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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

EuroCommerce Transparency Register ID: 84973761187-60

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

Retail/wholesale/distribution

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

See membership at eurocommerce.eu

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

New plant breeding techniques

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

EuroCommerce members do not conduct any research on, or is involved in the development of NGTs. However, retailers and wholesalers sell a broad range of food products, including GMO products where authorised in the EU. As such, as distributors our members could potentially sell products with ingredients produced via NGTs in their respective product portfolios, now or in the future.

In the light of this survey our responses refer to new plant breeding techniques (mutagenesis)

* **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

Yes. We represent the majority of retailers and wholesalers in Europe and therefore comprise a large variety of members. Some businesses explicitly do not sell any genetically modified food products. Others have dedicated non – GM own label. Most sell organics products which are explicitly non-GMO/NGT in origin.

* 2 bis. Have you encountered any challenges?
  - (●) Yes
  - ( ) No

* Please provide details

NGTs are already being used in certain raw material areas (bulk goods) in third countries. In trade and logistics with these bulk goods, the goods of many companies are mixed (commodity trade). For this reason, it is already no longer possible to trace which products in and from third countries have used genome editing processes.

* **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

This is a commercial decision. Our company members decide individually which products they offer to their consumers. While some have strategies which specifically state to only offer Non-GM (thus including NTGs) products, others could take a more general approach offering all products compliant with EU food Law.

* **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

Some members in line with the company strategy have developed dedicated non-GM supply chains for their own brand products, which have been expanded to cover non-NGT products the following the EUCJ ruling.

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

- (●) Yes
- ( ) No

* Please provide details

Other members indicated that although traceability and labelling requirements are clearly described, it is difficult to fulfill our obligation as per Article 17.1 of the General Food Law due to the lack of testing /analytical methodology. Members are working with suppliers to ensure compliance in this new situation.

* **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

Yes, as described in question 8 (see below), we fulfill regulatory requirements in full compliance with EU law:

Regulation No. 1169/2011 on the provision of food information to consumers provides that labelling must not mislead the purchaser as to the characteristics of the food and, in particular, as to its nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production.

Regulation (EC) No 1830/2003 on the traceability and labelling of genetically modified organisms (GMOs) and the traceability of food and feed products produced from GMOs. Audits take place at supplier level

According to the general food law (Regulation (EC) No 178/2002), it is a general principle of food law to provide a basis for consumers to make informed choices in relation to food they consume and to prevent any practices that may mislead the consumer. This obviously is the case for GMO-labelled food products (potentially also many other products such as plants, seeds, feed and other).

* What best practices can you share?

Regular practice of supplier audit

* 5 bis. What challenges have you encountered?

As described above the main responsibility lies further up the supply chain with farmers, importers, and food manufacturer. This compliance requirement has been included in the general quality assurance processes that retail and wholesale apply , including third party or private audits with their suppliers. However due to the lack of testing methodologies this would only be based on a paper trail (paper check) without being able to sample and analyse products.

* **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?

Regarding the European Authorities, we urgently need clarity on the testing methodology, further EFSA opinions on the safety of such techniques the and information on risk assessment such as in which countries, and commodities these techniques are applied.

Overall, we have been disappointed that this ruling has been passed without the proper impact assessment or tools for companies to ensure compliance.

Some debate is taking place at academia level but support or clarification from national entities is lacking.

* **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, the organics regulation provides for certification along the food supply chain. However, in the case of NGT techniques there is an additional difficulty in that these are applied in Non EU countries with different GMO regulatory regimes. Therefore, the focus would be on control bodies and approval of producers in third countries.

End to end transparency has been developed through block chain for some specific products.

All of the above require major investments in staff, IT and regarding supplier cooperation and approval including at the level of third countries. It is therefor necessary, before to require such heavy investments, to thoroughly research the safety of these NGT techniques.

* **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

NGT products are due to their nature difficult if not impossible to adequately trace and determine the origin, be it from a specific producer or if a similar gene-edited trait could be found in nature. This puts our members in a precarious position as we could become liable for selling products which we cannot verify or trace properly in origin in accordance with the 2018 ECJ ruling on GMOs (Case C-528/16).

Furthermore, labelling should improve and increase consumers' understanding of their choice of products and help them in their purchasing decisions and foster their confidence in the food purchases. Labelling must therefore be accurate, precise, and meaningful to consumers. For European consumers this also counts for GMOs. However, as many products, particularly wholesale products such as grain, enter the market from many different sources and are blended before being processed it is a complex procedure to verify the origin of such food products on supermarket shelves. This was already a challenge with traditional GMOs (techniques developed before 2001) and the issue has only increased in complexity with new techniques developed since then.

EuroCommerce considers it imperative that any regulatory regime:
- is absolutely clear and offers a legal certainty in which food business can operate with confidence
- is workable and enforceable and
- enhances consumer confidence and understanding.
- Should NGT food products be authorised for the European Market, then a practical solution needs to be found to enable traceability of these products along the whole food supply chain.

Regulatory fragmentation at global level is currently already undermining these key aspects.
Please also see the answer to question 5

* What best practices can you share?

Labelling is primarily the responsibility for manufacturers with retail verifying of the requirements are met

* 8 bis. What challenges have you encountered?

see earlier

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

- ○ Yes
- ◉ No
- ○ Not applicable

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

The maximum file size is 1 MB

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

Outside our remit

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

- ○ Yes
- ◉ No
- ○ Not applicable

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

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

- ○ Yes
- ○ No
- ◉ Not applicable

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

- ◉ Yes

- ○ No
- ○ Not applicable

* Please provide concrete examples/data

- Consumer research: Consumer understanding /perception/need
- Testing methodology
- Need of farmer/grower
- Use of NGT with regard to climate change

*** 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

See question 13

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 explain why not

We offer a wide range of food products in compliance with EU law

*** 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

NGTs can bring significant improvements in terms of sustainability, climate change and food security https://easac.eu/fileadmin/PDF_s/reports_statements/Genome_Editing/EASAC_Genome-Edited_Plants_Web.pdf

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

If safety (environmental & human) have been proven; if public opinion has evolved on these techniques and on science in general. If the necessary authorisation procedures are in place

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

- ○ Yes
- ◉ No

* Please explain why not

-

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

- ○ Yes
- ◉ No

* Please explain why not

As long as these methods are classified as GMO – no acceptance

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

- ○ Yes
- ◉ No

* Please explain why not

No, patents do not allow access for third parties (or too expensive)

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

The maximum file size is 1 MB

D - Information on potential challenges and concerns on NGTs/NGT-products

* **20. Could NGTs/NGT-products raise challenges/concerns for your sector/field of interest?**

- ◉ Yes
- ○ No

* Please describe and provide concrete examples/data

Yes. These challenges/concerns include products placed on the market, consumer choice and perception, competition with third countries, labelling of products and compliance/legal liability.
Firstly, NGTs offer a whole new range of products to European consumers. Although the EU is free to approve, restrict or ban certain technological treatments and uses, restricting NGTs will limit the products available to European consumers. However, there is an underlying lack of fairness and distortion of competition when EU products obtained through NGTs must be labelled as GMOs while those originating from outside the EU may go unnoticed and evade such requirements.
Second, this will put EU retailers and wholesalers in a legal uncertain situation but will also potentially be misleading to consumers. If NGTs will be widely used around the world it is likely that European consumers won't be able to avoid GMO-products if these stem from outside the EU.
Third, retailers are at risk of facing unfair compliance and liability requirements in relation to the selling of GMO products. It is broadly acknowledged by the scientific community including the Commission's Chief Scientific Advisors and the European network of GMO Laboratories (ENGL) that collecting the needed information on NGTs for all plant products would constitute an enormous task.
Adding to this is the fact that it is not currently possible to trace and detect an organism modified using NGTs such as Crisp-Cas9 techniques in compliance with existing EU law which requires the change to be uniquely traceable in the organism and to the original modifying entity (company, scientist etc). An NGT sold by a European retailer might then be labelled as an NGT/GMO product but in a legal court case a retailer would not be able to supply adequate proof of its origin. Adding to this complication is the fact that NGT changes to organisms can occur in nature making it impossible to determine whether a product is a 'GMO-product' or 'natural' in origin. It is therefore far beyond the capacities and capabilities nor within the reasonable scope for retailers to be able to exercise this level of control and verification. The burden of proof should therefore not lie with the intermediary who is purchasing goods in good faith but the producer.
In short, EuroCommerce adheres to the principle of responsibility at all stages of the food chain to be applied. Each stage should be liable for the traceability of its products and the accuracy of information on labels, in the limits of its activities, as required in the General Food law Regulation. Businesses should not be burdened with additional quantities of documentation from those stages in the food chain preceding their own supplier.

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

- (●) Yes
- ( ) No

* Please explain

see response - lack of testing methodology

* **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

No data available

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

Research has shown that consumers trust in business is low and that they are technology averse. Therefore, unless the information provided on NGT's is conclusive, objective and scientifically validated, it is unlikely that citizen's concerns would change. There is a role for EFSA and national food safety authorities. Public authorities, together with scientists, media and operators should continue to inform citizens about NTGs, its potential benefits, risks and impacts, so that consumers are not left without any knowledge; even if food safety and other assessments have proven such foods to be without risk. The difference between NTG' s and other GM products is one of the general areas which need to be clarified.

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

- ○ Yes
- ◉ No

* Please explain why not

Broader public opinion regarding technology/innovation and lack of trust in science

* **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

If there are extra requirements regarding authorization or certification in order to be able to market certain products this will create a market barrier for SMEs.

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

- ○ Yes
- ◉ No

* Please explain why not

Not applicable

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

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E - Safety of NGTs/NGT-products

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

EuroCommerce believes that any individual advance of technology must be properly tested for human health, food safety and environmental impact, but if a particular development passes these criteria, then it becomes an issue for the marketplace and for consumer choice.

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

- ○ Yes
- ◉ No

* Please explain why not

Not applicable

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

The maximum file size is 1 MB

F - Ethical aspects of NGTs/NGT-products

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

EuroCommerce believes that in the case of NTG's and other GMO products, ethical considerations play an important part with regard to consumer acceptance. It is therefore essential that besides scientific data, other legitimate factors, such as ethical considerations, are taken into account in the decision to allow NTG's in the EU.
EuroCommerce stresses the importance of a continued open, thorough and transparent discussion bringing together all actors, including civil society, in this debate. The Commerce sector itself however has no intention to participate in ethical debates.
Retailers and wholesalers are the interface between industry and consumers, therefore consumer acceptance is essential. In case of authorisation by the public authorities, retailers will retain the freedom to sell products from NGTs or not, in respect of the consumers' freedom of choice; any such product will be sold according to its acceptance by the consumer.

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

- ○ Yes
- ◉ No

* Please explain why not

The Commerce sector has no intention to participate in ethical debates.

Please upload any supporting documentation for this section here

The maximum file size is 1 MB

G - Consumers' right for information/freedom of choice

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

Labelling requirements currently in place for other GMO are not feasible due to the absence of analytical /testing methods.
Consumers have different preferences, and these should be respected in the simplest and clearest way possible. An internationally harmonised framework for the effective implementation NGT labelling would therefore be preferable.

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

H - Final question

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

- (●) Yes
- ( ) No

Please provide your comments here

There is a need for an honest, transparent, objective, science based and inclusive debate, while referring to, and providing evidence, of possible benefits of using these methods.

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

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Contact

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