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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

European Food and Feed Culture Association – EFFCA
Transparency Register - Identification number: 829186414110-38

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

Our members are active in the fields of deliberate release of live microorganisms used as food cultures in food, probiotics in food and food supplements, feed additives as probiotics and silage agents, agriculture as biocontrol and fertilizers, etc.

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

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

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 yes, we use NGTs. We do not see year 2001, which is the date of the directive, as a particular milestone from a scientific and technological point of view. We will use the term OGT (original genomic techniques) to refer to those techniques developed before 2001.

* **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

Every company has a quality system in place and, as part of that, needs to request information from its suppliers and to provide information to its customers, about the compliance of a product with all applicable legislation. GMO statements and GMO questionnaires are an integral part of these quality systems, for regulated products. However, both statements and GMO questionnaires may not (yet) contain specific wording on the use of genome editing.

* 2 bis. Have you encountered any challenges?

- ( ) Yes

- [x] No

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

- [x] Yes
- [ ] No
- [ ] Not applicable

* Please provide details

We have information that competitors outside the EU are using these technologies. With current EU-regulation, innovation is blocked and the EU-regulation gives a competitive disadvantage to EU companies. EU-Consumer will be deprived of the benefits of these products. Due to the nature of the technology it can be difficult, if not impossible, to determine if a microorganisms in a product was developed with NGT or OGT.

*** 4. Do you know of any initiatives in your sector to guard against unintentional use of NGT-products?**

- [x] Yes
- [ ] No
- [ ] Not applicable

* Please provide details

Currently, compliance is secured at the company level, but with non-harmonized regulations globally it is very difficult to completely guard against unintentional use. Due to the nature of the technology it can be difficult, if not impossible, to determine if a microorganisms in a product was developed with NGT or OGT. Please see also answer to question n. 3.

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

- [ ] Yes
- [x] 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

- [x] Yes
- [ ] No
- [ ] Not applicable

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

To the best of our knowledge, we comply with existing regulation, this includes raw materials, microorganism and products thereof.

* What best practices can you share?

not applicable

* 5 bis. What challenges have you encountered?

not applicable

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

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

* Please describe what type of support and what best practices you can share

Some members have useful dialogue with the national authorities.

* **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

The companies' traceability will depend fully on trust in information received from suppliers and through audits. See also answer to question n. 2. Especially if legislation is not harmonized globally and producers do not have to label in their country of origin, but only when exporting to EU.

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

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

* Please explain why not

Because our members currently have no NGT-organism authorized for deliberate release in the EU. Our products are in compliance with current EU Regulation.

* 8 bis. What challenges have you encountered?

not applicable

* **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 specify including subject, type of research, resources allocated, research location

Yes, in contained laboratories for research purposes

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

- (•) Yes
- ( ) No
- ( ) Not applicable

* Please specify

We assume and hear rumors that competitors outside the European Union are already using NGT with the intention of deliberate release. A recent review from Rothstein et al. 2020 (https://doi.org/10.1016/j.copbio.2019.12.015) demonstrates proof of concept of the use of NGT for lactic acid bacteria. Again, due to the nature of the technology it can be difficult, if not impossible, to determine if a microorganisms in a product was developed with NGT or OGT.

*** 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

European companies are postponing research or moving research outside the European Union. An innovation gap has formed between the European Union and other countries (e.g. the number of patents regarding NGT is much higher in US and China compared to the EU).

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

- (•) Yes
- ( ) No
- ( ) Not applicable

* Please provide concrete examples/data

NGT would enable many opportunities due to improved accuracy and speed. NGT-related techniques can be important enablers in meeting the EU Commission's policy goals and objectives to be outlined in the "EU Green Deal" and upcoming "Farm to Fork" strategy.

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

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

* Please provide concrete examples/data

NGT development and use for deliberate release is very strongly hindered by the restrictive EU-regulation and non-harmonized global legislation.

*** 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

The implementation of the research exemption for patents (WTO TRIPS agreement Article 30) in the EU is not clear and not harmonized. Clarification across EU is needed for R&D purposes.

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

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

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

Opportunities and benefits would be huge for the industry and the consumer (e.g. removal of undesired characteristics and enhancement of desirable characteristics) more difficult to find or remove undesirable . It will enable opportunities hard to achieve with classical methods and due to the precision of NGT´s it will have the benefit of improved accuracy and efficiency compared to classical methods.
For instance, microorganisms used in food and feed as cultures/probiotics 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 improved use of feed by animals, supporting less use of raw materials and less production of waste.
Microorganisms used in Agriculture: several agronomical properties such as increased nutrient uptake and resistance to heat or draught and protection against plant pests can be introduced into a single microorganism, which would in many cases be very challenging with “pre-2001” technology. The benefits are an improved use of nutrients and a more consistent yield of crops under challenging pest pressures and climate conditions, without additional or with reduced use of mineral fertilizers or chemical plant protection products.
These factors can support the upcoming Farm to Fork strategy.

* Are these benefits/opportunities specific to NGTs/NGT-products?
- (●) Yes
- ( ) No

* Please explain

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 have to be taken into account when performing risk assessments.

* **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

NGT will enable many opportunities with improved accuracy and efficiency. NGT-related techniques can be important enablers in meeting the EU commission policy goals and objectives outlined in the “EU Green Deal” and “Farm to Fork” strategy. See also answers to questions n. 13, 16 and 18.

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

not applicable

* Are these benefits/opportunities specific to NGTs/NGT-products?
- (●) Yes
- ( ) No

* Please explain

See also answers to questions n. 13, 16 and 18.

* **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

Use of NGT is not complex nor costly to implement. However under the current regulations of the EU, the administrative cost of bringing a product based on NGT to market will prevent SMEs from benefiting. Therefore operators simply abstain from creating products, requesting an authorization for, and from placing on the market, live microorganisms being under the scope of the Directive. The same obstacles apply for larger companies but these typically have the financial resources to be able to pass all regulatory hurdles.

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

Especially for NGT-products patenting is key, because any potential products could be easily reproduced following intentional release.

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 explain why not

To the best of our knowledge we see no new concerns regarding the new technologies compared to existing technologies.

* **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

- [x] No

* Please explain why not

To the best of our knowledge we see no new concerns regarding the new technologies compared to existing technologies. 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.

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

- [x] Yes
- [ ] No

* Please explain and provide concrete examples and data

Use of NGT is not complex nor costly to implement. However under the current regulations of the EU, the administrative cost of bringing a product based on NGT to market will prevent SMEs from benefiting. Therefore operators simply abstain from creating products, requesting an authorization for, and from placing on the market, live microorganisms being under the scope of the Directive. The same obstacles apply for larger companies but these typically have the financial resources to be able to pass all regulatory hurdles.

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

- [x] Yes
- [ ] No

* Please describe and provide concrete examples/data

The patent landscape for usage of certain NG-technologies is very complex to navigate, which deters certain companies from trying to get access to them for both R&D and commercial activities.

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

E - Safety of NGTs/NGT-products

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

To the best of our knowledge we see no new concerns regarding the new technologies compared to existing technologies. In contrary, two aspects cannot be emphasized enough in the discussion on the safety of products obtained with genome editing (a) the intrinsic higher precision and accuracy of state-of-the-art genome editing approaches to achieve a desired improvement as compared to the more traditional approaches of genetic engineering; and (b) the availability and ease of whole-genome DNA sequencing to confirm that the strain improvements have happened as planned and did not lead to unintentional side effects. The combination of both provides a sound basis for a scientific risk assessment, based on which meaningful conclusions can be drawn on the intrinsic safety of a particular product.

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

- ○ Yes
- ◉ No

* Please explain why not

We see no new concerns regarding the new technologies compared to existing technologies. In addition, existing regulations for food safety, laboratory safety and environmental safety already prevent the possible concerns for the sector.

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**

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. Based on the challenges facing mankind and the benefit NGTs could provide in creating solutions faster, it is unethical to not use them for political or ideological reasons.

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

- ◉ Yes
- ○ No

* Please explain

A number of challenges are presently facing our planet and societies: global warming, scarcity of resources, pollution, etc. Considering all of these, we find it unethical that the European Union does not do its utmost to promote technologies and products that address some of these challenges. Industrial biotechnology (and therefore NGTs) is among such technologies, and we find it unethical if the EU hesitates to take actions to promote adequate policies and legislation.
Examples from the Member States include the following example from Denmark: (Danish ref. “etisk råd”. https://www.etiskraad.dk/etiske-temaer/natur-klima-og-foedevarer/publikationer/gmo-og-etik-i-en-ny-tid-2019

Please upload any supporting documentation for this section here

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G - Consumers' right for information/freedom of choice

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

A decision to label a consumer product should be based on criteria that are understandable and make sense for the consumers. Basing a labeling decision on the technologies used to obtain the product is most of the time wrong, as it does not comply with such criteria. Labeling 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 (OGT) or post-2001 (NGT) technologies.

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

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H - Final question

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

- (●) Yes
- ( ) No

Please provide your comments here

Yes, Industrial biotechnology is essential if the EU wants to fight resource scarcity and climate change, and play its role in meeting the UN SDGs. The present GMO legislation, as well as the singling out of post-2001 technologies (NGTs), is preventing this essential tool from being used effectively.
Industrial biotechnology is in need of an updated legislation, as Directive 2001/18 is not fit for purpose anymore. As an industrial biotechnology organization, we have the following policy asks:

- 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.
- 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.
- This future-proof, science- and risk-based approach will instill confidence in the regulatory supervision /oversight system assuring safety for consumers and the environment.
- This approach will foster innovation and competitiveness in Europe and facilitate alignment with other legislations globally, as well as provide solutions for urgent current issues ranging from pollution to food supply.

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

The maximum file size is 1 MB

Contact

SANTE-NGT-STUDY@ec.europa.eu