Contribution ID: 95fa9c78-db96-4e29-8ede-da43f7eb7b62
Date: 15/05/2020 13:29:29

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

Federation of Veterinarians of Europe (FVE) Transparancy Register Number: 3959733732-78

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

Animal health, Animal Welfare, Public Health (zoonotic diseases, food safety)
Food producing animals, Companion animals, Lab Animals, One Health, Veterinary ethics

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

Filled in by FVE (in consultation with its members)

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

not applicable

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

* **1. Are your members developing, using, or planning to use NGTs/NGT-products?**
  - ○ Yes
  - ◉ No
  - ○ Not applicable

* Please explain why not

Our member Organisations are national professional associations and regulatory bodies; they don't develop, use or plan to use these techniques. Individual members of the FVE Member Organisations may use new techniques in their work.

* **2. Have your members taken or planned to take measures to protect themselves from unintentional use of NGT-products?**
  - ○ Yes
  - ○ No
  - ◉ Not applicable

* **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

NGT/NGT-products are currently used in veterinary prcatice.
Please see https://termis.org/veterinary-regenerative-medicine

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

- (●) No
- ( ) Not applicable

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

- (●) Yes
- ( ) No

* Please provide details

We are not aware of any particular challenges especially as regards the use of NGTs/NGT-products in treatment of non-producing animals.

NGTs/NGT-products are also promising in research area as they may have a positive impact on 3Rs, e. g. by refining the breeding and genotyping, thus reducing the number of laboratory animals used for research purposes used.

However, when it comes to food-producing animals concerns may be related to high costs, impact on public health as well as public acceptance and ethical dilemmas.
Veterinary sector, however, may have another dimension of concern related to the feed of animals. This has not been looked into so far.
Finally, veterinary ethics and deontology is an important aspect for further consideration by our profession.

* **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

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

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

* **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

Specialised veterinary labs can use specific techniques to identify changes in the genomic material of the organism.

*

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

see underneath

* 8 bis. What challenges have you encountered?

At the moment no measures are taken. However this might change. Main challenges that we consider that could be encountered have to do with feed and food, namely:

- The use of NGT-products in food-producing animals, either for feeding them or for treatment, and the impact on the products derived from them.
- The use of NGT-products for feeding animals in general.
- Issues related to veterinary ethics.

* **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

Not as far as we know. Our members are not research institutes. It can however be that a member organisation is a partner in a broader research consortium that is involved in this field.

* **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

* Please explain why not

we are not aware of it

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

- (●) Yes
- No
- Not applicable

* Please provide concrete examples/data

NGT-related research would certainly provide opportunities and open up possibilities for treatment options or prevention of disease, e.g. We can think of animals that have a more robust immune system or are protected against specific diseases, but also in a wide range of clinical pathology (see also https://termis.org/veterinary-regenerative-medicine).
NGT-related research many also greatly contribute to better implementation of 3Rs in research and the need for using less laboratory animals.
On the other side, the techniques could impact on the welfare of animals.

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

- (●) Yes
- No
- Not applicable

* Please provide concrete examples/data

NGT related research can face challenges, specifically in relation to societal acceptance, ethics and deontology as well as impact on human health and the ecosystem.

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

- 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

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

NGTs could contribute to the development of certain medicinal products and vaccines, new treatment options to manage and/or prevent from certain diseases or conditions. The area is very new for our sector.

Another opportunity could be in the field of animal breeding , however these might be outweighed by negative impact on animal welfare and consumer concerns.

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

- ( ) Yes
- (●) No

* Please explain why not

Depends on the outcome not on the specific techniques

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

For example medical treatments / medicinal products.
For animal health and welfare, one has to consider what the technique really does for the animal itself rather than for the interest of the owner and producer.

Looking at it from a One Health perspective, one has to consider the impact on the health of people, animals and the ecosystems. A potential advantage should be assessed by looking at all different elements.

On the social and economic side benefits will probably be limited to those who can use the techniques and products, but at the same time have a negative effect on those who cannot.

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

see above

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

- ( ) Yes
- (●) No

* Please explain why not

see above

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

There will be opportunities, but unlikely that FVE memebers will be involved.

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

See answer to question 17: Looking at it from a One Health perspective, one has to consider the impact on the health of people, animals and the ecosystems. A potential advantage should be assessed by looking at all different elements.

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

- ( ) Yes
- (●) No

* Please explain why not

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* **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

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

Problems could occur when evaluators consider an isolated benefit, without taking into consideration other effects that could disturb existing balances. Please check elements provided in previous in answering previous questions.

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

- ( ) Yes
- (●) No

* Please explain why not

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* **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

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

not sure, not really involved

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**

Safety can be an issue. Safety needs to be assessed on the base of independent high quality risk assessments.

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

- (●) Yes
- ( ) No

* Please explain

Disturbance of existing One Health balances in people, animals and/or ecosystems.

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**

As with any invasive technic, deontology should be in place and enforced. FVE recommends that ethical aspects are well considered and guidelines/rules on ethical development, products and use of NGTs/NGT-products in animals and humans are established as soon as possible.

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

- (●) Yes
- ( ) No

* Please explain

In the ethical discussion around using NGT in animals one should carefully consider what it means for the animals itself. Will the animal have a “better life”? Additionally, if that refers to a food producing animal the impact on both animal and human health should be considered.

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**

For transparency reasons consumers should have easy access to all relevant information about the origin /background of the product

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

In general we should approach NGTs/NGT-products via the following considerations:

- The importance and impact on animal health and welfare;
- The importance and impact on public health and ecosystems;
- Ethics and professional responsibility;
- The contribution to 3Rs in clinical trials;
- The pre- and post-authorisation regulatory procedures for such products/techniques for veterinary use to ensure safety of animals, humans and the environment.

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

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