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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?

Romania

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

Some of Romanian institutions has received different position papers from national and European professional organizations (industry and farmer groups) with regards to the EU debate on NGTs, one dated 9th of May 2019 – Regulating innovation in plant breeding; and other on 23rd of April, 2019 (also shared with the Permanent Representative of Romania to the European Union) regarding the legal proposal on innovative technologies in plant breeding.
Romania, through some of the institutions involved in the field of GMOs, participated at 3 different scientific outreach events on NGT, carry out between 2017-2019, and organized by US Embassy in Bucharest, the Agricultural University of Iasi, the Romanian Academy of Agricultural Sciences with the support of the national agri-food associations.

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

- (●) Yes
- ( ) No

* Please describe the measures and, if possible, their effectiveness

On January 2019, the competent authority in the field of GMOs informed the involved authorities regarding the use of the Eugenius Web application (www.euginius.eu) that contains compiled information on developments in genetic engineering at European and global level, including data on new breeding techniques (NBTs) that may prove to be relevant to Europe in the inspection and control activity. The application was presented in the meeting "Joint Working Group on the implementation of the ruling of the European Court of Justice Ruling (case C528 / 16)" and represents a database developed within a cooperation between Germany and the Netherlands together with partners from Poland, Austria and Italy.
Also on January 2019, the competent authority in the field of GMOs informed the involved parties on the fact that organisms obtained through the new breeding techniques (NBTs) are considered genetically modified organisms, according to the Decision of the Court of Justice of the European Union dated July 25, 2018, and are the object of the obligations regulated through the Directive 2001/18/EC regarding the deliberate release into the environment of the genetically modified organisms. In the same time, it was requested that when these institutions carry out research activities with genetically modified (micro) organisms using the new breeding techniques, they will have to notify the National Environmental Protection Agency and establish the measures that are required so that these activities comply with the provisions of the national and European Union legislation specific to the GMOs/MMG domain.

* What best practices can you share?

Please see the information written above.

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

- ○ Yes
- ◉ No

* Please explain why not

We look forward to receiving more information and guidance from the Commission on this matter and, in a subsequent phase, we are going to assess the costs of all required measures (other than inspection) related to the application of the GMO legislation to NGT-products. For the moment, we provide our staff in the central and field administration with updated info.

* **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

For the moment, we don’t have information regarding the inspection practices to cover all the NGT products because there is a different path in development of GMOs, which needs to be further studied, but we are interested and keen to participate and adapt our knowledge to cover the NGT-products.

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

- ○ Yes
- ◉ No

* Please explain why not

Romania has not adapted the inspection practices to cover all the NGT products because there is a different path in development of GMOs.

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

- ◉ Yes
- ○ No

* Please describe the traceability strategy, including details on the required financial, human resources and technical expertise required

Romania has an extensive experience in the application of the GMO legislation since 2005, including specific traceability requirements. If NGT products as food and feed are treated within the scope of the GMO legislation then the laboratory capacity is developed, the competent authority for GMOs in food and feed can adapt the control procedures based on the experience gained already and using its existing resources.

* What best practices can you share?

-

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

- (●) Yes
- ( ) No

* Please describe

Of course, there will be a need to personnel training and the adoption of new detecting methods.

* How could these challenges or limitations be overcome?

Trainings, including in detection methods, of the personal involved and financial resources for the analytical capacity.

* **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

In Romania, one notification has been registered under the Directive 2009/41/EC on the contained use of Listeria monocytogenes, in order to obtain a genetically modified strain of Listeria monocytogenes and to establish the mechanism of response to high pressure stress. This activity with GMOs, which was authorized in 2018, uses the classical mutagenesis and CRISPR - Cas 9 (NT) technique, but the purpose of the microorganism obtained by the new techniques in this project is not to be used in field tests or to obtain genetically modified plants.

* **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

Romania has one project related to NGT-product, financed by The Executive Agency for Higher Education, Research, Development and Innovation Funding through the National Plan for Research-Development and Innovation for the 2015 - 2020 period (PNCDI III) - Program 3: International and European Cooperation - Subprogramme 3.2 - Horizon 2020. The project title is Development of a novel industrial process for safe, sustainable and higher quality foods, using biotechnology and cybernetic approach.
The main goal of the project is to turn food products (ready-to-eat products based on meat, fish and vegetables) safer and more durable, by reducing or inhibit the ability of Listeria monocytogenes (LM) to recover from high pressure processing (HPP). This can extend the shelf-life of food, increasing its resistance to food-related bacteria (making the food “non-hospitable” for this type of bacteria) and decrease the amount of food waste from processing and throughout the food chain. The objectives of the project were:to analyze the way in which the mechanism of recovery of L. monocytogenes cells operates after the stress represented by high pressure, to identify the responsible genes in the process of restoring the cell wall, to identify the food additives and the optimal pressurization regime (cycles, duration and intensity) that will be applied to food to prevent Listeria monocytogenes from surviving.
Total Funding Requested: 711.000,00 lei (158.000,00 euro)
The beneficiary is "Dunarea de Jos" University of Galati, a public entity.

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

Romanian farmers are increasingly confronted with climatic challenges, like the extreme draught from the 2019/2020 winter. Being among those growers that firsthand used biotechnology in soybean and maize production in the past, they constantly voice their hopes that research and innovation in various fields, especially in agronomic, breeding, digital will be reflected on the research agenda of the EU.

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

Romania consider that NGT is a research important matter. Funding for research in this field are provided by the Ministry of Education and Research, based only by peer-review, call for proposals. There is no direct allocation or subsidize for any research topic. Furthermore, the Intellectual Property of research results belongs to the organizations (consortium) that implement the respective project. Additionally, it is compulsory to have approvals from the Ethics Commission, where applies.

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

- ( ) Yes
- (●) No

* **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

In Romania, NGT related research could bring opportunities and benefits in the agri-food sector through the development of new varieties obtained by NGTs than can manage biotic and abiotic stress, increases nutritional value. NBTs can be an opportunity for organic farming (there is even a stronger demand for crop varieties resistant to pests, diseases and abiotic stresses in organic farming). Also, the requirements triggered by the new European Green Deal will probably seek response in solutions provided by precision breeding.
Various examples were presented at different scientific events/conferences in Bucharest: TALEN used to create wheat varieties to prevent pre-harvest sprouting (Poland), blight-resistant rice, gluten-free wheat, virus-resistant cucumber, soybean with reduced trans-fats, etc.
Also, NGT may bring specific opportunities as long as it is scientifically proven that there are no side effects on human health.

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

Yes
No

* Please explain why not

We consider that NGTs have risks like any technology and can be used incorrectly, therefore should be thoroughly studied and assessed case by case. If proven safe, the technology has a high potential, by turning off genes for susceptibility to disease or inserting into modern varieties resistance genes from related wild varieties.

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 Romania, conferences and roundtables have been organized by industry organizations promoting technology in agriculture witch we mention above:
On 31st of May 2017 we participated at the Symposium “Innovative alternatives in plant improvement - the foundation of sustainable and efficient agriculture” organized by the Romanian Academy together with the Academy of Agricultural and Forestry Sciences, the Romanian Seed Industry Alliance and Agrobiotechrom.

Topics such as: "New plant breeding techniques: innovations for a sustainable and responsible growth" and "How will genome edited plants be regulated?" were discussed.

On 25th of September 2018, the Romania specialists with responsibility in the field of GMOs together with the NBTs Techniques Platform from Brussels,participated at a workshop on the risk assessment of the new plant breeding techniques.

The purpose of this event was to provide the decision makers and stakeholders, scientific information about the new breeding techniques and the benefits that these techniques can have to the agricultural sector and for society have been presented and also an overview of the legal, political and social implications of NBTs use in modern agriculture, was revealed.

On 26th of September 2018, we participated at the conference "Innovations in plant breeding - a new path to modern agriculture" organized by the United States Embassy and the Academy of Agricultural and Forestry Sciences, in collaboration with AgroBiotechRom, the Alliance of the Romanian Seed Industry and the Producers Association of Corn from Romania.

On 24th of September 2019, we participated in a round table on the topic of “Innovations in plant improvement - recent evolutions and future paths”, an event organized by the United States Embassy in Romania.

The competent authorities and institutes with responsibilities in the field of GMOs which participated at these reunions were : University Of Agronomic Sciences And Veterinary Medicine Of Bucharest, Romanian Biosafety Commission, National Environmental Guard, The Biology Institute Bucharest, Ministry Of Agriculture And Rural Development, National Agricultural Research and Development Institute – Fundulea, The National Sanitary Veterinary and Food Safety Authority and National Environmental Protection Agency.

* **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

Nowadays, there are medicines containing isolated compounds derived from NGT-products (e.g. isolated and purified phospholipids from Glycine max (L). Merr.) but, the future opportunities and benefits, are mainly related with ATMPs (advanced therapy medicinal products) development through new methods of genetic engineering.

* **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

-

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

Romania applied EU legislative framework. Based on the EU Green Deal, the significant reduction in the use of chemical pesticides will put greater pressure on the need and accessibility to innovation in plant breeding to meet the challenges of climate change and food security.

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

- (●) Yes
- ( ) No

* Please explain under which conditions

In general, surveys show that around 80% of the companies would invest in product development with NGTs if they would not be regulated as GMOs.

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

Despite the fact that, for the moment, Romania has not pursued this path, patenting has its benefits related to the fact that the substantial costs incurred by research programs and by meeting the legal requirements of bringing an innovative, regulated product to the market should be recovered, otherwise developers lack incentive to invest.

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

Please see the answer at point 12.

* **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

-

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

Romania through the competent authorities considers that depends on the approach. If NGT products will be approached in the same manner as GMOs, we can expect that same concerns to be raised. Those concerns can be addressed maybe by proper communication campaigns, increased trust in policy makers and regulators, increased value and depth of risk assessment.

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

- (●) Yes
- ( ) No

* Please explain under which conditions

Yes, as they perceive the current GM legislation extremely burdensome, a true disincentive to invest in such projects. It is also a matter of societal pressure in case NGT-derived products fall within the scope of the GM legislation.

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

Please see the answer at point 19.

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

The approach on NGT should take into account the principles of EU functioning - freedom of choice, free movement of goods and science-based decisions in reasonable timelines.

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

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