Contribution ID: 1e32ca84-4008-4766-819e-2aac04aecd03
Date: 19/05/2020 14:14:57

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?

Poland

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

Several individual cases have been reported when foreign companies involved in plant breeding presented an offer of possibilities offered by new breeding techniques in plant production. However, since the judgment of the Court of Justice of the European Union, there have been several questions from research institutes (universities, scientific institutes) regarding the legal status of new genomic techniques in scientific research. In 2019, the Ministry of Development held talks with the Ministry of Health to join the ELIXIR organization. Accession by Poland to the abovementioned initiatives could be an opportunity for the development of Polish scientific institutions conducting research and development activities and industry in the field of natural sciences. Thanks to participation in programs and projects, both universities and
and research institutes would gain access to a huge amount of life science data and support in finding the right software to analyze research results. Participation in the program would also enable scientists from the abovementioned entities participate in various types of training. In accordance with the assumptions of ELIXIR functioning, the organization enables, among others, proper data management, provides information on relevant research tools, contributes to increasing the availability of data and facilitating the ways of analyzing them in the direction of stimulation of innovation in biotechnology and the pharmaceutical industry. ELIXIR's task is to develop standards, services and conduct training in specific fields of life sciences, with the mission of building and operating a balanced biological information facility to meet current challenges in the collection, storage and dissemination of biomedical data. Participation in research projects, access to databases and development of competences of scientific employees may contribute to strengthening of scientific institutions, which indirectly is also in the interest of public administration units, such as the Chief Sanitary Inspectorate, which often use the expert and scientific resources of the abovementioned institutions. ELIXIR promotes the exchange of knowledge and support throughout Europe, smaller bioinformatics resources can be developed and connected to pan-European infrastructure. This makes new datasets available to scientists throughout Europe and gives them insight into information on diseases and the normal functioning of living organisms. Joining the organization requires the selection of a Center / Hub that would associate ELIXIR (Nodes) nodes to which the research units would belong, and the payment of an annual contribution of EUR 86,000.

* **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

Poland as a Member State of the European Union complies with the CJEU judgment on new genomic techniques under applicable law.

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

- ○ Yes
- ◉ No

* Please explain why not

As long as we don't have any available protocols, for example approved and publish by JCR, is difficult to predict any challenges, like methods, costs, etc. in relation to NGTs.

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

- ○ Yes
- ◉ No

* Please explain why not

The ability to adapt any practices of control bodies depends on the possibility of conducting laboratory tests that could clearly detect products produced using new genomic techniques. Available publications indicate that at the moment there is no methodology available that would clearly be able to detect products obtained with new genomic techniques. Following these publications, "if a DNA change is detected, there are currently no established procedures that make it clear that genome editing has caused the change. Therefore, plant products obtained by editing the genome may enter the market undetected. In addition, if a suspected product with an unknown or atypical DNA change was detected on the EU market, it would be difficult and even impossible to provide forensic evidence that the modified sequence is from genome editing. " (Https://gmo-crl.jrc.ec.europa.eu/doc/JRC116289-GE-report-ENGL.pdf)
For example, the Chief Veterinary Officer and the national reference laboratories for GMOs acquire knowledge in the area from data published by the European Reference Laboratory for GMO in food and feed (EURL for GM Food and Feed).
The Chief Inspectorate for Plant Protection and Seed Performs tasks based on the GMO Crop Control Program approved by the Minister of Agriculture and Rural Development and the Minister of the Environment, but crop control concerns the detection of genetic modifications that can be identified using identification methods developed by reference laboratories, not search in cultivated plants changes introduced using New Genomic Techniques

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

- ○ Yes
- ◉ No

* Please explain why not

As long as we don't have any available protocols, for example approved and publish by JCR, is difficult to predict any challenges, like methods, costs, etc. in relation to NGTs.

* **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 explain why not

Official control inspections responsible for control in the field of GMOs (veterinary inspection, plant protection and seed inspection as well as sanitary inspection) do not have experience or information regarding the strategy for detecting new genomic techniques. Only guidelines published by the European Reference Laboratory for GMO in food and feed (EURL for GM Food and Feed) are used.
Potential strategies for NGTs will only be possible with available detection techniques for products based on these technologies and their reference material, which at present seems impossible.

* **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

We do not have information within this issue.

Industrial sector

We do not have information within this issue.

Medicinal sector

We do not have information within this issue.

* **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

In accordance with the provisions of the seed law which contains only as many rules as follows from EU requirements reducing seed issues and in accordance with international guidelines, i.e. the International Union for the Protection of New Plant Varieties (UPOV) in Geneva and the Community Plant Variety Office (CPVO) in Angers, who submits a new variety to an entry in the National Register, encloses to the application for the entry of a variety into the National Register the so-called "Technical questionnaire for the application for entry of a variety into the National Register", in which, inter alia, is required to provide

information on the method of breeding and propagation of the variety, including the breeding scheme, and whether the variety has been obtained by means of crossing, mutation, discovery in the natural environment or otherwise.

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

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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

As part of basic research for biological progress in plant production, one topic is financed "Development and use of biotechnological methods to shorten the triticale breeding cycle and to improve the efficiency of selection - site-specific mutagenesis using site-specific nucleases", which uses editing techniques TALEN and CRISPR genes.
At the Institute of Zootechnics - National Research Institute the following projects have been carried out / implemented in the last 5 years:
project funded by the Ministry of Science and Higher Education "Analysis of expression of horse keratinocytes, transfected with expression vectors for E4 and E7 viral proteins, using the next generation sequencing technique in connection with the analysis of selected cell functional changes" (0127 / DIA / 2017 /46):
task planned for financing from the Own Research Fund 04-18-15-11, "Molecular genetics as a tool in modern animal breeding - development and implementation of new research methods"
task implemented from the funds of the Own Research Fund IZ-PIB 07-4.13.7 "Analysis of motility and invasiveness of horse sarcoid cells using the new generation sequencing technique (Rna-seq)".
To date, the National Center for Research and Development has financed 5 projects from domestic sources with a total grant amount of PLN 20,912,176.00 in the field of genomic techniques, including in the last 5 years, 1 project with a grant amount
17,501,783.00 PLN. However, it should be noted that these projects do not directly relate to the techniques indicated in the letter as "new genomic techniques", but relate to their subject matter.
Over the past 5 years, the possibility of funding research using the new genomic techniques indicated from domestic sources has appeared in the programs BIOSTRATEG, STRATEGMED and TANGO.
Thematic scope of these programs allowed genetic testing, the beneficiaries used them only in the above mentioned range.

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

We do not have information in this area.

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

New genomic techniques will be among the main factors conditioning the progress of plant breeding in such directions as: 1) resistance to biotic factors, 2) tolerance to environmental stress, including salinity and drought, 3) productivity and quality characteristics of the crop, 4) improving the so-called orphan crops (i.e. locally important species that are outside the area of interest of large breeding and seed companies), 5) domestication of new species. The last point is important in the context of a) the search for new species of crop plants for cultivation in a strongly changed environment, and b) the demand for plant products for industrial and energy purposes. Epigenetic techniques using e.g. RdDM (RNA-dependent DNA Methylation) will also be developed and used. These methods do not change the genetic record at all, but modify the way genetic information is read. Analogous epigenetic changes occur in plants in natural conditions, including under the influence of environmental stress. At the Institute of Plant Breeding and Acclimatization - National Research Institute IHAR-PIB, two teams, i.e. the Department of Genetic Engineering and the Department of Functional Genomics have in the techniques described above, in addition to publications in international journals, two patents: one for epigenetic techniques and the other Cas9 - methods editing cereals.
Works on editing the genome of plants using the CRISPR method are also underway in other scientific institutions in Poland. Currently, about 20 experiments of this type are conducted, most of which are commissioned by the American consortium "Monsanto" and the "AgroEva" company from Frankfurt. The originators are Polish scientists conducting research at the Institute of Biochemistry and Biophysics of the Polish Academy of Sciences in Warsaw and the Institute of Bioorganic Chemistry in Poznań. The team's success is to develop methods to modify lettuce cells to produce a hepatitis B vaccine. Meanwhile, scientists from the University of Wrocław are working on creating an alternative method for GMO to modify flaxseed. As in the case of genetic modification based on genome editing, they want to obtain epigenetic methods (RdDM) to change the content of flax isoprenoid, phenylpropanoid or glutathione compounds. In this way, it will be possible to obtain flax more resistant to pathogens, giving a higher yield or more seeds and better quality fiber and oil. The research is so advanced that scientists have already managed to obtain the seeds of the first plants resistant to fungi - in tonnes. Other plants, for example enriched in human-friendly phenylpropanoid compounds or those producing "ideal oil" obtained by epigenetic modification of the genome, are at the stage of semi-technical production.Genome editing tools are also used in modern livestock farming. This is due to the need to breed individuals with well-defined, positive characteristics. The sequencing of the farm animal genome has made it possible to know the thousands of metabolic pathways and genes responsible for given production traits. The advantages of animals, particularly popular, are rapid growth, significant increase in muscle mass, high milk yield and the content of bioactive ingredients in meat. Currently conducted research concerns the genome editing of the dairy cow population to obtain a product with properties similar to human milk (elimination of food allergies). Genome editing of farm animals towards the desired trait is already carried out at embryo level using embryotransfer and in vitro procedures. With the new genomic techniques, the agri-food sector has many legitimate hopes because they can be an alternative to GMOs.
The emergence of CRISP / CAS techniques has had a positive impact on projects
in the medical biotechnology sector. Earlier genomic techniques such as the use of meganucleases, zinc finger nucleases or TALEN were very rarely used in this sector due to low selectivity, cytotoxicity, and time and cost consumption. CRISP / CAS techniques were quickly used as an ideal tool to introduce changes in cell lines on which new therapeutic compounds are being tested. This resulted in a decrease in costs and a reduction in process time.
Poland sees the development of research using new genomic techniques. Advances in science, technology and biotechnology are extremely important for the further development of the bioeconomy as one of the most important areas of the economy in the EU.

*** 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

Discussions with breeders indicate their great interest in using these techniques. Breeders are aware of the possibilities that this field offers in solving specific breeding problems and are aware that global and European seed and breeding companies will take full advantage of these possibilities and can thus obtain a definite market advantage.
Commercialization of research results are interested in biotechnology companies and consortia operating in the agricultural sector.
Private and public sector interest has been noted in preclinical studies based on transgenic model animals.
Colleges and research institutes see great opportunities in research using new genomic techniques, but mainly in basic research to explore, for example, the biology of animals, plants or other organisms.

* **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

Research using new genomic techniques, including genomic editing, will strongly drive advances in plant breeding. New genomic techniques allow more accurate and faster induction of genome changes, which translates into a change in the characteristics of the final product, including agri-food sector products. By allowing for accurate, precise and easier interference with the genome, they create new possibilities for shaping the features of the final product, sometimes inaccessible to conventional methods. They are also helpful in obtaining new cultivars enriched with new useful features related to plant resistance to pathogens, as well as using such plants to produce more food with better quality characteristics or for the production of substances used for non-consumption purposes. Genome editing techniques can also be used to obtain forms with increased drought tolerance. New genomic techniques give the opportunity to manipulate many genes simultaneously, which is why they are used in both basic research and practical applications. At the same time, conducting research in this direction makes it possible to identify possible threats to the environment and man.
The use of genome editing techniques in the agri-food sector can therefore be crucial to maintaining the standard of living and food safety of consumers. The use of genomic techniques to obtain new crop varieties has enormous potential to obtain plants, crops and products in a 2-3 year period.
Unlike genetically modified food (GMO), the innovative CRISPR / Cas9 genome editing method relies on a simple mechanism for cutting the nucleotide sequence without inserting foreign DNA. Such genome modifications are one of the ways to preserve biodiversity and adapt plants to changing environmental conditions. Therefore, targeted editing of the plant genome is just as safe as varieties generated using conventional breeding techniques.
Innovative genome editing techniques can significantly accelerate the introduction of beneficial phenotypic traits into crop varieties. Yes, e.g. using the CRISPR method, scientists developed a wheat variety resistant to powdery mildew, introducing a small change in one gene (Mlo1) in one step that determines the trait of resistance to fungus. This type of gene change also exists in nature, but conventional breeding methods are very difficult and time consuming. There is also an Ethiopian wheat variety that has a natural Mlo1 gene mutation, but not as effective as chemical mutants. Another example may be the genome-modified Innate potato, which produces less carcinogens or non-browning fungi during frying.
The use of new biotechnology techniques can accelerate the selection processes of the best genotypes -

potential new varieties. New techniques can also contribute to the faster introduction of new varieties resistant to abiotic and biotic factors (diseases and pests) or products with a high content of healthy ingredients. Good examples are drought-resistant soybean oil (Canolina oil) with a high content of omega 3 produced from calder, allowed to be traded on the US market without any additional legal regulations (Wang et al. 2019). Also, understanding the pathogenicity mechanisms using these techniques can significantly accelerate the development of new, environmentally safe plant protection methods.
In the US, breeders already use seeds of plants modified with the CRISPR / Cas9 method. The DuPont Pioneer concern has genomically edited the genetic material of maize to change the proportions of the types of starch in grains to be more useful for industry. In turn, the small company "Calyxt" edited the soybean genome to increase the synthesis of oleic acid with health-promoting properties. Other research already carried out at the stage of implementing the modified product includes rapeseed and wheat. Already in 2020, a new variety of wheat grains with lower gluten content and higher fiber content is expected to reach the agri-food sector.
Therefore, the benefits for the agri-food sector and the consumer from conducted research and experiments to obtain the abovementioned plants and their products can rely primarily on less chemical and energy consumption during product processing, less food loss, and less pesticide use.
The current business model of enterprises is based on knowledge and modern technologies. New technologies and research using new genomic techniques can be one of the elements that increase the competitiveness of enterprises.

* **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 agri-food sector faces many challenges. There is a great demand for cereals produced by modern technologies that will not raise controversy and concern of society. The development of innovative genome editing tools based on cisgenesis seems to meet these conditions. The simplicity and stability offered by these methods creates unique opportunities for the agri-food sector. They will allow faster and more effective ways to obtain new high-oxygen varieties, resistant to diseases and environmental conditions, giving the product a high nutritional value. And because these new methods are effective and easy to use, they can also be used by small and medium-sized farms. A very important challenge facing the agri-food sector will be the issue of maintaining high standards of food safety modified by methods of genome editing and crop environment. Food entering the consumer market must be safe, and modified crops introduced into the environment must not cause damage to biodiversity and protected areas. At present, due to applicable legal regulations, it is not possible to apply new genomic techniques in practice. The main challenge currently facing the use of new genomic techniques is the lack of social acceptance resulting from a lack of communication and in many cases from deliberate misinformation. Each technology has its imperfections, which should be considered, assessed and limited where possible. It is currently difficult to rule on any negative consequences. In the case of livestock, the appropriate selection of modifications without harm to the animal, checking and verifying the product in terms of biosecurity and strict reproduction control of modified individuals should eliminate all hazards. Carrying out research using new genomic techniques does not carry risks. Possible risk may only be the release of crops into the environment or the introduction of the product on the market. It is important to identify potential threats, assess them, and develop a way to manage those risks. Safety aspects during the release into the environment of plants obtained as a result of the use of new genomic techniques should focus on the specific characteristics of the species and its interaction with the environment. At the same time, the risk assessment should consider the impact of such crops and the resulting product, e.g. food or feed, on human and animal health. Like any new technology,

genomic techniques also bring new challenges as well as problems. These are techniques that directly interfere with genetic material and allow its modification. Therefore, there is scope for abuse and use of these technologies in unethical intentions or in a harmful manner. However, these technologies used in the right way, e.g. in agriculture, they provide tools for quick response climate change and adaptation to changing conditions. The same effect can be achieved using classic technologies, but this type of research is very time-consuming and therefore inefficient. In zootechnics, genomic techniques are used mainly for recreational animals and those of high commercial value (Arabian horses, thoroughbred horses, dairy bulls). In the context of farm animals, the use of recalled technology, however, can be inefficient and costly, and the genetic potential of highly selected animals is not realized due to deficiencies in the environment (nutrition) and well-being (disease). One of the challenges that industry identifies in connection with the use of new genomic techniques are costs, mainly for small-, medium-sized enterprises that will not be able to afford such research. In-depth analysis would be needed to identify additional challenges / problems.

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

The Institute of Plant Breeding and Acclimatization - PIB in Radzików organized seminar presentations and discussions with breeders on the possibilities of new genomic techniques. In unofficial conversations, breeders signal that they are interested in research and the possible use of CRISPR techniques.
The Plant Breeding and Biotechnology Department of the Institute of Cultivation of Fertilization and Soil Science - PIB in Puławy organized lectures as part of organized Open Days on unconventional use of tobacco (GMO) as a green bioreactor for obtaining substances useful for humans.
Topics regarding new genomic techniques were discussed and discussed as part of lectures for students, researchers and breeding associations employees or open lectures at the National Research Institute of Animal Production.
On April 26, 2019, on the occasion of World Intellectual Property Day in Warsaw, the Polish Patent Office organized a conference entitled "Whose genome is it? Biotechnology and intellectual property protection. " The conference was co-organized by the World Intellectual Property Organization (WIPO). New genomic techniques were in particular related to the presentation of dr Sławomir Sowa from the Plant Breeding and Acclimatization Institute, National Research Institute from Radzików. During other speeches and discussions, questions arose regarding new genomic techniques also in the context of the possibility of patents for inventions concerning them or using such techniques.
It should be remembered that inventions using new techniques must meet all patentability criteria, just like other inventions. The Act of 30 June 2000 - Industrial Property Law does not contain special provisions exclusively for this type of solution. However, genetically modified microorganisms and organisms are patented by the Patent Office of the Republic of Poland and, as indicated above, from the standpoint of patentability are treated like all other inventions. Below are examples of this kind of inventions, i.e. inventions regarding based methods

o CRISPR, which are included in the new breeding techniques:
• P.425134 "The nucleotide sequence of the synthetic Cas9 gene, the cassette directing the sgRNA for editing the plant genome and an efficient system for the targeted mutagenesis of the selected region of the plant genome" - by decision of 19 February 2020 the patent was granted - the subject of protection is the Cas9 protein, synthetic CRISPR system / Cas9 for obtaining mutations in the plant genome - barley. Ww. the system ensures that mutations are obtained
with high efficiency,

• P.411316 (PL226294) "Lactobacillus rhamnosus strain and method of obtaining calcium L-lactate using this strain" - by decision of 12 January 2017 a patent was granted, the patent remains valid - the subject of protection is the strain of Lactobacillus rhamnosus containing the system CRISPR-Cas. The strain produces calcium L-lactate.

* **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

Increasing plant production is possible through continuous improvement of crop varieties. The size and pace of implementing biological progress for major plant species will depend on the use of modern biotechnology methods and DNA-based technologies in mass selection in breeding. Genome editing techniques create new opportunities for faster and more precise progress compared to conventional breeding methods. Improving plant varieties using genome editing techniques can help adapt agriculture to rapidly changing climatic conditions. The ease and stability of use offered by these new farming methods creates unique opportunities and benefits for the agri-food sector.
The use of new genomic techniques will significantly accelerate the development of new efficient crop varieties specially adapted to their environment. Growing problems caused by pests, diseases, drought caused by climate change and degradation of arable land can be more effectively minimized using genome editing techniques. The conscious and controlled use of the above the technician will improve plant varieties in the direction of increased resistance to diseases and pests as well as increased energy and nutrients. Climate change means that we need plants more resistant to drought and salinity. Also, restrictions on the use of chemicals mean that hopes for an efficient crop lie in new plant varieties. Allowing breeders, farmers and producers to use biotechnologically improved seeds can significantly improve progress in yielding and obtaining high quality agricultural products and an adequate level of food production.
Even niche crops and very expensive crops can benefit from breeding advances. There is no doubt that one of the most important tasks facing plant breeding is both the effective use of naturally occurring genetic biodiversity, as well as the enrichment of plant biodiversity and genetic variability, which is the starting material for further work. The latest methods of genomic engineering using new genomic techniques allow for targeted and precise cisogenesis that can be included in the breeding process. Their application could also contribute to supporting ecological activities.
The use of new genomic techniques has enabled the creation of, among others maize with reduced wax content on leaves, soy with a high content of oleic acid, rice with a very pleasant smell, early-flowering cabbage, tomato with an increased content of antioxidants (anthocyanin), wheat with an increased grain mass and an increased content of protein, maize and potatoes with a high content amylopectin, corn resistant to agricultural drought. Achievements to date indicate that the use of new genomic techniques may be beneficial for the agri-food sector.
The use of genome editing tools in the targeted improvement of crop varieties can help solve the problems of sustainable development and the future of agriculture. In 2015, the UN agenda for sustainable development - 2030 was adopted, containing 17 goals to eliminate, among others poverty, sustainable consumption and production, and economic growth. Solutions to these problems must be sought in many ways. European agriculture can make a significant contribution to the goals of sustainable economic development set by the UN. For the agri-food sector, which must meet the requirements of a growing global population, the introduction of products edited using innovative CRISPR tools on the market will help to achieve the set goal faster and more effectively. Of course, extensive research is needed to use these tools effectively and safely, not only in the private sector but also in public space.
"Live bioreactors" - transgenic farm animals producing therapeutic proteins are a fact. To date, information on the scale of use of "live bioreactors" is fragmentary. As more and more effective and precise methods for editing genomes are developed, the scale of the use of transgenic breeding animals producing therapeutic proteins serving as models will increase. This should also have a positive impact in the agri-food sector - e.g. disease-resistant animals, better assimilable feeds or environmentally friendly will be obtained.
In the light of current EU regulations this is not possible.
The use of new genomic techniques and products produced using them can have a positive impact on the competitiveness and innovation of enterprises. It will allow the development of new technologies, including in the area of pharmaceutical products.

*** 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

Plant protection is a constant battle between the pathogen and host. With the emerging newer forms of pathogens, often more virulent, there is a need to improve crop varieties and introduce resistance traits to selected diseases. Currently, the most commonly used are the classic methods consisting in crossing with the species carrying the resistance gene. However, the resource of natural sources of immunity is limited, hence the increasingly emerging forms obtained by genome editing methods. Herbicide-tolerant corn, rice, soybean, potatoes and flax, bacterial blight rice, powdery mildew resistant wheat and tomato.
Understanding the mechanisms of pathogenicity using new genomic techniques can significantly accelerate the development of new, environmentally safe methods of plant protection. In the case of pathogens showing particular virulence, the use of natural sources of immunity may not be sufficient, hence in the medium and long term the use of modern genomic techniques may become necessary.
The object of breeding supported by new genomic techniques will be the so-called orphan crops, i.e. locally important species that are outside the area of interest of large breeding companies. Improving these species will definitely reduce genetic erosion resulting from farming for large-scale agriculture. Obtaining varieties with better water, nitrogen and phosphorus utilization will reduce the consumption of water resources and mineral fertilizers. However, obtaining varieties resistant to biotic factors will allow less consumption of chemical plant protection products.
Possible benefits / possibilities for plant protection can only be considered in the long term. They may appear when new research results are used. However, the development and validation of procedures is a time consuming process. The development of new varieties focused on deriving plant lines with increased resistance to pests, environmental and climatic conditions, etc. brings with it promising short-, medium- and long-term perspectives. Especially in times of collision with the challenges that climate change brings.
In the long term, the development of new technologies may allow for a more sustainable use of environmental resources, environmental protection and protection of human health.
The use of products produced using new genomic techniques can have a positive impact on the competitiveness and innovation of enterprises on average
and long-term.
Pharmaceutical and biotechnology companies see enormous opportunities in using these technologies, which would enable faster development and production of new products.

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

general opinion

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

- (●) Yes
- ( ) No

* Please explain under which conditions

Access to new genomic techniques gives small and medium-sized enterprises a chance to appear internationally and gives the opportunity to develop and develop innovative products.

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

- (●) Yes

No

* Please describe and provide concrete examples/data

New techniques can lead to products and methods that can benefit the most, as the examples of protected inventions cited above show.

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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

The development of innovative genome editing techniques has initiated a series of questions about ethics, biohazard, agriculture, and intellectual property protection. One of the challenges for the agri-food market is the development of innovative genomic engineering techniques and active participation in the development of clear authorization procedures obtained by editing genome, agricultural products and food in the EU.The risk associated with editing genomes is much lower than in techniques based on classical genetic transformations because changes often affect only a few nucleotides, which makes them similar to those found in natural populations.The European Court of Justice in 2018 recognized that the existing GMO regulations should be applied to plants for which new genomic techniques were used. The challenge for the agri-food sector is therefore the Court's judgment itself, indicating the need to cover a wider spectrum of arable crops with supervision assigned to genetically modified plants. With regard to plants created using new breeding techniques, this task may prove to be highly problematic or even impossible to perform, as the changes caused do not cause significant changes in the plant genome. Laboratories responsible for controlling such products will in many cases not be able to assess whether they are products from plants obtained in the laboratory or from conventional varieties without using the breeding techniques mentioned in the judgment of the Court of Justice. In the current legal framework, it is important to differentiate between the different uses of genome editing for regulatory assessment purposes. The road to commercialization of research results and the implementation of products obtained by genomic techniques in the agri-food sector is still distant, nevertheless, the research results have already gained interest in financing by the private sector. Biotechnology companies that were created in the hope of commercializing CRISPR technologies estimate that the agri-food sector will be one of the profitable areas for food production based on the genome editing method. It should also be remembered that the development of modern strategies for obtaining products using genomic editing techniques will require an increase in financial resources for innovative research and commercialization of the results obtained in the private sector, and above all in the public space. The solution could be to intensify the financing of agricultural research from public funds. Regardless of the opinions of scientists, state policy or protests of environmentalists, the final decision regarding the acceptance or rejection of products modified by genome editing techniques belongs to consumers. Another challenge for the agri-food sector will be the profitability of their use - the costs of

obtaining specific products in this way will be much higher, which is associated with the current efficiency and labor consumption of genome editing methods. The prospect of large-scale production of products (e.g. milk with therapeutic protein content) that can only be obtained by using methods of safe genomic modification, opens up the possibility of expanding the range of products offered as well as extends the sector's contribution to the impact on society's health. The use of new genomic techniques and the introduction of products obtained with their participation must be preceded by detailed research on their safety for humans and animals. An important aspect is also the effects on the environment, especially in relation to herbicide-tolerant and pathogen-resistant varieties. Appropriate legal regulations ensuring safe and ethical research will allow obtaining appropriate knowledge and its adequate use for a specific purpose. This will eliminate any possible risks associated with the use of new genomic techniques.

* **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

We do not have such information. However, any new technology is controversial in society, and until we have legal / control tools to bring technology into widespread use and later products produced using it, it's difficult to talk about potential challenges for the environment, human, animal and plant health or about challenges social / economic.

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

General opinion

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

- (●) Yes
- ( ) No

* Please explain under which conditions

Access to new genomic techniques for entrepreneurs is / will be a challenge. This is primarily associated with high costs, as well as access, collection and use of information (big data) and the acquisition of qualified staff.

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

We see challenges and possible problems associated with patenting this type of solutions. The Ministry of Development and the Patent Office of the Poland are trying to keep up to date with current events, new national and European case law, in particular the European Patent Office or the CJEU.

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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

For a broader analysis of issues related to new genomic techniques, the European Commission should regularly update problems / challenges, especially for the agri-food, medical and industrial sectors, which would significantly facilitate the adaptation of EU and national law of individual Member States to the current development of new technologies.

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