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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?

Portugal

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 Portuguese Environment Agency (APA), competent authority for Directive 2001/18/EC and Directive 2009/41/EC and the General Diretorate for Food and Veterinary (DGAV), competent authority for Regulation 1829/2003, have been consulted by some companies/organisations/research institutes who were interested in getting information and/or providing their reasoning regarding new genomic techniques (NGTs).

* **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

APA complies with the European legislative framework regarding GMOs within the scope of its respective competences, namely as the competent authority for Directive 2001/18/EC and Directive 2009/41/EC. The same situation with DGAV regarding the regulation 1829/2003, but we didn´t take any specific measures related to the application of the GMO legislation to NGT-products. We remain aware of the EU/COM progresses in this matter and will be looking forward to future developments under the NGTs.

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

- (●) Yes
- ( ) No

* Please describe

No control analytical methods can be used to support official controls

* How could these challenges or limitations be overcome?

Robust control methods, including analytical ones, that can be used in official controls and that can be defended in possible litigation cases are needed

* **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

Clear guidance's from the EC regarding the possible methods for control that can be used by competent authorities and that can be used in court cases

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

- ○ Yes
- ◉ No

* Please explain why not

There are no validated guides or control methods that can be used

*** 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

in the control systems that we normally apply there is the possibility of, in addition to document control, if analytical control can be carried out, either in the final product or in the raw material used.

* How could these challenges or limitations be overcome?

Clear guidance's from the EC regarding the possible methods for control that can be used by competent authorities and that can be used in court cases

*** 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:**

- ☑ **Agri-food sector?**
- ☑ **Industrial sector?**
- ☑ **Medicinal sector?**

Agri-food sector

APA is the national competent authority responsible for authorisation of deliberate releases of GMOs into the environment for experimental purposes (field trials and clinical trials) under Directive 2001/18/EC.
Up to the present time, we haven't received any notification for deliberate release of GMOs obtain by NGTs under Part B of Directive 2001/18/EC, either for field trials or clinical trials.
It should be noted that the last GMO notification submitted to APA for field trial dates from 2010 and the last notification for clinical trial dates from 2016.

Industrial sector

APA is the national competent authority responsible for authorisation of deliberate releases of GMOs into the environment for experimental purposes (field trials and clinical trials) under Directive 2001/18/EC.
Up to the present time, we haven't received any notification for deliberate release of GMOs obtain by NGTs under Part B of Directive 2001/18/EC, either for field trials or clinical trials.
It should be noted that the last GMO notification submitted to APA for field trial dates from 2010 and the last notification for clinical trial dates from 2016.

Medicinal sector

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Up to the present time, we haven't received any notification for deliberate release of GMOs obtain by NGTs under Part B of Directive 2001/18/EC, either for field trials or clinical trials.
It should be noted that the last GMO notification submitted to APA for field trial dates from 2010 and the last notification for clinical trial dates from 2016.

* **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

The breeder has to indicate the breeding method 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

* 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

The only known project, financed by the Foundation for Science and Technology, with the receiving entity being the Institute of Chemical and Biological Technology of the Universidade Nova de Lisboa is the following:
Title: How do Phytocrome Interacting Factors mediate the cross-talk between light and temperature signaling in rice?
Brief summary and objectives:
Rice is a very important crop worldwide and its production is highly challenged by cold and heat, namely in Portugal and Brazil, respectively. Given that rice yield must grow 1.0?1.2% annually to feed the still-growing world population and keep prices affordable, it is urgent to develop rice cultivars with higher yield and more resistant to abiotic stresses. To achieve this goal, we need to better understand the molecular mechanisms by which rice plants regulate their growth and development to cope with adverse conditions. In Arabidopsis, phytochrome interacting factors (PIFs) play an essential role mediating responses to light and temperature, but in rice this regulation is poorly understood. Thus, the main goal of this proposal is to investigate which and how PIF-Likes mediate the temperature response in rice. We will use CRISPR/cas9 technology to produce rice mutants for the functional characterization, which will include physiological and transcriptomic studies (mutants RNA-seq).
Referencia FCT: PTDC/BIA-FBT/31070/2017 Total budget: 239.965,17€

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

The only challenge in funding this project was the assessment of the quality of the research and their outcomes

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

A clarification concerning the classification of the NGTs within legislation, and whether some or all of them should be considered GMOs and therefore comply with the EU legislation on GMOs will allow the research industry to be able to adjust and develop its activities accordingly.
Although NGTs are a broad group of technologies, research is mainly focused on the application of techniques that involve the use of CRISPR-Cas. In this context, there are two important avenues of investigation: 1 - the optimization of the CRISPR-CAS tool, especially in the context of increasing its precision and the absence of production of of-targets; and 2 - the application of CRISPR-CAS to improve plant characteristics, especially in the sense of silencing genes that confer greater sensitivity to biotic factors and genes that control the differentiation and growth processes in plants.

*** 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

NGTs are powerful tools for modulating characteristics associated with crop response to environmental factors. In the context of the countries most affected by climate change, the use of techniques that accelerate the development of varieties adaptable to new edapho-climatic conditions and more resilient to new pests or diseases is essential to reduce production losses due to the impacts of these changes. The reduction of 3 to 5 years in breeding programs, allowed by the use of NGT, may be the difference to guarantee the sustainability of agricultural production in these countries, where Portugal fits.

The development of breeding programs where these technologies would be introduced at an early stage would be the appropriate way to reduce the time needed to obtain varieties adjusted to the needs

* **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

Science: The functionality of the genes annotated in the genomes of different organisms is often verified using their mutation silencing. Although several techniques have been used over the last decades to perform knockouts, CRISPR-CAS allows them to be performed more accurately and more quickly, allowing to accelerate the process of identifying the functions of genes in different species, in particular those that constitute agricultural crops.
Society: the use of these technologies significantly increases the precision with which the genome is manipulated, whether the purpose is the silencing of a gene or the introduction of a change in a specific position in the genome that gives a desirable characteristic. This substantial increase in accuracy allows society to be more relaxed about the possible side effects of an introduced genetic modification.
Agri-food: The precision and relatively low cost of technology increases the prospect of developing tailor-made varieties that suit the needs of the agri-food industry, both from the point of view of nutritional qualities and from the point of view of qualities organoleptic, technological and nutraceutical.

* **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

Research using these technologies aims to understand how the genome works and what is the functionality of the different genomic components that exist in different organisms. This understanding is essential to understand the living phenomenon and, in cases where humanity needs them, to shape cultures in order to produce according to needs, in a context of sustainability.

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

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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

On different occasions, seminars were held for different audiences - students, farmers, reporters, professors - to explain these technologies and their potential. The methodology used was always that of seminars with an opening for in-depth discussion of the questions raised by the audiences. As a general rule, conclusions form the sense of the need for wider audiences to interact with credible scientists who are able to communicate in an intelligible way. In these contexts, the public tends to understand the characteristics and scope of the technologies, significantly increasing their confidence in the technologies to be applied. A final conclusion is that a higher level of communication between researchers and society in general is needed. This aim is difficult to achieve due to the high degree of exposure and the conflict generated by the widespread controversy surrounding the use of these technologies to improve crops

* **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 describe briefly the content, methodology and conclusions

The National Council of Ethics for Life Sciences introduced this theme in its annual Seminar in 2018. Although two lectures were presented which were briefly discussed by the public present, no conclusion or opinion on these technologies was issued by the Council.

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 benefits will be the reduction in the time and costs to obtain the desired product, the increase in the precision of obtaining the product and the reduction of risks associated with undesired side effects of the manipulation of the genome

*** 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

There are plenty examples in scientific literature were the use of NGT to mutate specific genes in crops reduces the virulence of different plant pathogens. In general these modifications constitute point mutations, not different from the ones that may appear spontaneously in the environment. The use of varieties with these characteristics in the fields will reduce the use of pesticides, increasing the sustainability of the system, reducing the exposition of farmers to pesticides and reducing the impacts on the ecosystems.

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

There is no need for more specific conditions than those accepted for registration of new varieties obtained by conventional breeding methods.

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

- (●) Yes
- ( ) No

* Please explain under which conditions

SMEs have been unable to use genomic modification in their breeding programs because there are time consuming and expensive and also because it is difficult to comply with European regulations on GMOs given the high associated costs and the controversy existing in the EU vis-à-vis GMOs. The NGT are less expensive than the older technologies and reduce the time to obtain the desired plant variety.

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

- ( ) Yes
- (●) No

* Please explain why not

Yes for patenting NGTs. The development of more accurate technologies depend on the investment that asks for its return. And this assumption does not depend on the public or private source of funding. In general, however, governments tend not to finance technology development.

No for patenting the products if they are crop varieties. These should be following the breeder's rights established.

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

The precision attained with the NGT lead to the obtaining of products where there would be no unwanted modifications nor unwanted alogenic genomic sequences, is very high. If the introduction of the new characteristic is somehow adverse the traditional agronomic evaluations together with the bioinformatics and new omics techniques will most probably detect it very early in the evaluation process.

* **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 explain why not

On one side the precision involved will guaranty that the desired modification is introduced. Together with the modern evaluation methodologies will give reasonable degree of confidence in detecting eventual hazards. On the other hand the characteristics to be modulated will increase the sustainability of the production processes as well as the final quality of the products.
The fact is that the widespread and well-understood use of these technologies will make us understand how inaccurate and how high the risks are, compare to the ones using the new NGT, when using traditional breeding technology.

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

- ◉ Yes
- ○ No

* Please explain under which conditions

If all NGTs will be considered as GMO SMEs may have difficulties investing in this area, both due to the high costs necessary to comply with all legal requirements and also due to the position of consumers in general with regard to GMOs

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

- ○ Yes
- ◉ No

* Please explain why not

The granting of patents and also the plant breeders rights have a clear legislation to all intervenients.

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

There should be a clarification concerning the classification of the NGTs within the legislation framework, and whether some or all of the NGTs should be considered GMOs and therefore comply with the EU legislation on GMOs – Directive 2001/18/EC and Directive 2009/41/EC.
This clarification should be included in the legislation –preferably by amending the annexes of Directive 2001/18/EC, or by implementing decision or reflected in a common guidance. In the case of amendment of the annexes to the Directive, we consider that it would be enough to exempt the NBTs that are consider non-GMO, including new mutagenesis techniques, from Annex I-A, Part 2, and to include the NBTs considered GMO in Annex I-A, Part 1.
This clarification will allow an effective regulation of products obtained by new techniques of genetic modification that are considered GMO, enabling an harmonized implementation of the legal framework at the Member States (MS) level.
We therefore welcome and consider urgent to have this clarification regarding NBT in order to be able to accommodate the developments foreseen in this area, namely in agri-food and medicinal or industrial sector, including production, research, development, innovation, etc.
We are also of the opinion that the work done so far by the European institutions, can already be a good basis for further development and decision making, namely:
o EFSA – elaboration of guidance on the risk assessment of products obtained by specific NBTs and an overview on the topic NBTs/new mutagenesis techniques;
o EURL-EURL (European Union Reference Laboratory for GMO - European Union Reference Laboratory) update of the report “Detection of food and feed plant products obtained by new mutagenesis techniques”, considering the technical/scientific advances towards the identification and detection of plant products obtained by NBTs.

Finaly, we would like to mention that when a point mutation is introduced artificially into a genomic sequence using a NGT, it is impossible, without access to the record of that modification, to guarantee how it was produced, or whether it is the result of an spontaneous mutation. This fact has important legal implications as it prevents any reliable inspection procedure, especially when the varieties or their products come from third countries. Especially in the case of countries that do not segregate events or varieties, this task is clearly impossible to fulfil.

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

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