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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?

Latvia

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

Ministry of Agriculture has been consulted by the State Scientific Institute “Institute of Food Safety, Animal Health and Environment “BIOR” (BIOR), University of Latvia and GMO Scientific Committee on issues in respect of new genomic technologies.

* **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

As so far, we do not see necessity to take any specific measures including amendments in national legislation. There are too many uncertainties in respect of legal aspects and consequences resulting from the Court of Justice’s judgment.

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

- ( ) Yes
- (●) No

* Please explain why not

As we haven't taken any specific measures it is hard now to marke any possible challenges.

* **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

There is no clarity in this filed, no detection methods, no traceability opportunities, we think common approach is needed to exclude burden for common EU market.

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

- ( ) Yes

- [x] No

* Please explain why not

As we haven't taken any specific measures it is hard now to marke any possible challenges.

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

- [ ] Yes
- [x] No

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

- [x] Yes
- [ ] No

* Please describe

As so far there is no clear detection and control methodology it is not possible to ensure traceability of NGT-products.

* How could these challenges or limitations be overcome?

Centralized approach is needed to exclude impact on free circulation of goods.

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

Agri-food sector

The competent authority of Latvia has not received any application in respect of GMO experimental release concerning NGT-product.

Industrial sector

The competent authority of Latvia has not received any application in respect of GMO experimental release concerning NGT-product.

Medicinal sector

The competent authority of Latvia has not received any application in respect of GMO experimental release concerning NGT-product.

* **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 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

* Please provide an overview of the project/program including title of project, a brief summary with scope and objectives, the amount of national funding received and possibly specify if the receiving entity is public or private

In 2020 BIOR has started national project “Detection of food, feed and food additives obtained by NBTs and scientific risk assessment of such products”. The main objectives of the project are evaluating of diagnostic methods and potential risks of food, feed and additives obtained with help of NGTs, exposure assessment using the new scientific analytical methods (such as digital PCR, sequencing methods (Sanger sequencing, new generation sequencing methods – Illumina, MinION etc.)), development of risk management guidelines. This is two-year project, funded by MoA (40400EUR in 2020 + 71100EUR in 2021).

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

The potential challenges encountered:

- scientific capacity affected by limited experience and knowledge in respected field,
- limited resources affecting the duration and scope of the project,
- public awareness and perception of NBTs, ethical aspects.

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

In general, our position is positive, and we think the NGT-related research is challenging but perspective and an area with high growth potential.

* **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

Yes, but mostly from medical industry. We have also received questions from agriculture sector and control institutions in respect of detection and control of such products.
In the frame of the National project mentioned in point 8 it was identified the necessity to develop the risk management guidelines for competent authorities and methods for detection of NGT-products.

* **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

Mostly we see the benefits in the use of NGTs in:
- medicine (the treatments of genetical diseases),
- gene therapy (the first gene therapy clinical trials using NGTs in Europe have started in 2019. These technologies are likely to provide major benefits for early adaptors and not only in medicinal sector. It is also clear that other regions and countries are willing to engage into use of NGTs),
- agri-food chain (development of new plants with improved nutritional benefits. The NGT-related research could give good possibilities for the agricultural sector to combat plant pests like Drosophila suzukii.
- NGTs can also benefit to development of animals with changed genome (for examples GM mosquitos).

* **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

- The main concerns relate to possible NGTs impact on environment and nontarget organisms which can be caused by new plants and their uncontrolled spread.
- There is also limited knowledge and information on NGTs, and society needs to be educated in respect of benefits and risks connected with NGTs. Proper information activities have to be organised for the society otherwise people will be against these technologies.
- Challenges for the science could be related with fast need to develop precise detection methods for NGT-products or NGT-plants available on the market. However, it has to be clear that case-by-case approach should be adapted since majority of NGTs applications are unlikely to result in any unique risks. New agricultural varieties should be separated from potentially much more complex targeted impact on wild animal (pest) populations. Otherwise extremely restrictive policies will be created.
- Meantime, all other major economies will engage into NGT development and increase advantage over the EU in long term.
- In the medicinal sector society in general easily accepts applications of new technologies for diseases to be cured. This sector specific acceptance illustrates that better understand of benefits (not only risks) of technologies is really required, looking both at individual and society levels. For instance, some of early gene therapy trials had severe side effects, but that did not result into restrictive policies or bans. Now the EU is region with seven gene therapies registered and available to citizens.

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

* Please describe briefly the content, methodology and conclusions

In March 12th, 2020 BIOR organized workshop “GMO in food, feed and plant propagating material – current events, risk assessment” for different stakeholders: farmers, animal feed producers, experts from control laboratories and state institutions, as well as scientists in order to explain the main differences between the traditional GMO and new-NGT products.
The main topics discussed: GMO risk assessment, control, legislation, “classic” GMO and organisms obtained with help of NGTs, possible risks and benefits of NGTs.
During the workshop the participants were asked to fulfil the questionnaire in Latvian (basically the “Questionnaire on new genomic techniques to contribute to the study requested by the Council” was used). Only 10 % of participants had willingness to answer to the questions. The reason for this low response rate could be explained by the fact that NGTs are too new technologies yet and participants had low level of knowledge on current issue.

There has also been regional cooperation on NBTs in the frame of two workshops:
1-Nordic/Baltic project workshop on "Ecological and socio-economic impacts of gene drive organisms" hold in Tallin, Estonia, 24 – 25 October 2019. The main aim of the workshop was to facilitate the dialogue and knowledge-exchange between the GMO-authorities in the Nordic and Baltic countries, to learn more about the scientific developments of gene drive organisms, and to provide productive discussions on crucial issues of environmental risk assessment management, socio-economic considerations and regulatory frameworks of gene drive organisms. This in turn can provide valuable input from the Nordic and Baltic countries into the current processes on gene drive organisms regionally and internationally.
2-The Nordic/Baltic GMO meeting “We cannot detect it – what is the way forward? – The ECJ decision on mutagenesis and its implications for GMO control” was held in Roskilde, Denmark, 30. September -2 October, 2019.The colleagues from the competent authorities responsible for GMO (food, feed and seed) discussed the challenges and implementation measures after the ECJ ruling on the interpretation of the Directive 2001/18/EC on deliberate release and new mutagenesis techniques.

*** 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

The agri-food sector: to combat particular plant pests like, Drosophila suzukii. Another good example could be wheat varieties with reduced amount of gluten. With the help of NGTs it is possible to obtain the products with improved nutrition, the plants with more targeted modifications, the plants with resistance to diseases and pests.
Medicinal sector: organ transplantation, treatment of genetic diseases, infectious diseases control, drug manufacturing.

* **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

In the short terms we see benefits in respect of human and animal health.
Long term opportunities can be linked with various possible new products in agri-food sector. For example, eradication of invasive plant pests like Drosophila suzukii, control of diseases and pests, production of wheat varieties with reduced amount of gluten, development of plant varieties with drought tolerance, potato varieties resistant to late blight Phytophthora infestans etc. In long term the use of NGTs could address the challenges of environment pollution and also can be linked with solutions for the treatments of genetical diseases in medicinal sector.

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

The EU needs fast solutions in this field including appropriate legislative approach to fulfil needs of science and industry to allow NGT-products to be placed no the market. At this moment taking into account ECJ judgment we do not see the perspectives for these products.

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

- (•) Yes
- ( ) No

* Please explain under which conditions

Now it is difficult to evaluate the possibilities for the SMEs to access to NGTs. But it is undoubtedly that there is the necessity to increase the access to resources and information. From our point of view if GMO legislation should be applied in respect of NGT-products it is too expensive and long process to be capable for SMEs.

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

- (•) Yes
- ( ) No

* Please describe and provide concrete examples/data

Now it is difficult to evaluate possible benefits/opportunities in patenting or accessing patented NGTs or NGT-products. Although access to information on new techniques and new product development would be welcome.

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

Risks associated with every new technology, new procedures, new control and supervision methods.

*** 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

Consumers awareness and perception of NGTs and products. Possible risks to human and animal health and environment. Economic impact on the EU market, competitiveness with the third countries without so strict legislative approach.

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

In case the general public is not informed and educated properly. In case if legislative approach is too strict and restrictive, in case if issuance of a permit for NGT-products is too expensive, time consuming and involves a high administrative burden.

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

- (●) Yes
- ( ) No

* Please explain under which conditions

Access to resources, relatively high costs in case of commercialization.

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

Access to resources, costs, disputes on key patents.

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

Please provide your comments here

Basic problem on this issue is limited knowledge and information on NGT and NGT products. Public perception and acceptance also will be a challenging issue.

In addition the overlowed approach in respect of EU legislation in case of NGT products will prevent the development of science in this field and willingness of the new scientists to perform the investigations in EU.

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

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