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Member State 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

endorsed in the Joint Working Group of GMO competent authorities on new genomic techniques on 15 January 2020

Introduction

With this questionnaire the Commission is collecting contributions from Member States competent authorities to respond to the Council's request[1] for "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). The scope of the study goes beyond new mutagenesis techniques, as there are other new techniques, for which the Council seeks clarification. Therefore, the study covers all new genomic techniques, which have been developed after 2001.

For the purpose of the study, the following definition for new genomic techniques (NGTs) is used: techniques, which are capable to alter 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-organims and derived food and feed products obtained by NGTs for agri-food, medicinal and industrial applications and for research. GMO competent authorities are invited to seek input from other competent authorities when appropriate.

The questionnaire is meant to provide information primarily, but not exclusively, at national level. 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 a specific NGT, please indicate this in the reply. With regard to agri-food applications, replies may include considerations on specific sectors, such as the organic sector.

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

Instructions

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 30 April 2020 (closure of business) to submit the questionnaire via EUsurvey.

QUESTIONNAIRE

* Which Member State are you representing?

Slovak Republic

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

* **1. Have you been consulted by companies/organisations/research institutes for regulatory advice or another issue on products developed or to be developed by NGTs ?**

- (●) Yes
- ( ) No

* Please provide details on the request

Questions from research institutes concerned the scope of regulation. The Slovak Environmental Inspectorate instructed that "the Act on the Use of Genetic Technologies and Genetically Modified Organisms (Act No. 151/2002 as amended)" applies to all techniques that can be used to "alter the genetic material of an organism".
Following the ruling of the Court of Justice (EC) of the EU in the Case C-528/16, the State Veterinary and Food Institute cooperated with the ENGL in creating the document "Detection of food and feed plant products obtained by new mutagenesis techniques", focused on current and anticipated food and feed detection methods, and therefore is ready to respond questions from companies or organisations.

* **2. Have you taken specific measures (other than inspection) related to the application of the GMO legislation to NGT-products?**

- ( ) Yes
- (●) No

* Please explain why not

We have not recorded any cases of NGT-products recently. GMO legislation is automatically applied to NGT-products.

Among the measures, conformity in labeling must be followed – based on the national (Decree (MPRV SR) No. 245/2015 Coll.) end EU legislation (Regulations (EC) No 1829/2003 and No 1830/2003), as well as other legislation related to GMO.

* 2 bis. Have you encountered any challenges or limitations, including administrative burden or costs?

- ( ) Yes
- (●) No

* Please explain why not

We have not recorded any cases of NGT-products recently. GMO legislation is automatically applied to NGT-products.

* **3. Have you adapted your inspection practices to cover all NGT-products and to ensure the enforcement of traceability requirements?**

- ( ) Yes
- (●) No

* Please explain why not

The Slovak Environmental Inspectorate has not adjusted its activities to cover all NGT-products and ensure the traceability due to the limited number of inspectors. These limitations can be overcome by increasing the number of inspectors.

State Veterinary and Food Institute and the national reference laboratories use reference methods validated by the European Reference Laboratory for Genetically Modified Food and Feed (EURL GMFF) for GMO analysis. No NGT product is authorized in the EU at this time. Therefore, the EURL has not yet provided the NRL with any method for their detection that could be used in the analysis of samples taken during official control. If this happens, we will implement and use methods to detect NGT products in our national reference laboratories.

Site-directed mutagenesis is not easily distinguishable by laboratory techniques from a common mutation. The issue of identification of "GMOs" prepared by the so-called new gene techniques has not yet been addressed at the EU-RL level.

* 3 bis. Have you encountered challenges or limitations, including administrative burden or costs?

- (●) Yes
- ( ) No

* Please describe

The Slovak Environmental Inspectorate has not adjusted its activities to cover all NGT-products and ensure the traceability due to the limited number of inspectors.
In the case of a PCR method (the reference methods used so far), the costs of its implementation will be bearable, but if it was another type of method requiring new instrumentation (eg NGS), the cost of laboratory equipment, staff training and analysis would increase significantly.
We currently do not have the premises and equipment, as well as enough staff for such analyzes.

* How could these challenges or limitations be overcome?

These limitations can be overcome by increasing the number of inspectors.
For laboratories, more staff members and higher expenses.

* **4. Do you have experience or information on traceability strategies, which could be used for tracing NGT-products?**

- ( ) Yes
- (●) No

* 4 bis. Have you encountered any challenges or limitations, including administrative burden or costs?

- (●) Yes
- ( ) No

* Please describe

Detection methods have not been clearly defined.
The Slovak Environmental Inspectorate has not adjusted its activities to cover all NGT-products and ensure

the traceability due to the limited number of inspectors.
In the case of a PCR method (the reference methods used so far), the costs of its implementation will be bearable, but if it was another type of method requiring new instrumentation (eg NGS), the cost of laboratory equipment, staff training and analysis would increase significantly.
We currently do not have the premises and equipment, as well as enough staff for such analyzes.

* How could these challenges or limitations be overcome?

There should be clearly defined detection methods.
These limitations can be overcome by increasing the number of inspectors.
For laboratories, more staff members and higher expenses.

* **5. What other experience can you share on the application of the GMO legislation, including experimental releases (such as field trials and clinical trials), concerning NGT-products in the:**

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

Agri-food sector

We have no other experience on the application of the GMO legislation in this sector.

* **6. Have plant varieties obtained by NGTs been registered in national catalogues?**

- ( ) Yes
- (•) No

* **7. Do you require specific information in national catalogue when registering plant varieties obtained by NGTs?**

- (•) Yes
- ( ) No

* Please specify

When registering a new variety, the breeder / applicant shall declare in the application form whether it is a GMO variety. Depending on his statement, seeds / plants would be treated as GMRs if one of the listed NGTs was used.

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 and innovation

* **8. Have you supported with national funding programmes NGT-related research projects/programs (ongoing or finalised in the last 5 years), including on identification or traceability?**

- ○ Yes
- ◉ No

* 8 bis. Please highlight the potential challenges encountered when supporting/funding NGT-related research and any consequences from these challenges.

National funding programmes (APVV) and national academic funding programmes (VEGA) support research projects in general, these programmes do not distinguish the projects depending on the technique used.
There is insufficient interest in funding such a research topic at national level.
Projects are not aimed at the development of the given techniques (Crispr-Cas9) only at the applications of already developed techniques for our research purposes and therefore no applications for their funding are submitted.

* **9. How do you see NGT-related research evolving?**

NGT-related research has a huge potential not only in the treatment of various huma diseases at the genetic level, but also in agriculture and in the industrial sector. NGT can bring a lot of new knowledge into aethiogenesis of many human diseases. NGT can be, and will be used for development of many novel and instrumental preclinical human disease models. Namely methods crispr/cas, TALEN (effector nuclease similar to transcriptional activator), zinc finger nuclease, meganuclease, prime-editing. All of these methods allow the nucleic acid to be changed. Many NGT need to be improved, tested, or monitored for possible impact on life. Among all these revolutionary developments, bioethical concerns need serious attention.

* **10. Have you identified any NGT-related research needs from private or public entities?**

- ◉ Yes
- ○ No

* Please specify which needs and how they could be addressed

Research in the terms of gathering information on existing NGT products in the agri-food sector that could potentially appear on the EU market, could facilitate the EURL GMFF prepare methods for detection of NGT.

* **11. Could NGT-related research bring opportunities/benefits to science, to society and to the agri-food, medicinal or industrial sector?**

- ◉ Yes
- ○ No

* Please provide concrete examples/data

The NGT-related research could be useful in animal and plant breeding, in enhancing disease resistance in crops, in the field of preclinical models for many so far untreatable human diseases, and in different other areas.

* **12. Could NGT-related research bring challenges/concerns to science, to society and to the agri-food, medicinal or industrial sector?**

- ◉ Yes
- ○ No

* Please provide concrete examples/data

use in humans, tene therapy, ethical issues, effect on animal and human health, side effects, environmental risks

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 public dialogues and national surveys

* **13. Have you or other institutions/bodies/entities organised national dialogues concerning NGTs?**

- ○ Yes
- ◉ No

* **14. Have you or other institutions/bodies/entities organised national surveys, which assessed public opinion on NGTs?**

- ○ Yes
- ◉ No

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 ethical aspects

* **15. Have any national bodies or expert groups discussed or issued opinion on the ethical aspects of NGTs?**

- ○ Yes
- ◉ No

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 - Information on opportunities and benefits from the use of NGTs and NGT-products

* **16. Could the use of NGTs and NGT-products bring opportunities/benefits to the agri-food, medicinal or industrial sector?**

- (●) Yes
- ( ) No

* Please provide concrete examples/data

Recent experiments showed that NGTs have potential to be useful to wipe out genetic diseases, improve drought resistance, pest and disease resistance, boost nutrient efficiency, prolong shelf life, produce healthier animals used for food, in many microbial engineering applications, including bacterial strain typing, immunization of cultures, autoimmunity or self-targeted cell killing, in the engineering or control of metabolic pathways for improved biochemical synthesis, in treatment of diseases like AIDS, Alzheimer disease, cardiovascular disease, cancer. Plus the same answer as in question 11.

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

- (●) Yes
- ( ) No

* Please provide concrete examples/data

Recent experiments showed that NGTs have potential to be useful to wipe out genetic diseases, improve drought resistance, pest and disease resistance, boost nutrient efficiency, prolong shelf life, produce healthier animals used for food, in many microbial engineering applications, including bacterial strain typing, immunization of cultures, autoimmunity or self-targeted cell killing, in the engineering or control of metabolic pathways for improved biochemical synthesis, in treatment of diseases like AIDS, Alzheimer disease, cardiovascular disease, cancer. Plus the same answer as in question 11.

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

Long term should show more about the effects/benefits/opportunities of NBTs.

* **18. Do you see particular opportunities for SMEs on the market access to NGTs?**

- ( ) Yes
- (●) No

* Please explain why not

Probably not in the current atmosphere in the EU regarding GMOs and NGT products. Also, it can be more complicated for SMEs due to experts and financing need.

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

Patenting NGTs and NGT- products may encourage further research and development in this field.

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 - Information on potential challenges and concerns of NGT products

* **20. Could the use of NGTs and NGT-products raise challenges/concerns for the agri-food, medicinal or industrial sector?**

- (●) Yes
- ( ) No

* Please provide concrete examples/data

We do not know all the possible adverse effects.

* **21. Could the use of NGTs and NGT-products raise challenges/concerns society in general, such as for the environment, human, animal and plant health, consumers, animal welfare, as well as social and economic challenges, in the short, medium and long term?**

- (●) Yes
- ( ) No

* Please provide concrete examples/data

NGTs and NGT products are excellent implements for improving of life. NGTs and NGT product, that were assessed they should not represent a risk for human, environment, social and economic field. In the treatment of people NGT are subject to clinical trials and therefore challenges/concerns may arise in long term.

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

Long term should show more about the effects/challenges/concerns of NBTs.

* **22. Do you see particular challenges for SMEs on market access to NGTs?**

- (●) Yes
- ( ) No

* Please explain under which conditions

Mostly in the short term.

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

- (●) Yes
- ( ) No

Please describe and provide concrete examples/data

*

New ethical issues may occur. It is highly likely that the list of inventions that are excluded from patentability as their commercial exploitation would be contrary to public or morality (see Article 6 of Directive 98/44/EC OF the European Parliament and the Council of 6 July 1998 on the legal protection of biotechnological inventions) will have to be revised.

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

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G - Final question

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

- ○ Yes
- ◉ No

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Contact

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