Contribution ID: 7680d858-e8fd-4f4e-9064-75c2663d1750
Date: 27/04/2020 08:58:33

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?

Lithuania

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

The Government of the Republic of Lithuania held a meeting on “New Genome Editing Methods” (Minutes No. LV-257 on the 27th of September, 2019) on the 19th of September, 2019, where a researcher from the Institute of Biotechnology of Vilnius University briefly presented the issues of legal regulation of new genome editing methods, concept of genetically modified organisms (GMOs) and gave an over view about the benefits of this technology.
Representatives of all participating ministries (The Ministry of Environment of the Republic of Lithuania, The Ministry of Agriculture of the Republic of Lithuania, The Ministry of Health of the Republic of Lithuania, The Ministry of Education, Science and Sport, The Ministry of Justice of the Republic of Lithuania, The Ministry of Foreign Affairs of the Republic of Lithuania) unanimously agreed that Directive 2001/18/EC of the European Parliament and of the Council on the 12th of March, 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC is technically outdated and no longer reflects current scientific discoveries and technologies, including of new genome editing methods. Representatives of the ministries agreed on the need to revise and amend Directive 2001/18 / EC in order to address the issue of the legal regulation of the new genome editing methods.

* **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

There was no need.

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

- ( ) Yes
- (●) No

* Please explain why not

The Lithuanian GMO legislation is also applicable to the NGT-products, therefore there was no need to apply any specific measures.

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

- ( ) Yes

- [x] No

* Please explain why not

The Lithuanians inspection and control authorities (The State Plant Service under the Ministry of Agriculture, State Food and Veterinary Service) carry out control and monitoring of genetically modified products; carry out import controls that can consist of both a document check and a physical check on the batch to be imported; carry out control according to annually updated list of risk countries and risk species, but this list covers only transgenic GMOs (there is no inspection plan specifically for NGTs). The basis for this check is a risk based approach in which the country of origin, type of product and crop are taken into account. If necessary, when legislation or recent events require so, accents can be placed on specific products and/or specific countries.

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

- [x] Yes
- [ ] No

* Please describe

1. In the meantime, Lithuania does not carry out control and surveillance of organisms obtained by NGTs because the comprehensive data on the species to which these methods were applied and the nature of alterations made to the genome are lacking. Another issue – it is essential to have harmonised EU strategy for detection and identification of the organisms obtained by NGTs.
2. Experts on detection and identification from the National Reference GMO laboratory of Lithuania (National Food and Veterinary Risk Assessment Institute) are following the JRC activities. We note the challenges (methodology and costs) of distinguishing products of the new methods from products of natural or “traditional” mutagenesis.

* How could these challenges or limitations be overcome?

It is essential to have harmonised EU strategy for detection and identification of the organisms obtained by NGTs.

* **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?

- [ ] Yes
- [x] No

* Please explain why not

The Lithuanian inspection and control authorities (The State Plant Service under the Ministry of Agriculture, State Food and Veterinary Service) do not have any information on the aspirations and (or) opportunities of the Republic of Lithuania and (or) foreign companies to produce the food products developed by NGTs or

place them, as well as veterinary medicines, feed, animals, etc. on the market. Therefore, the SFVS has not accumulated the data on the NGT traceability. The NGT-products should be properly labelled so that they can be traced at all stages of their production.

* **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

No such experience.

Industrial sector

No such experience.

Medicinal sector

No such experience.

* **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

According to the rules set by the State Plant Service under the Ministry of Agriculture, the plant breeders applying for entry of a plant variety in the National List of Plant Varieties must provide information on the genetic modification of the plant variety. So far, no such applications were submitted.

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.

No NGT-related research projects have been supported at Lithuania. The main challenge would be application of potential products developed as current approval system of NGT products is extremely resource and time-demanding.
Due to date there are 16 registered institutions for contained use in Lithuania (Directive 2009/41/EC) who did not use NGT in their research projects in the last 5 years. So, any of this institution did not submit any potential challenges encountered when supporting/funding NGT-related research and any consequences from these challenges.

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

Opinion of the Lithuanian scientists (Lithuanian Research Centre for Agriculture and Forestry, LLC CasZyme, Institute for Horticulture): NGT and more specifically gene editing research are evolving very rapidly. It is used by more and more research scientists. It could be illustrated by number of papers published in this year, which increases by more than 30 % each year (https://www.ncbi.nlm.nih.gov/pubmed /). NGTs are especially attractive as tools for gene/mutation functional validation. NGT-related research is vital in study of diseases, resistance to pathogens, rare disease research. CRISPR will be very common tool in laboratories in several years; many research institutions are developing this technique and other genome-editing systems so they will continue to improve. NGT will eventually replace older genome editing techniques, such as Agrobacterium mediated techniques or gene gun.
Agency for Science, Innovation and Technology* considers NGT-related research and discovery of new NGTs as an inevitable process. NGTs themselves should not be considered as a source of risk. On the contrary, NGTs can simplify and speed up the process of genome modification. However, the possible consequences of altering the genetic material of an organism are still unknown and pose many questions. It' s the reason why regulation of this process should adapt to the technical and scientific progress in a timely and proportionate fashion and to ensure flexibility and allow evolution of certain measures.
* Agency for Science, Innovation and Technology (MITA) is the main governmental institution, responsible for implementation of innovation policy in Lithuania.

*** 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

Opinion of the Members of Lithuanian Biotechnology Association:
1) LLC CasZyme: Generation of custom industrial strains of microbes, developing of new CRISPR based gene editing tools.
2) Lithuanian Research Centre for Agriculture and Forestry: NGT offers novel possibilities to speed-up plant and animal breeding process by making it more directed, or precise. There is a high demand for novel plant varieties/animal breeds in agri-food sector.

* **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

Opinion of the Lithuanian scientists (Lithuanian Research Centre for Agriculture and Forestry, LLC CasZyme, Institute for Horticulture) and Agency for Science, Innovation and Technology:
1) NGT (more specifically gene editing) brings a lot of new opportunities for science which latter are translated to benefits to society and medical, agri-food sectors. For example, the benefits in medicine could be illustrated by clinical trials to cope with genetic diseases (such as β-thalassemia) or successful applications of CAR-T cell therapies; NGT-related research enables to create resistant to diseases and pests cultivars in agriculture, to improve nutritional value of conventional crops.
2) Novel genotypes developed through NGT applications might be a viable source of highly-demanded biodiversity to tackle climate adaptation as well as mitigation challenges in agri-food and bioenergy, or more broadly bioeconomy sector.
3) The application of NGT aims at developing new qualities/characteristics of certain organism/product (resistance to various diseases (viral, fungal, bacterial), resistance to herbicides, better adjustment to weather conditions (heat, cold, salinity, etc.), higher soil productivity (weight, number, size), higher nutritional value). It would not be possible to achieve these results by means of traditional mutagenesis. The research and discovery of NGT can simplify, speed up or improve various processes.

* **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

Yes, but there is currently a lack of scientific information, reasoned evidence that NGT-products are useful in various industries, agriculture and whether a risk assessment has been carried out for the population and animal health, taking into account a short-term and long-term consumption of such products.
Beyond the purely scientific aspect, the question of how to balance potential benefits against the potential negative consequences must consider the acceptability of the risks involved. NGT-related research (and more importantly – the application of NGTs) raises a lot of controversial discussions and deep ambiguities regarding the risks and implications of research on genome editing. There is no consensus on this point among researchers, society and industry, therefore this issue always brings a lot of legal and ethical challenges when it comes to genetically modified agricultural products.
Opinion of the Members of Lithuanian Biotechnology Association:
1) Lithuanian Research Centre for Agriculture and Forestry: NGT is a high precision technique and no challenges/concerns are specifically related to this technique.
2) According to a 2019 study ‘Analysis of New Plant Breeding Techniques’ by LLC CasZyme (page 20): “Introducing new traits to plant breeds may pose some environmental risks. It can result in plants with improved fitness through resistance to disease or herbicides and better adaptation to the environment as well as increased production of valuable compounds. It is important to note that these traits can be introduced even without the use of new plant breeding techniques (NPBT) but through other methods such as transgenesis and conventional plant breeding techniques as well. The only difference is that using NPBT is a much more rapid and precise process of modification compared to traditional methods. Therefore, the risks are not associated with the method used but rather with the specifics of introduced modification and the

resulting new characteristics. As such, the risks must be assessed on a case-by-case basis. Modifications such as increased resistance to salinity, drought or soil contamination may help some plants to adapt and spread to new areas. However, these same modifications can increase plant productivity as well as reduce the production costs and the amount of land required for farming.

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

A public discussion was organized by the Lithuanian Academy of Sciences in collaboration with several research institutions on the 25th of April, 2019. The outcome of this event was a signed petition to support the movement of European research organizations for the revision of GMO Directive to exclude NGTs from it.

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

- (●) Yes
- ( ) No

* Please describe briefly the content, methodology and conclusions

In 2019 The Ministry of Agriculture of the Republic of Lithuania has commissioned to the Kaunas University of Technology to conduct the study “Prospects for the Use of Organisms Obtained by New Mutagenesis Techniques in Lithuanian Agriculture”. One of the main tasks of this study was to compare the opinion of Lithuanian consumers, farmers and producers on conventional GMO and NGT organisms. The survey of consumers (251 respondents), farmers (50 respondents) and food producers (56 respondents) concluded that:
1. All the groups of respondents identified that they are more familiar with GMOs than with NGTs. Overall self-rated higher awareness of GMOs compared with NGTs was statistically significant in all groups of respondents. Statistically significant differences about the awareness of GMOs stand out in the separate groups of respondents: food producers know the most about GMOs, farmers know the least. The awareness of NGTs is relatively low and about the same (no statistically significant differences detected) in all groups of respondents.
2. The GMO food is regarded more negatively than neutral in all groups of respondents. The food produced with raw material obtained from NGTs was regarded more positively than food produced with raw material obtained from GMOs in all groups of respondents. The level of favourability of the attitude towards NGTs and GMOs was about the same in all groups of respondents (no statistically significant differences detected).
3. Even though final products were identical, to all groups of respondents it would be important to know

which methods (traditional selection or new mutagenesis techniques) were used to obtain the organism.
4. Statistically significant overall higher probability to use in the future NGTs than GMOs was detected. Tendency to use in the future GMOs was less prevailed among producers than farmers and consumers. The same tendencies were observed when it comes to NGTs - statistically significant intentions differ among consumers, farmers and producers.
5. The most important factors for consumers when choosing food are food properties, perceived benefits for health and price attractiveness. Less important factors – sale promotions, public opinion and easy food preparation.
In the overall conclusion of the study it is stated that less negative consumer attitude towards NGTs than towards GMOs and the scientific research in this field, shows potential opportunities for the application of directional mutagenesis as well as other NGTs in the plant breeding sector. It is advisable to evaluate the NGT plant varieties on case by case basis, considering a product-based approach. Therefore, current EU legislative framework should be reviewed.
The final report is available here:
http://zum.lrv.lt/uploads/zum/documents/files/LT_versija/Veiklos_sritys/Maisto_sauga_ir_kokybe/GMO/NMM%20gaut%C5%B3%20organizm%C5%B3%20panaudojimo%20Lietuvos%20%C5%BEem%C4%97s%20%C5%ABkyje%20perspektyvos.pdf

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

Opinion of the LLC CasZyme (Member of Lithuanian Biotechnology Association): Use of NGTs provides a lot of opportunities/benefits for all sectors. In medicine, the medications against the incurable genetic diseases started to be developed. In addition, specific modifications provide a lot of opportunities for cell therapies.
The Lithuanian competent authorities:
1) There is a lack of evidence based data to support our opinion that NGM-products are useful in various industries, agriculture and whether a risk assessment has been carried out for the population and animal health, taking into account a short-term and long-term consumption of such products.
2) NGTs follow the same breeding principles which were used at the dawn of agriculture but with higher precision. Unlike the traditional breeding, recent breakthroughs in plant research allow breeders to know exactly where the change will occur and to better predict the effects of the changes. Development of new plant varieties and animal breeds were always aimed to improve public welfare and reduce the environmental impact of agriculture. New plant varieties obtained by NGTs could help reaching these goals. Without these technologies Lithuanian agriculture will lose extraordinary opportunity not only to adapt to the changing climate conditions and combat new plant diseases, but also to meet ambitious public health and environmental objectives.

* **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

Opinion of the LLC CasZyme (Member of Lithuanian Biotechnology Association): Yes, it could bring opportunities and benefits for all groups. Because of climate change and growing populations humanity needs new agriculture approaches, which could help increase yields by conserving spear resources (land, water …).
The Lithuanian competent authorities: See answer to the question 16.

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

Because of climate change and growing populations humanity needs new agriculture approaches, which could help increase yields by conserving spear resources (land, water …).

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

- (●) Yes
- ( ) No

* Please explain under which conditions

Yes and no. It will depend if the NGT will be excluded from the GMO Directive as SMEs can‘t afford resource and time-demanding approval of developed products according to GMO Directive. If NGTs will be subject to the same risk assessment and authorisation requirements as conventional GMOs, these technologies would only be available to the large companies.

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

- (●) Yes

No

* Please describe and provide concrete examples/data

The Lithuanian competent authority (The State Patent Bureau of the Republic of Lithuania*): Regarding the benefits of patenting, providing possibilities to protect certain technologies by patents contributes to fostering innovations in that area. Also, patenting an invention requires to disclose it in such full and clear terms as to enable any person skilled in the art to which it pertains to use the invention (Art. 16(2) of the Patent Law), therefore the public obtains free access to the information on the methods of manufacture and/or operation and properties of the patented invention in national and international databases.
Opinion of the LLC CasZyme (Member of Lithuanian Biotechnology Association): The NGT (or more specific Gene editing field) is expanding very rapidly. Better and more specific tools are developed, therefore patenting of Gene editing tools/technologies helps to secure the intellectual property.
*Footnote. The State Patent Bureau of the Republic of Lithuania (SPB) grants patents according to the Patent Law of the Republic of Lithuania. Article 5 of this law sets out an exhaustive list of grounds, on which patents cannot be granted. Inventions of any technical areas, that are not included in this list, are considered to be patentable, including inventions related to genetically modified organisms (GMOs). Patent Law does not include any special provisions concerning NGTs, therefore such inventions would be evaluated for their patentability on general grounds. Such legal regulation is in compliance with international law and laws of other countries. Also, in this context, we note that decisions not to grant patents may not be taken on mere grounds that utilisation of such inventions is prohibited by other laws (Art. 5(1)(3) of the Patent Law).

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 explain why not

Opinion of the LLC CasZyme (Member of Lithuanian Biotechnology Association): All the scientific evidence suggests that with proper guidance and controls NGT are as safe as or even safer than currently used methods (for example traditional breading techniques in the Agriculture). In addition, each year safer and more effective NGTs are created.
The Lithuanian competent authorities: See answer to the question 16.

* **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

Opinion of the LLC CasZyme (Member of Lithuanian Biotechnology Association): In short term extensive use of NGTs could provide some challenges for traditional sectors, but in middle and long term all should benefit from advantages created by NGTs.
The Lithuanian competent authorities: Do not know. There is a lack of evidence based data to support our opinion.

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

Do not know. There is a lack of evidence based data to support our opinion.

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

- (●) Yes
- ( ) No

* Please explain under which conditions

SMEs can‘t afford resource and time-demanding approval of developed products according to GMO Directive. If NGTs will be subject to the same risk assessment and authorisation requirements as conventional GMOs, these technologies would only be available to the large companies.

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

The Ministry of Agriculture of the Republic of Lithuania is cautious about patenting NGT products. In this context, it is important that NGT product developers* do not create additional barriers for farmers who choose to grow NGT plant varieties.
*Footnote. The owner of a patented invention may prevent other persons from manufacturing, using, offering for sale, selling, importing and exporting the said invention without his permission for the term, which is limited to 20 years, depending of the payment of renewal fees.

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

G - Final question

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

- (●) Yes
- ( ) No

Please provide your comments here

Lithuanian scientists' (LLC CasZyme) 2019 study related to NGTs “Analysis of New Plant Breeding Techniques” is published on the Ministry of Environment of the Republic of Lithuania GMO website: http://gmo.am.lt/page?page=view&format=frontend&id=4b5bc12d-6b7b-4a77-8c18-851f36f8405f.

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