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Stakeholder 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

Discussed and finalised in the Ad-hoc Stakeholder meeting on 10 February 2020

Background

The Council has requested [1] the Commission to submit, by 30 April 2021, "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).

To respond to this Council's request, the Commission is collecting contributions from the stakeholders through the questionnaire below. The study covers all new genomic techniques that have been developed after 2001.

Instructions

For the purpose of the study, the following definition for new genomic techniques (NGTs) is used: techniques that are capable of altering 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-organisms and derived food and feed products obtained by NGTs for agri-food, medicinal and industrial applications and for research.

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 specific NGTs/organisms, please indicate this in the reply.

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

Guidelines

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 15 May 2020 (close of business) to submit the questionnaire via EUsurvey.

QUESTIONNAIRE

Please provide the full name and acronym of the EU-level association that you are representing, as well as your Transparency Registry number (if you are registered)

If the name of the association is not in English, please provide an English translation in a parenthesis

EUROPATAT, the European Potato Trade Association, is an international non-profit association established under Belgian legislation (1919). Europatat is registered in the EU register of interest representatives under n° 16057181340-75.

Please mention the sectors of activity/fields of interest of your association

Europatat, comprises both national associations and individual companies involved in the trade of seed, ware and early potatoes throughout Europe. Its members include a wide range of traders (including breeders, distributors, storers, packers, importers and exporters) delivering seed potatoes to farmers, as well as raw material to the food industry, packed potatoes to the retailers and food service sector.

Potatoes are the most important vegetable crop and the fourth most important food crop in the world. The potato is an important food for the fresh market and it is also the raw material for many processing industries. New varieties are central to the health and growth of the European potato industry and for feeding the world's growing population. Research on the genetic improvement of this crop is therefore important.

If applicable, please indicate which member associations (national or EU-level), or individual companies /other entities have contributed to this questionnaire

If applicable, indicate if all the replies refer to a specific technique or a specific organism

A - Implementation and enforcement of the GMO legislation with regard to new genomic techniques (NGTs)

* **1. Are your members developing, using, or planning to use NGTs/NGT-products?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please provide details

Yes, but not in every market or every player in a given market.

In France: It has been initiated as part of the "Genius" project (https://www6.inrae.fr/genius-project_eng /Project/General-presentation) first with TALEN technic and then with Crispr-Cas9. First targeted trait was GBSS (for amylose free starch). In the continuation of the project and in collaboration with the French public research there is work other traits related to resistance to diseases (virus, blight) and tuber properties (cold induced sweetening, starch metabolism). There is also work on extending the collaboration with a USA university.

In other countries/other players: No, since NGT products (in our case potato varieties) are considered GMO and the deregulation cost for these are too high, the trajectory fully unclear and trait advantages commercially insufficient to warrant the high investment both in the techniques as in product deregulation. Also, they do not seem to be accepted by consumers and chain partners supplying to consumers, even in countries (as the US) where NBTs are accepted.

* **2. Have your members taken or planned to take measures to protect themselves from unintentional use of NGT-products?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please provide details

In France: They ask for non GM declaration from the provider when they receive genetic material (e.g. parents for crossings, etc). NBT modified material fall under that definition for the time being.

In the Netherlands: For potato, this is fairly easy. Since it is a clonally propagated crop and as NGT-products are legally considered GMO's all varieties brought to the market in the EU are easily identifiable. It is highly unlikely that new varieties are on the market that in fact are NGT-products since typically the modifications are of recessive nature and modifications will not pass in an economically meaningful sense to offspring by traditional breeding techniques. Also, when varieties would be brought to the market with traits we know could not easily be obtained by traditional breeding, this immediately would raise suspicion.

The traceability from reliable resources is very relevant (following Nagoya protocol).

* 2 bis. Have you encountered any challenges?

- ( ) Yes
- (●) No

* **3. Are you aware of initiatives in your sector to develop, use, or of plans to use NGTs/NGT-products?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please provide details

Only in countries and under the circumstances where this is allowed.

For the time being there are two main utilisations:
- Breed new varieties for the markets where NBTs are allowed
- Use NBTs as a breeding tool to improve the knowledge of the genome, develop markers and breed conventional varieties

Crispr-Cas9 and related technics are the main focus.

* **4. Do you know of any initiatives in your sector to guard against unintentional use of NGT-products?**

- ( ) Yes
- (●) No
- ( ) Not applicable

* 4 bis. Are you aware of any challenges encountered?

- ( ) Yes
- (●) No

* **5. Are your members taking specific measures to comply with the GMO legislation as regards organisms obtained by NGTs?**

Please also see question 8 specifically on labelling

- ○ Yes
- ○ No
- ◉ Not applicable

* **6. Has your organisation/your members been adequately supported by national and European authorities to conform to the legislation?**

- ○ Yes
- ○ No
- ◉ Not applicable

* **7. Does your sector have experience or knowledge on traceability strategies, which could be used for tracing NGT-products?**

- ◉ Yes
- ○ No
- ○ Not applicable

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

According to some members, mutagenesis products cannot be traced as those mutations can happen in nature as well. Likely, varieties bred by NBT such as gene editing by Crispr-Cas9 will be untraceable (some evolution of the gene editing technics allow modification without any integration of foreign DNA).

For other members, an important distinction needs to be made:
1) If NGT-products remain to be considered GMO's, it is likely that in the procedure for market approval the applicant needs to provide for a detailed description of the changes made in the genome that, by standard laboratory practices, can be easily detected by third parties and followed in varieties and offspring created with such varieties. Furthermore, it is likely that applicant have to provide a detailed protocol for that, that normally will be made publicly available.
2) If NGT-products would no longer be considered as GMO's, the traceability, if this would be needed necessary, of modifications in third party varieties would become more cumbersome. Then, based on the new traits a variety is being promoted for, one would need to guess which genome sequences could have been altered. Consequently, these potential gene targets need to be sequenced and compared to wild type alleles hoping for detection of key mutations made that are responsible for the altered trait(s).
The required financial and human recourses for the first described situation would be very modest. One needs a molecular lab and skilled staff though. The situation that is described secondly, requires considerable time and money without success guaranteed.

* **8. Are your members taking specific measures for NGT-products to ensure the compliance with the labelling requirements of the GMO legislation?**

- ○ Yes
- ○ No
- ◉ Not applicable

* Please describe the measures and their effectiveness including details on the required financial, human resources and technical expertise

n/a

* What best practices can you share?

n/a

* 8 bis. What challenges have you encountered?

n/a

* **9. Do you have other experience or knowledge that you can share on the application of the GMO legislation, including experimental releases (such as field trials or clinical trials), concerning NGTs/NGT-products ?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please describe for the:

- [x] Agri-food sector
- [ ] Industrial sector
- [ ] Medicinal sector

Agri-food sector

France: The GM legislation is very restrictive and requires the R&D facility to be officially approved for the handling of GM material. Field experimentation is impossible, which is significantly hindering the development of agronomically sound varieties. It is also the reason why we have to rely on partnerships to acquire experience on those technics, either with public labs that are GM certified or foreign entities that are allowed to perform field experimentation.
The restrictions are drastic and are causing a competitive disadvantage to the European breeding companies. Given the potential of these technics and the challenges we are facing (climate change, increasing pressure of pests and diseases, less chemical solutions) it is urgent to facilitate the experimentation for breeders, even if the varieties cannot be sold in Europe. We will otherwise surrender our market positions to non-European players at some point.

Netherlands: In the past, we have worked on ‘traditional’ GMO’s for many years. Relative to traditionally bred varieties, the restrictions, obligations and permissions were extremely complicated, costly and inefficient. They intended to avoid imaginary or highly theoretical risks. The path towards market access seemed to be indefinite and the spectrum of requirements that ultimately had to be met was totally unclear.

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 on NGTs/NGT-products

*** 10. Are your members carrying out NGT-related research in your sector?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please specify including subject, type of research, resources allocated, research location

Yes, but not in every market or every player in a given market.

Some companies have worked on varieties with added value like high level of resistance against Phytophthora. However, those will not be launched on the EU market as those will be considered as GMO in the EU. They will bring those to countries outside the EU.

There is also some gene discovery research externally for research purposes.

In France: It has been initiated as part of the “Genius” project (https://www6.inrae.fr/genius-project_eng /Project/General-presentation) first with TALEN technic and then with Crispr-Cas9. First targeted trait was GBSS (for amylose free starch). In the continuation of the project and in collaboration with the French public research there is work other traits related to resistance to diseases (virus, blight) and tuber properties (cold induced sweetening, starch metabolism). There is also work on extending the collaboration with a USA university.

In Switzerland, Agroscope (federal research) has conducted field trials with cisgene potatoes and other products containing GMOs. More information is available under the following link, although unfortunately, the results are not yet available:
https://www.agroscope.admin.ch/agroscope/en/home/topics/environment-resources/biosafety/gmp-benefits-risks/protectedsite/projects/potatoes-with-improved-late-blight-resistance.html

In other countries/other players: No, since NGT products (in our case potato varieties) are considered GMO and the deregulation cost for these are too high, the trajectory fully unclear and trait advantages commercially insufficient to warrant the high investment both in the techniques as in product deregulation. Also, they do not seem to be accepted by consumers and chain partners supplying to consumers, even in countries (as the US) where NBTs are accepted.

*** 11. Are you aware of other NGT-related research in your sector?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please specify

Some major breeders have on-going work with Universities, private and public partners. The increasing use of diploid material in breeding is an indication of the willingness to use NBT as they are more efficient and easier to implement on diploids than on tetraploids.

Academic groups publish about it.

Some examples include:

- Late blight (Phytophthora)-resistant potato using cisgenesis
- Potato with minimised reducing sugars by genome editing (by transcription activator-like effector nuclease TALENs, repaired by non-homologous end joining NHEJ)
- Potato with high amylopectin content (using CRISPR/Cas9, repaired by NHEJ)
- Potato with increased resistance to potato virus Y infection and increased tolerance to salt and osmotic stress (using CRISPR/Cas9)

*** 12. Has there been any immediate impact on NGT-related research in your sector following the Court of Justice of the EU ruling on mutagenesis?**

Court of Justice ruling: Case C-528/16 http://curia.europa.eu/juris/documents.jsf?num=C-528/16

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please describe

Due to the ECJ ruling, some companies have decided not to work on NGT's for the EU market and only launch those outside the EU. But research and development work continues.

It has been deprioritized versus other R&D tools as the European market remains our main target. Nevertheless some projects continue, but experimentation is very limited.

The ongoing negotiations for commercial application of the Crispr patents have been stopped.

It is our strategy to no longer invest in product development if the route to market is not crystal clear.

Delay in improving genetic material and therefore in development of improved varieties. Europe is getting behind other regions, and that will affect the potential of European based companies. We notice some are considering moving part of R&D to other regions in the world.

*** 13. Could NGT-related research bring benefits/opportunities to your sector/field of interest?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please provide concrete examples/data

There is no unanimous response among Europatat's membership regarding this point.

1) Some members think it will bring benefits/opportunities:
Breeding techniques are used by the sector to address market and production limiting traits. Indeed, potato breeders aim to produce new cultivars better adapted than existing ones to conditions in which they are going to be grown and stored, and the ways in which they are going to be used. This leads to several economic, social and environmental benefits:

- More yield of saleable product at less cost of production, whether for processing or table use;
- Reduced use of pesticides, fungicides and sprout suppressants, and increased water and fertiliser use efficiency;
- Reduced pressure on farmers, related to disease control in the framework of weather conditions (e.g. phytophthora infestans warning schemes)
- Convenience foods, improved nutritional and health benefits (such as lower glycaemic index, lower potential acrylamide production or higher micronutrient content), improved flavour and novel products.

This is very important. Breeding potatoes goes very slowly due to the complex genetics. NGT's is a huge tool for potato breeders with a huge opportunity to improve the quality of the potatoes for the benefit of food supply in the world. It will reduce the use of chemicals etc.

Yes. Improve or restore resistance to diseases (notably virus, blight, nematodes, and black leg) in varieties and ease their combination in one variety.
Improve the processing characteristics: reduce cold induced sweetening and limit the production of acrylamide during frying
Improve resistance to physiological disorders of the tuber: resistance to shocks and internal damages.

2) Other members have a more nuanced response: Yes, albeit to a rather limited extent. In potato, which is a tetraploid, clonally propagated crop, NGT-related research brings the opportunity to perform target mutagenesis whereby for one to four dominant alleles a conversion is obtained to recessive allele variants in an existing variety. The number of targets of known genes that can be mutated such that a gain in plant characteristics is obtained is limited. In potato, the typical examples are: reducing black spot susceptibility, reducing starch complexity for the starch industry and maybe lowering the amount of sugar built up during storage. However, the majority of traits of interest in potato breeding cannot be targeted due to genetic complexity and dependence of functional rather than defect (recessive) genes. Furthermore, potato is highly vulnerable for somaclonal variation if forced through a single cell stage as is essential in obtaining the NGT-product. This makes the technique highly inefficient and cumbersome and for a number of commercial varieties it will not be successful at all. So, even in the case NGT-products would not be considered GMO, it is not yet clear if we would start the application whatsoever.

*** 14. Is NGT-related research facing challenges in your sector/field of interest?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please provide concrete examples/data

Many options do exist from a technical point of view. Challenges are present as we need to come to agreements with the owners (patentholders) of those NGT's.

The field experimentation must be allowed, as well as the use of NBT modified material in non-GM facilities to perform test on the tubers.

The GMO-status makes that essential field experiments are too complicated from a regulatory point of view.

Companies have to develop more complicated and time consuming alternative routes.

Also there is no consumer acceptance.

*** 15. Have you identified any NGT-related research needs/gaps?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please specify which needs/gaps, explain the reasoning and how these needs/gaps could be addressed

More genetic information, and resistances.

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 potential opportunities and benefits of NGTs/NGT-products

*** 16. Could NGTs/NGT-products bring benefits/opportunities to your sector/field of interest?**

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

There is no unanimous response among Europatat's membership regarding this point.

1) Some members believe it can have huge benefits. For example for phytophthora. All classic breeders work with phytophthora resistances. However, the disease mutates as well. Quicker than breeders can breed. Hence double resistant mechanisms are required. That is not easy in a classic way. With NGT this is relatively easy. Also creating potatoes with higher food value (more vitamins), or higher yields, or better storability, or better processing characteristics etc. etc. It will also reduce the use of chemicals etc.

Improve or restore resistance to diseases (notably virus, blight, nematodes, and black leg) in varieties and ease their combination in one variety
Improve the processing characteristics: reduce cold induced sweetening and limit the production of acrylamide during frying
Improve resistance to physiological disorders of the tuber: resistance to shocks and internal damages.

2) Other members thing that no, they are not specific to a great extent. For all examples mentioned there are alternatives that can be reached by classical breeding strategies, albeit that sometimes these are very time consuming and cumbersome. There is a big difference between the possibilities of traditional GM-techniques where genes of any other organism could be used and NGT's that are limited to within species variations. For example, resistance to insect pests is easily obtained by GM-approaches but not at all by NGT-applications or traditional breeding.

* Are these benefits/opportunities specific to NGTs/NGT-products?

- ○ Yes
- ◉ No

* Please explain why not

n/a

* **17. Could NGTs/NGT-products bring benefits/opportunities to society in general such as for the environment, human, animal and plant health, consumers, animal welfare, as well as social and economic benefits?**

- ◉ Yes
- ○ No

* Please describe and provide concrete examples/data

They will allow to improve the resistance to the major potato diseases (blight and virus notably) that are currently controlled thanks to chemical substances (fungicides, insecticides, mineral oils, etc.).
They can also help to maintain the productivity in spite of the increasing pressure of those diseases.
They can bring improved stress tolerance of varieties against climatic conditions such as drought, salinity, heat, etc.
They can help to improve the storability of the potatoes and ease the production of healthy products after storage: main example is the possibility to develop frying varieties with low sugar and acrylamide.

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

n/a

* Are these benefits/opportunities specific to NGTs/NGT-products?

- ○ Yes
- ◉ No

* Please explain why not

n/a

* **18. Do you see particular opportunities for SMEs/small scale operators to access markets with their NGTs/NGT-products?**

- ◉ Yes
- ○ No

* Please describe and provide concrete examples/data

There is no unanimous response among Europatat's membership regarding this point.

Yes, if the owners of the technique do license the techniques for acceptable conditions to SME's, all companies can work with it. Not if it is considered as a GMO. Than the costs for market access are too high.

The access to the patents is to be negotiated and will be expensive, which can be a limitation and big players might have stronger negotiation position vis-à-vis the patent owners. Other than that, those technics are relatively inexpensive to use. They can improve the general knowledge of the genome (knock-out genes and observe the impact on the plant development and characteristics). They can lead to the development of commercial product quiet fast. Small scale operators will be as competitive of the big one in terms of R&D.

NO. The patent environment around NGT's is not at all a suitable terrain for SME's to operate in. Also, these techniques are far too complicated for the majority of traditional potato breeders.

Not with current EU legislation and position concerning NBT's.

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

- ○ Yes
- ◉ No

* Please explain why not

No. It we talk about mutations, it is an essential biological product and should not be patented.

It limits competition and is very expensive.

Only big AG-Biotech companies know how play that game. Furthermore, in almost all cases, the patent protection period is way too short for successful exploitation of obtained rights given the long timelines need for product development after establishing a priority date.

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 potential challenges and concerns on NGTs/NGT-products

*** 20. Could NGTs/NGT-products raise challenges/concerns for your sector/field of interest?**

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

Several answers were received by members on this point:

1. We have the breeder's exemption. If I bring an NGT product to the market in the USA, it will be a normal product. Another breeder do not know it is a NGT and will use it as a parent and introduces the product in the EU. Nobody can trace this as long as the NGT is a mutagenesis.

2. They raise the question of Essentially Derived Varieties: who is the owner of the Plant Breeders Right for a variety that results from the gene editing of an existing variety? Where is the limit between the rights of the breeder of the original variety and the rights of the "editor"? How do you quantify the proximity between the two varieties or the two versions of a variety? Does it depend of the function that have been added or knocked-out, or on the modified characteristics, knowing that the modification can be efficient or visible only in some specific conditions?

3. Traceability is an issue.

4. Especially in the case where NGT-products would no longer be considered GMO's, and given the dominance of big Ag-Biotech companies in relevant patent ownership, there is serious danger that our plant breeders rights (PBR) protected varieties, which we rely on, are taken and modified by these powerful AG-Biotech companies in to NGT-products. Such varieties are probably considered "essential derived varieties" which gives us some rights, but it will, anyhow, push us as smaller businesses in a highly dependent position and it would damage our profitability and therefore income to spent in traditional breeding. This "danger" was very real during the turn of the millennial when the potential of GMO was emerging. Only the strict deregulation provisions for GMO's which made it unattractive to push GMO-varieties even for big AG-Biotech in the EU protected us from this scenario to happen.

Another concern is that, a part from patenting the NGT-techniques (which is fine), in specific applications, also mutant genes will be patented that are also available as natural occurring gene variants in traditional breeders' germplasm. Natural occurring biodiversity should not be patentable at all.

The world of traditional potato breeding is (practically) free of interfering patents.

5. There is no consumer acceptance.

* Are these challenges/concerns specific to NGTs/NGT-products?

- (●) Yes

- [ ] No

* Please explain

n/a

* **21. Could NGTs/NGT-products raise challenges/concerns for society in general such as for the environment, human, animal and plant health, consumers, animal welfare, as well as social and economic challenges?**

- [x] Yes
- [ ] No

* Please describe and provide concrete examples/data

There is no unanimous response among Europatat's membership regarding this point.

YES: The challenge for our sector is to prove there are benefits for the society and the consumers of the products, which GM did not do (focusing on easing crop management). We should also build an open market around those products and no GM-like captive business models (tech fee, seeds + chemicals). NBT issued products will have a positive impact on the environmental impact of agriculture and help developing healthier products, so there should be no challenge.

NO: Not more than in comparison to traditional bred crops. And traceability is an issue.

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

n/a

* Are these challenges/concerns specific to NGTs/products obtained by NGTs?

- [ ] Yes
- [x] No

* Please explain why not

n/a

* **22. Do you see particular challenges for SMEs/small scale operators to access markets with their NGTs /NGT-products?**

- [ ] Yes
- [x] No

* Please explain why not

If the NGT's are a GMO, it is impossible for SME to bring those to market. If it is not, the main issue is to get a license for the technology.

The only challenge is the negotiation of the access to the patent. It is open, but financial conditions are to be explored and might put smaller players under pressure.

What is seen in the market is that SME's nor big corporations have an incentive to apply for market access due to the restrictions accompanying the GMO-status. If this GMO status would no longer exist, the market is equally accessible for all actors. (Apart from the situation of patents as explained earlier).

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

Depends on the owners. Are they willing to license for reasonable conditions or not?

It limits competition because it is very expensive to put in place for both the patent holder and the licensor.

Status of the patents is still unclear, especially in Europe: two Crispr patents (Broad Institute vs Berkeley) challenging each other's.

Negotiation of the rights is very challenging as the legal status of the technics is not clear in Europe.

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 - Safety of NGTs/NGT-products

*** 24. What is your view on the safety of NGTs/NGT-products? Please substantiate your reply**

There is no unanimous response among Europatat's membership regarding this point.

1) Some members see no issue. They are as safe as any other product. Mutagenesis (non-targeted) do exist for decades. The ECJ even concluded; never a negative issue. Targeted mutagenesis will not be more risky. Contrarily.

NBT do nothing (when there is no introduction of foreign DNA) that would not happened naturally. No safety issue in my opinion.

2) Other members think that as long as "knock out" applications are concerned (where genes are made non-functional), there is no safety concern. If "knock in" applications are concerned (where new gene functionalities are introduced), we're in the area of "traditional" GMO's and potentially hazardous products may emerge. The risk, however, in a majority of cases will be very modest and an evaluation of the safety can be carried out with a limited set of experiments.

*** 25. Do you have specific safety considerations on NGTs/NGT-products?**

- (●) Yes
- ( ) No

* Please explain

There is no unanimous response among Europatat's membership regarding this point.

Some members refer to the previous question.

Mutagenesis products are not dangerous. They are natural. Transformation products might have a risk.

Other members think that yes: an example that is unsafe for the environment, but which has serious interest in academia and maybe the corporate world, is the introduction of apomixes. If an emerged form of apomixes would behave in a dominant manner and it escapes to natural potato populations it will ravage biodiversity of which humankind is so dependent.

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 - Ethical aspects of NGTs/NGT-products

*** 26. What is your view on ethical aspects related to NGTs/NGT-products? Please substantiate your reply**

Ethically product-wise no issue. It is not ethical to consider those as a GMO and to withhold those products from society. Society can benefit enormously from those improved products.

What is less ethical between (i) inducing targeted modifications (that could happen naturally at random and lower frequencies) of the DNA to improve varieties, without integrating any foreign DNA to the genome, and (ii) not using one of the most promising tools we have to maintain the productivity of our agriculture in a fast changing environment as well as reducing its environmental impact and improving the sanitary quality of the products at the same time?

If NGTs would be unethical, agriculture itself would be.

*** 27. Do you have specific ethical considerations on NGTs/NGT-products?**

- ○ Yes
- ◉ No

* Please explain why not

See 26

Please upload any supporting documentation for this section here

The maximum file size is 1 MB

G - Consumers' right for information/freedom of choice

*** 28. What is your view on the labelling of NGT-products? Please substantiate your reply**

There is no unanimous response among Europatat's membership regarding this point.

Some members believe that if it is needed to have them allowed, labelling will have to be accepted. Consumers have the right to know what they eat (in case of food applications that is), if they wish.

Other members believe this a too pragmatic approach. Mutants appear in nature as well, and will not be labelled. If NBTs are considered as non-GMO, labelling should not be necessary.

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

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H - Final question

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

- ◉ Yes

No

Please provide your comments here

As reflected in the Europatat answer to the questionnaire (thought he input of its members), there are many questions still open regarding NBTs and there is no clear answers or unanimity regarding some aspects raised in the questionnaire.

We hope that the future work of the European Commission and other European institutions and agencies will help in bringing the needed clarity to secure the safe application regarding technical and legal aspects.

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