnology. Many of our members are global companies, having R&D facilities around the globe.

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The Court of Justice of the EU (CJECU) ruling on mutagenesis has had an immediate impact on NGT-related research in our sector. The CJEU ruling emphasized the fact that the technology-based approach of Directive 2001/18 makes it obsolete considering the innovation rate in modern biotechnology. Subsequent debates around the ruling made it clear that it would take a lot of efforts to modernize the legislation and facilitate global trade. This led to debates in the global-orientated industrial biotechnology sector on whether it was still worth keeping R&D facilities and jobs in the EU and placing innovative products on the EU market as regards the uncertainty brought by the ruling.

NGT-related research could bring benefits and opportunities to COFALEC's field of interest. There have been many significant scientific advances in the past 19 years; one example is the CRISPR set of tools, which allows genetic changes to be made with improved (precision) accuracy, control and efficiency, and with much less non-targeted effects than with "pre-2001" technologies (e.g. classical mutagenesis). It helps to limit mutation to beneficial mutation and eliminate non beneficial random mutation.

Nevertheless, the uncertainty brought by the CJEU ruling and the subsequent debates around it made it clear that it would take a lot of efforts to modernize the legislation and facilitate global trade. This led to debates in the global-orientated industrial biotechnology sector on whether it was still worth keeping R&D facilities and jobs in the EU and placing innovative products on the EU market as regards the uncertainty brought by the ruling.

<u>Potential opportunities and benefits of NGTs/NGT-products</u>

There are many opportunities and benefits from modern biotechnology. Microorganisms used to support healthy Food and Feed as cultures/probiotics/silage agents: the genetic basis for e.g. antibiotic resistance and or toxigenic/virulence factors can be accurately and easily eliminated.

The benefits include assured food safety as well an improvement in the nutrients (e.g. removal of antinutritional factors) and or use of scarce resources. This could lead to use of such products in the feeding of animals, supporting less use of raw materials and less production of waste.

In addition, the use of NGT technology can afford a reduce environmental impact by shortening the time to development, by reducing the waste of resources during development, by producing organisms that are more fine-tuned, capable of using industrial inputs more efficiently. Certain type of microorganisms produced by NGTs also allow the fermentation of natural products that avoid wasteful destruction of natural resources in a contained, highly controlled and efficient fermentation-based environment. The volumes of products that NGT-based microorganism can generate are also at scales where often the agricultural-based route would not be able to match, which allows the support of growing populations (e.g. amino acids, vitamins, specialty oligosaccharides, specialty fatty acids, specialty flavours and fragrances, specialty enzymes). In additional, the use of NGT has allowed or is allowing the development of novel food proteins, potentially capable of helping to reduce the global consumption of meat and its impact in the environment, including global warming.

When it comes to microorganisms used to support sustainable agriculture, several agronomical properties such as nutrient uptake and resistance to heat or draught can be introduced into a single microorganism, which would not be possible with "pre-2001"

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technology. The benefits could include stimulated better/improved uptake of nutrients and a more consistent yield of crops under challenging climate conditions, without additional use of mineral fertilizers or chemical pesticides. Additionally, NGTs allows the efficient and scalable production of organisms producing biopesticides, helping to reduce the impact on the environment.

Regarding microorganisms used in medicine, biomedical biotechnology has embraced NGT. A new wave of novel microorganisms is being developed or has been developed to produce vaccines, therapeutic proteins. New “microbial biotic medicines”, organisms able to be administered as live cells to treat specific metabolic or degenerative or proliferative diseases of the human gut or bladder are being developed using NGT. Better microorganisms for the fast and efficient production of vaccines or therapeutic proteins such as interferons more and more rely on NGTs for improving production and purification pipelines.

The opportunity of advanced understanding of the microbial genomes, the ability to modify these with high accuracy, the laboratory selection tools, and the characterization methods (e.g. sequencing) have been tremendously improved over the past 10-20 years. This also led to a much better in-depth understanding of the genomic characteristics that must be considered when performing risk assessments. NGTs allow precise, targeted, modifications of the genomes, improving our ability to precisely modify cell metabolism toward the efficient and controlled production of beneficial end products. Other non-NGT approaches make these modifications impossible, or extremely laborious, expensive, and often cost-prohibitive to the point where an opportunity is abandoned or never explored if we had no access to NGTs.

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. Common features of many industrial biotech solutions are the ability to decrease raw material use and waste production, improve human, animal and plant health, replace increasingly scarcer resources, substitute hazardous chemicals, e.g.: For instance, the production of proteins from yeast and the use of yeast as ferments for the production of food rich in new plant based protein, could reduce land use and animal meat consumption, with obvious positive impacts on global warming. The contained fermentation for flavour and fragrances can reduce the energy cost and the environmental impacts of extraction industries; the production of amino acids, vitamins and protein extracts for feeds, along with live microbiomes, can improve the efficiency and health of animals, reduce the use of resources and the environmental impact.

For this to be the case, there needs to be a political acceptance of the fact that industrial biotechnology provides benefits that are crucial to society in general such as for the environment, human, animal and plant health, consumers, animal welfare, as well as social and economic benefits. That commitment needs to be implemented explicitly in policies such as the Green Deal and Farm to Fork. It must result in a legislation that secures consumers’ and environmental safety, while allowing innovative products of industrial biotechnology to reach the market in a timely and proportionate way. Innovation in industrial biotechnology relies on the use of up-to-date technologies and tools. Such tools provide specific, essential benefits.

There are opportunities for SMEs/small scale operators to access markets with their NGTs/NGT-products. Certain technologies developed in the last 10 years are less

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complex or costly to implement than older gene technology tools. This makes them in principle more accessible to SMEs.
Regarding patenting, as for other technologies where patent is possible, we do not see any opposition at patenting them. Patent will protect companies who are innovative on EU territory. Therefore, as for other technologies we do see benefits in patenting or using patented NGT.

Potential challenges and concerns on NGTs/NGT-products

COFALEC members do not think that NGTs/NGT-products raise challenges/concerns for our sector. NGTs are an essential part of industrial biotech's toolbox. Some of the end-products from NGTs (derived or otherwise) are nature identical both in terms of safety in use and none have led to or raised safety concerns and or challenges.
When it comes to society in general such as for the environment, human, animal and plant health, consumers, animal welfare, as well as social and economic challenges, we think that innovation in industrial biotechnology must be able to take place under a legislation that addresses possible safety and societal concerns posed by the products/organisms. Provided that this is done, the technology itself is not an issue. There is no reason for NGTs (compared to random mutagenesis) to raise specific concerns. The challenges or concerns would be connected to the genetic changes made to an organism, and these are not technology specific. On the other hand, we believe that arbitrarily giving a name ("NGTs") to a set of technologies that merely have in common the time period when they were developed, creates irrelevant concerns in the mind of many people. Products should be assessed on their safety as and when placed on the market, not on the technique used to create them, to create a clear and trustworthy system.
SMEs/small scale operators to access markets with their NGTs/NGT-products will face challenges, depending on which type of regulatory burden they will face. In case of GMO it is nearly impossible to obtain authorizations for release.
The patent landscape for certain technologies (e.g. CRISPR) is complex to navigate, as it is for other technologies, and it is our responsibility to check how and if we can get access to them for our R&D work.

Safety of NGTs/NGT-products

The degree of understanding of the microbial genomes, the ability to modify them with accuracy, the laboratory selection tools, and the characterization methods (e.g. using bio-informative tools such as sequencing) have been tremendously improved over the past 10-20 years. This also led to a much better in-depth understanding of the genomic characteristics that have to be taken into account when performing risk assessments. Therefore, compared to 20 years ago we have the means to develop and improve microorganisms that are even safer. The safety of a product depends on and should be assessed based on what has been modified, not as a function of when the technique used was invented (i.e. before or after 2001). Most of the end-products from NGTS are nature identical and in terms of safety in use.
The safety of a microorganism depends on the safety of its parental strain, and on the safety of the genetic changes that have been performed on it. It has nothing to do with

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the technologies used for making these changes or the time when a technique was invented.

Ethical aspects of NGTs/NGT-products

The ethical aspects of innovation in biotechnology should not be viewed in the light of the technologies used – but rather by looking at the product/organism and its intended uses. Therefore, COFALEC does not have specific views on the ethical aspects of the technologies in question. This is not any different with products sourced via other processes/technologies other than NGTs. The issue is making exception for a technology whilst there are other technologies leading to the same product and that no one raises an issue about. All NGT-products should be evaluated using a rationale scientific analysis of the risks and benefits.

A number of challenges are presently facing our planet and societies: global warming, scarcity of resources, pollution, etc. Considering all of these we would find it unethical that the European Union does not do its utmost to promote technologies and products that could help safely address some of these challenges. Industrial biotechnology (and therefore NGTs) is among such technologies, and it would just be ethical that the EU commits to using it by promoting adequate policies and legislation. EU is claiming to be the leader on scientific and innovative developments but appears to be somewhere lasting behind other peer institutions with which it currently holds bilateral scientific/other agreements.

Consumers' right for information/freedom of choice

On the labelling of NGT-products, a decision to label a consumer product should be based on criteria that are understandable and that make sense for the consumers. Basing a labelling decision on the technologies used to obtain the product is most of the time insufficient and/or confusing. Therefore, labelling of industrial biotechnology products, should it be considered, must be based on the products' characteristics, not on whether they have been developed with pre-2001 or post-2001 technologies. This particularly goes for organisms developed using NGTs (e.g. SDN-1), that cannot be distinguished from similar organisms developed using pre-2001 technology or obtained directly from nature. It would simply be misleading to consumers to label the former as GMOs and not to label the latter – since they are for all purposes identical.

Additional remarks

Industrial biotechnology is essential if the EU wants to fight resource scarcity and climate change and to play its role in meeting the United Nations Sustainable Development Goals (UN SDGs). The present GMO legislation, as well as the singling out of post-2001 technologies, is preventing this essential tool from being used effectively.

Industrial biotechnology needs an updated legislation, as Directive 2001/18 (as well as Directive 2009/41) is not fit for purpose anymore. As an industrial biotechnology organization, COFALEC has the following policy asks:

- We call for a future-proof science and risk-based and operational legislation that is predictable and proportionate, based on the characteristics of organisms rather than on the technologies used to develop them.

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- Similar organisms can be obtained through application of different technologies. By regulating these organisms in an identical way, the approach will be transparent, fair, and enforceable, whilst assuring safety".
- This future-proof science and risk-based approach will create confidence in the regulatory supervision/oversight system assuring safety for consumers and the environment.
- This approach will foster innovation and competitiveness in the European Union and facilitate alignment with other legislations globally.

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