

# 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 / E C ) .

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 a f t e r 2 0 0 1 .

### 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

[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 as 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

CEFS (Comité Européen des Fabricants de Sucre) - ID- 49679062863-35

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

CEFS stands for le Comité Européen des Fabricants de Sucre, or in English: the European Association of Sugar Manufacturers. Founded in 1953, CEFS represents European beet sugar manufacturers, cane sugar producers and refiners covering sugar production in 19 EU countries (Austria, Bulgaria, Belgium, Croatia, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Italy, Lithuania, Poland, Romania, the Netherlands, Slovakia, Spain, Sweden) plus the United Kingdom. It is a reference for technical expertise at EU and international level .

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

CEFS represents European beet sugar manufacturers, cane sugar producers and refiners covering sugar production in 19 EU countries (Austria, Bulgaria, Belgium, Croatia, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Italy, Lithuania, Poland, Romania, the Netherlands, Slovakia, Spain, Sweden) plus the United Kingdom.

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

Our replies refer to the use of NGTs in plants

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

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

- Yes
- No
- Not applicable

\* Please provide details

CEFS members are sugar manufacturers that yearly process across the EU more than 108 million tonnes of sugar beet into sugar.

Reducing the use of plant protection products is an objective that the beet sugar chain has set already by committing to Integrated Pest Management which in turn has led to the use of techniques such as coated /pelleted seeds, optimising crop rotation, precision farming. More recently, the development of robotics and digital farming have also started complementing the agricultural toolbox.

Currently given the lack of appropriate normative framework there are no sugar beet New genomic techniques (NGTs) products on the European market. NGTs in sugar beet cultivation would be used by farmers to cultivate sugar beet which after sowing are collected and processed in factories by manufacturers to produce sugar.

But the investments in terms of R&D and the time required to overcome technical barriers have been and are so considerable that the legal uncertainty has so far prevented NGTs from becoming a permanent part of the agricultural toolbox and to bring further research also in EU sugar beet cultivation.

As soon as a clear normative framework that allows NGTs is available at the EU level, CEFS members are ready and would plan to use them.

The agricultural community in the EU and more specifically the European sugar beet chain faces several challenges: produce sufficiently for a growing population, produce sustainably to address environmental and climate change issues, ensure competitiveness in a sector that is exposed to international markets whilst generating a decent income.

To face these inevitable challenges, the development of NGTs is crucial not only for the agricultural community but also for the downstream industry chain and ultimately for the consumer.

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

- Yes
- No
- Not applicable

\* Please explain why not

At the moment given the lack of appropriate normative framework, there are no sugar beet NGT-products on the European market. Given the impossibility to distinguish among plants derived by conventional plant breeding and those obtained by NGTs, our view is that making reference to unintentional use is not appropriate.

The current situation where NGTs products fall under the GMO regulation creates a strong challenge as regards consumer acceptance.

However, based on the ECJ ruling, Member State authorities and operators are left with concrete queries as to how they should integrate the findings of the ECJ in practical and operational terms. If not properly guided, there are risks generating a patchwork of situations arising in the various EU Member States, which is detrimental to the farming community and as a result to the downstream production chain.

We support a thorough reflection and discussion to work out a workable and adapted solution. A legal framework for NGTs should be based on scientific evaluation, allowing to guarantee the safety of food produced via NBTs, with a clear process of evaluation and authorisation and regulatory costs in proportion to the potential markets.

CEFS members support the need that consumers can trust that the food on their plate is safe, even if produced via NGTs, that a scientific body needs to assess any potential health concerns and that a coherent and well-balanced regulatory process is in place.

NGTs are mostly unknown to consumers, as is their potential to reduce e.g. food waste and in lowering the environmental impact and cost of producing food. Ignorance breeds intolerance.

To raise awareness of the potential of NGTs, we look first and foremost to Plant Breeding companies and to the farming community. Moreover we firmly believe that decision-makers and notably EU decision-makers have a responsibility in reaching out to the public to contain unsubstantiated scare-mongering and give a factual explanation of what NBTs are and are not and what added-value they can bring to consumers.

\* 2 bis. Have you encountered any challenges?

Yes

No

\* Please provide details

The current situation where NGTs products fall under the GMO regulation creates a strong challenge as regards consumer acceptance.

As stated above, we support a thorough reflection and discussion to work out a workable and adapted solution. A legal framework for NGTs should be based on scientific evaluation, allowing to guarantee the safety of food produced via NGTs, with a clear process of evaluation and authorisation and regulatory costs in proportion to the potential markets.

\* 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

The investments in terms of R&D and the time required to overcome technical barriers have been and are so considerable that the legal uncertainty has so far prevented NGTs from becoming a permanent part of the agricultural toolbox and to bring achievements by plant breeders and further research also in EU sugar beet cultivation.

Provided that a clear normative framework allows NGTs, CEFS members are ready and would plan to use them.

\* **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

\* Please provide details

Currently given the lack of appropriate normative framework there are no sugar beet NGT-products on the European market. Given the impossibility to distinguish among plants derived by conventional plant breeding and those obtained by NGTs referring to unintentional use, in our view is not appropriate.

The current situation where NGTs products fall under the GMO regulation creates a strong challenge as regards consumer acceptance (see also reply to Q. 2).

\* **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

\* What challenges have you encountered?

Based on the ECJ ruling, Member State authorities and operators are left with concrete queries as to how they should integrate the findings of the ECJ in practical and operational terms. If not properly guided, there are risks of generating a patch-work of situations arising in the various EU Member States, which is detrimental to the farming community and the downstream production chain in any case.

CEFS members support the need that consumers are to be able to rely on the fact that the food on their plate is safe, that a scientific body needs to assess any potential health concerns and that a coherent and well-balanced regulatory process is in place.

We support a thorough reflection and discussion to work out a workable and adapted solution. A legal framework for NGTs should be based on scientific evaluation, allowing to guarantee the safety of food produced via NGTs, with a clear process of evaluation and authorisation and regulatory costs in proportion to the potential markets.

NGTs are mostly unknown to consumers, as is their potential to reduce e.g. food waste and in lowering the environmental impact and cost of producing food. And ignorance breeds intolerance.

To raise awareness of the potential of NGTs, we look first and foremost to Plant Breeding companies and to the farming community. Moreover we firmly believe that decision-makers and notably EU decision-makers have a responsibility in reaching out to the public to contain unsubstantiated scare-mongering and give a factual explanation of what NBTs are and are not and what added-value they can bring to consumers.

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

- Yes
- No
- Not applicable

**\* Do you have suggestions on possible traceability strategies and/or methods?**

- Yes
- No

**\* Please describe**

Given the lack of appropriate normative framework there are no sugar beet NGT-products on the European market. Given the impossibility to distinguish among plants derived by conventional plant breeding and those obtained by NGTs referring to traceability strategy specific for NGTs products in our view is not appropriate.

However, on the basis of the ECJ ruling, Member State authorities and operators are left with concrete queries as to how they should integrate the findings of the ECJ in practical and operational terms. If not properly guided, there are risks of generating a patch-work of situations arising in the various EU Member States, which is detrimental to the farming community and the downstream production chain in any case.

CEFS members support the need that consumers can trust that the food on their plate is safe, that a scientific body needs to assess any potential health concerns and that a coherent and well-balanced regulatory process is in place.

We support a thorough reflection and discussion to work out a workable and adapted solution. A legal framework for NGTs should be based on scientific evaluation, allowing to guarantee the safety of food produced via NBTs, with a clear process of evaluation and authorisation and regulatory costs in proportion to the potential markets.

NBTs are mostly unknown to consumers, as is their potential to reduce e.g. food waste and in lowering the environmental impact and cost of producing food. And ignorance breeds intolerance.

To raise awareness of the potential of NGTs, we look first and foremost to Plant Breeding companies and to the farming community. Moreover we firmly believe that decision-makers and notably EU decision-makers have a responsibility in reaching out to the public to contain unsubstantiated scare-mongering and give a factual explanation of what NGTs are and are not and what added-value they can bring to consumers.

**\* 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 explain why not



In our view there is no need for specific measures for NGT-products to ensure the compliance with the labelling requirements of the GMO legislation. Given the specific nature of NGTs the current GMO legislative and regulatory framework is not fit for purpose.

CEFS members support the need that consumers can trust that the food on their plate is safe, even if produced via NGTs, that a scientific body needs to assess any potential health concerns and that a coherent and well-balanced regulatory process is in place.

NGTs are mostly unknown to consumers, as is their potential to reduce e.g. food waste and in lowering the environmental impact and cost of producing food. And ignorance breeds intolerance.

To raise awareness of the potential of NGTs, we look first and foremost to Plant Breeding companies and to the farming community. Moreover we firmly believe that decision-makers and notably EU decision-makers have a responsibility in reaching out to the public to contain unsubstantiated scare-mongering and give a factual explanation of what NGTs are and are not and what added-value they can bring to consumers

- \* 8 bis. What challenges have you encountered?

See above reply 8

- \* **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 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**

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

- Yes
- No
- Not applicable

- \* Please explain why not

Currently given the lack of appropriate normative framework there are no sugar beet NGT-products on the European market.

NGTs are key complementary tools that can allow meeting society's demand to reconcile agricultural production with sustainability and respect for the environment. But the investments in terms of R&D and the time required to overcome technical barriers have been and are so considerable that the legal uncertainty has so far prevented NGTs from becoming a permanent part of the agricultural toolbox and to bring further research also in EU sugar beet cultivation.

Within the EU there are operational 13 Beet Research Institutes. They are composed by scientists and field trials operators that work on research projects for the European beet chains - in cooperation also with seed producers - and deliver technical information through a wide range of activities. They are equally supported by both European sugar manufacturers and beet growers.

Once a clear normative framework allowing the development of NGTs is put forward, EU Beet Research Institutes, are ready to take action and support all involved operators also in the research on genetics and new varieties.

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

- Yes
- No
- Not applicable

\* Please specify

NGTs are key complementary tools that can allow meeting society's demand to reconcile agricultural production with sustainability and respect for the environment. But the investments in terms of R&D and the time required to overcome technical barriers have been and are so considerable that the legal uncertainty has so far prevented NGTs from becoming a permanent part of the agricultural toolbox and to bring further research also in EU sugar beet cultivation. Breeders are looking also to sugar beet to obtain new varieties even with NGTs but the current normative framework evidently stops further innovation in this field even for sugar beet.

**\* 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

Breeders are looking also to sugar beet to obtain new varieties even with NGTs but the current normative framework evidently stops further innovation in this field even for sugar beet.

According to the information provided by seed companies the following consequences can be experienced:

- Stopping of R&D activities with NGTs
- Change of product focus to non-EU markets
- Re-evaluation of projects; planned projects did not start
- Moving R&D activities with NGTs out of EU

The EU's agricultural markets cannot be seen in isolation from global markets. Some of the EU's key trading partners (US, India, Canada, Japan,...) have developed or are in the process of developing a regulatory framework for NGTs. These regulatory frameworks are most often based on case-by-case assessment and do not systematically refer NGTs to the GMO framework.

By doing so, these trading partners allow for innovation, for underpinning R&D and commercial development of their economy. If the EU chooses a different path or leaves too much uncertainty for too long, the impact on the Plant Breeding industry and the agricultural sectors will be substantial. The EU risks lagging behind the rest of the world in terms of using innovative tools that allow sustainable progress of its agri-food chain.

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

- Yes
- No
- Not applicable

\* Please provide concrete examples/data

In the last 30 years sugar beet yields have increased by 2.2% per year. Moreover while areas over time have decreased, in 2018/19 yields were up 30% compared to 1989/90 (data EU 15, Source: CEFS sugar Statistics).

Breeding progress has been one of the key elements of the productivity gains achieved by the EU sugar beet chain. If the sector wants to further progress in this path, NGTs are even more needed also in the context of the current process of rapid removal of currently available Plant Protection Products (PPPs) and a slow development of new ones (e.g. PPPs containing low risks active substances). The absence of an appropriate transition to allow for the development of economically and environmentally sustainable crop, like we have witnessed in recent months and years, will jeopardise crop yields and quality.

There are not only economic issues in relation to productivity. The world is facing even more complex and unprecedented challenges:

- Increased greening programs will need breeds with natural resistance against diseases and insects;
- Climate changing is speeding up with the need for varieties with less water needs;
- Avoiding extensive use of pesticides and herbicides needs much more and precise and specific mechanical treatment on the fields;
- Organic farming will face its limits of possible production and needs to go hand in hand with the conventional one.

New Genomic Techniques in this respect are key complementary tools that will allow meeting society's demand to reconcile agricultural production with sustainability and respect for the environment. NGTs represents a crucial tool for further reduction of the use of Plant Protection Products and would inevitably accelerate plant variety selection. CEFS is committed to contribute to society and consumer expectations in view of healthy diets, biodiversity and a sustainable agricultural.

We are convinced that targeted mutagenesis breeding (including with genome editing) can contribute to various goals of the European Green Deal including the EU Farm to Fork and Biodiversity Strategies by saving land resources, reducing crop protection products, and emissions while stabilizing and increasing crop yields to ensure food security.

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

- Yes  
 No  
 Not applicable

**\* Please provide concrete examples/data**

NGTs are key complementary tools that can allow meeting society's demand to reconcile agricultural production with sustainability and respect for the environment. But the investments in terms of R&D and the time required to overcome technical barriers have been and are so considerable that the legal uncertainty has so far prevented NGTs from becoming a permanent part of the agricultural toolbox and to bring further research also in EU sugar beet cultivation.

Given the specific nature of NGTs the current GMO legislative and regulatory framework is not fit for purpose.

**\* 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

NGTs can speed up the development of new sugar beet varieties significantly.  
Main targets of breeding techniques for sugar beet are mainly sugar yields and sugar content, and resistances/tolerances against the main pests and disease like Rhizomania, nematodes and leaf diseases like cercospora beticola. Moreover, there are virus diseases like Virus yellows which is transmitted by aphids.

Sugar beet is generally protected from external damaging factors by different means. Plant Protection Products are used to prevent crop infection/infestation in situations where no other suitable solutions are available. Other crop protection techniques are used and go hand in hand with the use of Plant Protection Products such as coated/pelleted seeds, optimising crop rotation, precision farming. However not all crop infection/infestation can be tackled.

One example is Virus Yellows. Breeders efforts to date have been unable to identify major sources of resistance to virus yellow from global germplasm collections because virus yellow is a complex of three different virus species. Virus yellows can heavily damage the beet crop bringing the loss of productivity, in some case at the levels of 30% with huge economic losses both for farmers and the sugar producer. This is a consequence of climate change and lack of proper instruments. Research and Development is being intensified notably by a pre-breeding project exploring and developing the genetic diversity in beet relatives and identifying candidates showing resistance/tolerance to virus yellows. The aim is to develop beet varieties with durable and effective resistance to beet virus yellows without yield drag in the absence of disease, but such varieties are not expected to be available in the short term particularly without a clear normative framework.

If the sugar beet sector wants to further progress in its increasing competitiveness path, NGTs are even more needed also in the context of the current process of rapid removal of currently available Plant Protection Products (PPPs) and a slow development of new ones (e.g. PPPs containing low risks active substances). The absence of an appropriate transition to allow for the development of economically and environmentally sustainable crop, like we have witnessed in recent months and years, will jeopardise crop yields and quality.

*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

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

- Yes
- No

\* Please describe and provide concrete examples/data

In the last 30 years sugar beet yields have increased by 2.2% per year (data EU 15, Source: CEFS sugar Statistics). Breeding progress has been one of the key elements of the productivity gains achieved by the EU sugar beet chain. If the sector wants to further progress in this path, NGTs are even more needed also in the context of the current process of rapid removal of currently available Plant Protection Products (PPPs) and a slow development of new ones (e.g. PPPs containing low risks active substances). The absence of an appropriate transition to allow for the development of economically and environmentally sustainable crop, like we have witnessed in recent months and years, will jeopardise crop yields and quality.

There are not only economic issues in relation to productivity but the world is facing even more complex challenges:

- Increased greening programs will need breeds with natural resistance against diseases and insects;
- Climate changing is speeding up with the need for varieties with less water needs;
- Avoiding extensive use of pesticides and herbicides needs much more and precise and specific mechanical treatment on the fields;
- Organic farming will face its limits of possible production and needs to go hand in hand with the conventional one.

New Genomic Techniques in this respect are key complementary tools that will allow meeting society's demand to reconcile agricultural production with sustainability and respect for the environment. NGTs represents a crucial tool for further reduction of the use of Plant Protection Products and would inevitably accelerate plant variety selection. CEFS is committed to contribute to society and consumer expectations in view of healthy diets, biodiversity and a sustainable agricultural.

We are convinced that targeted mutagenesis breeding (including with genome editing) can contribute to various goals of the European Green Deal including the EU Farm to Fork and Biodiversity Strategies by saving land resources, reducing crop protection products, and emissions while stabilizing and increasing crop yields to ensure food security.

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

- Yes  
 No

\* Please explain

NGTs can speed up the development of new sugar beet varieties significantly by requiring less generations and plants to achieve the appropriate products.

\* **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

See reply to question 15.

History shows that when faced with challenges, society has always turned to innovation. Notably the agricultural sector has proven that the use of innovative techniques is the path to progress. With plant protection products being criticised and a general call to reduce their use, New Breeding Techniques are an efficient and necessary tool to accompany a new agricultural evolution.

Reducing the use of plant protection products is an objective that the maize and beet growers have set themselves already years ago by committing to Integrated Pest Management which in turn has led to the use of techniques such as coated/pelleted seeds, optimising crop rotation, precision farming,... More recently, the development of robotics and digital farming have also started complementing the agricultural toolbox.

NGTs are key complementary tools that will allow meeting society's demand to reconcile agricultural production with sustainability and respect for the environment. But the investments in terms of R&D and the time required to overcome technical barriers are so considerable that the uncertainty currently generated at EU level risks preventing NGTs from becoming mainstream and a permanent part of the agricultural toolbox.

In general:

- improved resistance against diseases to be able to use less pesticides in a more sustainable agriculture;
- improved resistance against abiotic stress in order to mitigate climate change effects on our food production;
- improved agronomic traits in order to safe crop yields, improve productivity, and avoid pre harvest losses.

The EU risks lagging behind the rest of the world in terms of using innovative tools that allow sustainable progress of its agri-food chain

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

Given the specific nature of NGTs the current GMO legislative and regulatory framework is not fit for purpose. Thorough reflection and discussion are needed to work out a workable and adapted solution.

In our view it is crucial to develop an adapted and workable regulatory framework that addresses the specificities of NGTs. This should not be built on the current regulatory GMO legislation given also the impossibility to distinguish among plants derived by conventional plant breeding and those obtained by NGTs (see also report of the Joint research Centre "Detection of food and feed plant products obtained by new mutagenesis techniques", published on 26 March 2019). A legal framework for NGTs should be based on scientific evaluation, allowing to guarantee the safety of food produced via NGTs, with a clear process of evaluation and authorisation and regulatory costs in proportion to the potential markets.

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

- Yes  
 No

\* Please explain

NGTs can speed up the development of new sugar beet varieties significantly by requiring less generations and plants to achieve the appropriate products.

**\* 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

Breeders are looking also to sugar beet to obtain new varieties even with NGTs but the current normative GMO legislative and regulatory framework evidently stops further innovation in this field also for SME. There could be opportunities but only with a revised legislative framework

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

- Yes  
 No

\* Please describe and provide concrete examples/data

In our view, if the use of NGTs can bring and provide innovation, access to them should be allowed.

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The maximum file size is 1 MB

## **D - Information on potential challenges and concerns on NGTs/NGT-products**

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

- Yes  
 No

\* Please describe and provide concrete examples/data



The EU's agricultural markets cannot be seen in isolation from global markets. Some of the EU's key trading partners (US, India, Canada, Japan,...) have developed or are in the process of developing a regulatory framework for NGTs. These regulatory frameworks are most often based on case-by-case assessment and do not systematically refer NGTs to the GMO framework.

By doing so, these trading partners allow for innovation, for underpinning R&D and commercial development of their economy. If the EU chooses a different path or leaves too much uncertainty for too long, the impact on the Plant Breeding industry and the agricultural sectors will be substantial. The EU risks lagging behind the rest of the world in terms of using innovative tools that allow sustainable progress of its agri-food chain.

Given the specific nature of NGTs the current GMO legislative and regulatory framework is not fit for purpose. Thorough reflection and discussion is needed to work out a workable and adapted solution.

To raise awareness of the potential of NBTs, we look first and foremost to Plant Breeding companies and to the farming community. Moreover we firmly believe that decision-makers and notably EU decision-makers have a responsibility in reaching out to the public to contain unsubstantiated scare-mongering and give a factual explanation of what NBTs are and are not and what added-value they can bring to consumers.

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

- Yes  
 No

\* Please explain

For classical transgenic GMOs all countries require premarket assessment

\* **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?**

- Yes  
 No

\* Please explain why not

NGTs are part of the agriculture toolbox. If they would not be usable, it would:

- prevent farmers in EU to use respective NGT plant varieties and all efforts towards more sustainable farming at risk
- prevent the use of less pesticides because farmers cannot access more resilient NGT varieties that are resistant against pests and diseases,
- put plant health at risk and make farmers less competitive.

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

- Yes  
 No

\* Please explain and provide concrete examples and data

Any additional regulatory requirements to those already applicable to all plant breeding products, including specifically excessive authorisation costs, the time needed for assessment and authorisation and any additional level of legal uncertainty are particularly prohibitive for smaller scale companies.

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

- Yes  
 No

\* Please describe and provide concrete examples/data

If products from mutagenesis are classified as GMO in the EU, a costly and burdensome traceability system would need to be set up. This could be circumvented using fraud due to the lack of reliable analytical detection methods.

Among other challenges:

- Potential limitation of access to germplasm and technology
- GMO regulation might increase complexity of licensing due to stewardship requirements
- GMO regulation specifically limits SMEs from investing in R&D with NGTs which consequently prevents them from being innovators and patent owners
- Consolidation effect especially under GM regulation

*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

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

Based on the ECJ ruling, Member State authorities are left with concrete queries as to how they should integrate the findings of the ECJ in practical and operational terms. If not properly guided, there are risks of generating a patch-work of situations arising in the various EU Member States, which is detrimental to the farming community and the downstream production chain in any case.

Consumers need to be able to trust that the food on their plate is safe, that a scientific body needs to assess any potential health concerns and that a coherent and well-balanced regulatory process is in place.

Given the impossibility to distinguish among plants derived by conventional plant breeding and those obtained by NGTs we consider NGTs/NGT-products as safe as varieties obtained via conventional breeding and would be subject to same safety and quality checks applied by EU sugar manufacturers also for products obtained via conventional breeding.

We call on the EU Commission to explore, in close cooperation with Member States and stakeholders, the development of such a framework soon. The EU beet sugar chain is ready to contribute with the support of their relevant Beet Research Institutes equally supported by both European sugar manufacturers and beet growers.

Once a clear normative framework allowing the development of NGTs is put forward, EU Beet Research Institutes, are ready to take action and support all involved operators also in the research on genetics and new varieties.

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

Yes

No

\* Please explain why not

Based on the ECJ ruling, Member State authorities are left with concrete queries as to how they should integrate the findings of the ECJ in practical and operational terms. If not properly guided, there are risk of generating a patch-work of situations arising in the various EU Member States, which is detrimental to the farming community and the downstream production chain in any case.

Consumers need to be able to rely on the fact that the food on their plate is safe, even if produced via NGTs, that a scientific body needs to assess any potential health concerns and that a coherent and well-balanced regulatory process is in place.

Given the specific nature of NBTs however, the current GMO legislative and regulatory framework is not fit for purpose.

Given the impossibility to distinguish among plants derived by conventional plant breeding and those obtained by NGTs we consider NGTs/NGT-products as safe as varieties obtained via conventional breeding and would be subject to same safety and quality checks applied by EU sugar manufacturers also for products obtained via conventional breeding.

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

## F - Ethical aspects of NGTs/NGT-products

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

History shows that when faced with challenges, society has always turned to innovation. Notably the agricultural sector has proven that the use of innovative techniques is the path to progress. With plant protection products being criticised and a general call to reduce their use, New Breeding Techniques are an efficient and necessary tool to accompany a new agricultural evolution.

Reducing the use of plant protection products is an objective that beet growers have already set themselves by committing to Integrated Pest Management which in turn has led to the use of techniques such as coated /pelleted seeds, optimising crop rotation, precision farming,... More recently, the development of robotics and digital farming have also started complementing the agricultural toolbox.

NGTs are key complementary tools that will allow meeting society's demand to reconcile agricultural production with sustainability and respect for the environment. But the investments in terms of R&D and the time required to overcome technical barriers are so considerable that the uncertainty currently generated at EU level risks preventing NBTs from becoming mainstream and a permanent part of the agricultural toolbox.

We are convinced that targeted mutagenesis breeding (including with genome editing) can contribute to various goals of the European Green Deal including the EU Farm to Fork and Biodiversity Strategies by saving land resources, reducing crop protection products, and emissions while stabilizing and increasing crop yields to ensure food security.

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

- Yes  
 No

\* Please explain

See Reply N. 26

History shows that when faced with challenges, society has always turned to innovation. Notably the agricultural sector has proven that the use of innovative techniques is the path to progress. With plant protection products being criticised and a general call to reduce their use, New Breeding Techniques are an efficient and necessary tool to accompany a new agricultural evolution.

Reducing the use of plant protection products is an objective that beet growers have set themselves already years ago by committing to Integrated Pest Management which in turn has led to the use of techniques such as coated/pelleted seeds, optimising crop rotation, precision farming,... More recently, the development of robotics and digital farming have also started complementing the agricultural toolbox.

NGTs are key complementary tools that will allow meeting society's demand to reconcile agricultural production with sustainability and respect for the environment. But the investments in terms of R&D and the time required to overcome technical barriers are so considerable that the uncertainty currently generated at EU level risks preventing NGTs from becoming mainstream and a permanent part of the agricultural toolbox.

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## **G - Consumers' right for information/freedom of choice**

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

CEFS supports clear, informative, science-based, and non-misleading labelling of food products to help consumers make informed choices. The implementation of Regulation (EU) 1169/2011 on food information to consumers (FIC), establishes the general principles, requirements, and responsibilities governing food information, including food labelling.

As regards NGTs it must be noted that labelling requires traceability, an aspect that links to the enforcement of any legislation that distinguishes products based on the plant breeding strategies used, whether conventional, GM, NGTs or another categorisation.

If products from mutagenesis are classified as GMO in the EU, a costly and burdensome traceability system would need to be set up. This could be circumvented using fraud due to the lack of reliable analytical detection methods. The current situation where NGTs products fall under the GMO regulation creates a strong challenge as regards consumer acceptance. Moreover, given the impossibility to distinguish among plants derived by conventional plant breeding and those obtained by NGTs any specific labelling related to NGTs would risk misleading consumers.

Based on the ECJ ruling, Member State authorities are left with concrete queries as to how they should integrate the findings of the ECJ in practical and operational terms. If not properly guided, there are risks of generating a patchwork of situations arising in the various EU Member States, which is detrimental to the farming community and the downstream production chain in any case.

Consumers need to be able to rely on the fact that the food on their plate is safe, that a scientific body needs to assess any potential health concerns and that a coherent and well-balanced regulatory process is in place.

We call on the EU Commission to explore, in close cooperation with Member states and stakeholders, the development of such a framework soon.

The need for information sharing must be acknowledged to:

- 1) enable regulators to control compliance of operators with respective regulations,
- 2) provide different markets with specific requirements as well as the respective market operators and consumers with relevant reply to further individual/private information requests from customers.

Further information requirements on breeding methods that will be shared publicly must:

- be meaningful and scientifically appropriate,
- not discriminate innovative companies and products,
- assure a level playing field between operators EU wide, but also internationally and
- avoid consumer misinformation and fraud, especially in view of the international context and the lack of distinguishability regarding NGTs and conventional products.

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## H - Final question

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

Yes

No

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## **Contact**

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