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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

International Confederation of European Beet Growers - C.I.B.E. or CIBE - TR n°89930126483-54

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

CIBE defends and represents the interests of sugar beet growers vis-à-vis European Institutions and international organisations since 1927. We facilitate contact between our members and provide platforms for information, analyses and exchanges. Our aim is to promote technical progress, innovation in the cultivation of sugar beet and efforts to strengthen the position, competitiveness and sustainability of European/EU sugar beet growers and the European/EU beet sugar sector. Since sugar beet is grown in rotation with other arable crops (e.g. wheat, barley, maize, potatoes, peas, sunflowers, oilseed rape), these crops are of course also of interest to CIBE and its members.

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

All of CIBE's member associations (EU as well as non-EU) were consulted during the drafting of CIBE's response to this questionnaire, to wit:
1. Confédération des Betteraviers Belges/Confederatie van de Belgische Bietenplanters - CBB
2. Svaz pěstitelů cukrovky Čech - SPCC
3. Danske Sukkerroedyrkere - DKS
4. Dachverband Norddeutscher Zuckerrübenanbauer e.V. - DNZ
5. Verband Süddeutscher Zuckerrübenanbauer e. V. - VSZ
6. Rheinischer Rübenanbauer-Verband e. V. - RRV
   - the 3 German organisations are grouped under a coordination body: Arbeitsgemeinschaft Deutscher Rübenbauerverbände - ADR
7. Confédération Générale des Planteurs de Betteraves — CGB
8. Fédération Nationale des Coopératives de collecte et de transformation de la Betterave — FCB
10. Cooperativa Produttori Bieticoli – COPROB
11. Cukorrépa Termesztők Országos Szövetsége – CTOSZ
12. Koninklijke Coöperatie Cosun U.A. /Royal Cosun
13. Die Rübenbauern — Vereinigung der österreichischen Rübenbauernorganisationen / VÖR
14. Krajowy Związek Plantatorów Buraka Cukrowego – KZPBC
15. Federaţia cultivatorilor de sfeclă de zahăr din România - FCSZR
16. Zväz pestovateľov cukrovej repy Slovenska — ZPCRS
17. Central Union Of Agricultural Producers - MTK
18. Betodlarna
19. National Farmers' Union — NFU SUGAR BOARD
20. Fédération Suisse des Betteraviers - FSB/Schweizerischer Verband der Zuckerrübenpflanzer - SVZ
21. PANKOBIRLIK — Pancar Ekicileri Kooperatifleri Birligi "Union of The Beet Growers Cooperatives"

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

CIBE considers new breeding techniques (NBTs) or new genomic techniques (NGTs) as breeding techniques developed and/or discovered after 2001. Products (notably plants) developed by these NGTs cannot be distinguished from products (notably plants) obtained by:
- conventional/traditional plant breeding;
- mutations that occur spontaneously in nature;
- the techniques listed in Annex 1.B. of Directive 2001/18, i.e.:
*mutagenesis;
*cell fusion (including protoplast fusion) of plant cells or organisms that can exchange genetic material through traditional breeding methods.
Essentially, our focus is on those applications NGTs & applications of NGTs that lead to plants that could also have been obtained using older/earlier conventional/traditional breeding methods, or that might have been obtained from natural processes without human intervention, e.g. spontaneous mutagenesis in nature. This includes plants where:
1. there is no novel combination of genetic material (i.e. there is no stable insertion in the plant genome of one or more genes that are part of a designed genetic construct) or
2. the final plant product contains only the stable insertion of inherited genetic material from sexually compatible plant species or
3. the genetic variation is the result of spontaneous or induced mutagenesis.

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 explain why not

European sugar beet growers do not develop NGTs/NGT-products. European sugar beet growers do not use sugar beet varieties obtained by NGTs because such varieties are not yet available. As far as we know, no such NGT sugar beet varieties exist yet. However, our members plan to and will be ready to use NGT-products (i.e. sugar beet varieties obtained by NGTs) once these will be available and provided that they give rise to improved beet varieties to help tackle the multiple present and future challenges, resulting in particular from the reduction of availability of plant protection products (PPPs) and from climate change.
Such NGT-derived sugar beet varieties would be adopted by growers if they provide certain advantages, notably:
- good agromonic characteristics (yield, quality, input use efficiency, productivity, general VCU (Value for Cultivation and Use) characteristics),
- resistance and/or tolerance to diseases & pests and/or to damage from pests,
- resilience to climate change related stresses (drought, excess rainfall, greater intra- and inter-day temperature fluctuations).
However, in order to be adopted by growers, such NGT-derived sugar beet varieties would also need to be:
- available on the European market,
- accepted by the buyers (consumers and/or agri-food chain), i.e. contractual conditions with sugar beet processors/purchasers do not exclude/forbid/ban the use of sugar beet varieties obtained by NGTs.
Last but not least, given that sugar beet growers grow sugar beet in rotation with other arable field crops, they would certainly be ready to adopt NGT-derived improved varieties of other arable crops commonly grown in rotation with sugar beet (e.g. wheat, barley, maize, potatoes, sunflowers, oilseed rape), provided of course such NGT-derived improved varieties provide certain advantages, notably:
- good agromonic characteristics (yield, quality, input use efficiency, productivity, general VCU (Value for Cultivation and Use) characteristics),
- resistance and/or tolerance to diseases & pests and/or to damage from pests,
- resilience to climate change related stresses (drought, excess rainfall, greater intra- and inter-day temperature fluctuations).
However, in order to be adopted by growers, such NGT-derived varieties of arable crops commonly grown in rotation with sugar beet would also need to be available on the EU market and accepted by the buyers.

* **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

There are no such NGT-products on the EU market for the moment. Nevertheless, given the fact that NGTs currently have to comply with GMO regulation and given the inevitable consequences on consumer perception, behaviour and choice, sugar beet processors and downstream users of products derived from sugar beet would very likely have to try to protect themselves in the same manner as they have done vis-à-vis GM-sugar beet, i.e. to ban such NGT sugar beet varieties from any sugar beet growing contract. A similar situation is likely to arise in the case of NGT-derived varieties of other arable crops commonly grown in rotation with sugar beet (e.g. wheat, barley, potatoes, maize, sunflowers, oilseed rape).

* 2 bis. Have you encountered any challenges?

- ◉ Yes
- ○ No

* Please provide details

With regards to mutagenesis techniques, as there is no way to determine whether a mutation has been induced by an NGT or is a spontaneous mutation, it is difficult to see how it can be possible to protect against unintentional use of NGT-products if these cannot be distinguished from non-NGT-products. Nevertheless, given the fact that NGTs currently have to comply with GMO regulation, and given the inevitable consequences on consumer perception, behaviour and choice, sugar beet processors and downstream users of sugar beet products are very likely to have to try to protect themselves in the same manner as they have done vis-à-vis GM-sugar beet, i.e. to ban such NGT sugar beet varieties from any sugar beet growing contract. A similar situation is likely to arise in the case of NGT-derived varieties of other arable crops commonly grown in rotation with sugar beet (e.g. wheat, barley, potatoes, maize, sunflowers, oilseed rape).

*** 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

We are aware of such initiatives, but do not have access to concrete details because of confidentiality in the research & and development. However, plant breeders (and notably companies involved in breeding improved sugar beet varieties such as for example Deleplanque/Strube, KWS and SESvdH/Florimond Desprez) have clearly stated the potential of NGTs to contribute to the faster and more targeted development of new, improved crop varieties (including sugar beet) varieties to help tackle the changing, multiple, complex and specific challenges, resulting in particular from the reduction of availability of plant protection products (PPPs) and from climate change.
Since beet growers grow other arable crops in rotation with sugar beet, the same applies to other arable crops commonly grown in rotation with sugar beet (e.g. wheat, barley, potatoes, maize, sunflowers, oilseed rape).
NGTs complement breeders' and farmers' tool boxes and offer additional opportunities to enhance plant breeding. Plant breeders respond to the challenges for sustainable agriculture (climate change, new fungal infections, the desire for less chemicals on the field and for high-quality agricultural products) with new varieties, using the most suitable breeding methods, and they see great potential in NGTs thanks to their simplicity of use. Breeders consider that NGTs can add to farmers' tool boxes because they allow breeding objectives to be achieved more quickly and precisely than ever before, thereby expanding the genetic variation of a wider variety of crops and contributing to ensuring yield progress, improved resistance of plants against diseases, pests and abiotic stress, high quality of seeds and agricultural products, reducing the use of resources &, boosting energy and nutrient content. Even niche crops and crops that are very expensive to breed can benefit from breeding progress.
NGT-derived sugar beet varieties which cannot be distinguished from varieties obtained by spontaneously occurring mutations may help European growers, consumers and the environment. European beet growers are ready to adopt NGT-derived sugar beet varieties with characteristics that meet societal and market demands and that have environmental and economic advantages for beet growers. The current strict interpretation of the GMO directive vis-à-vis NGTs risks continuing to prevent/discourage European universities, research institutions and plant breeders from developing and making use of safe and precise mutagenesis techniques, European sugar beet growers risk being left behind in global development. Since beet growers also grow other arable crops in rotation with sugar beet, the same applies to other arable crops commonly grown in rotation with sugar beet (e.g. wheat, barley, potatoes, maize, sunflowers, oilseed rape).

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

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

* Please provide details

There are no such NGT-products (sugar beet or other arable crops commonly grown in rotation with sugar beet) on the EU market for the moment. However, given the fact that NGTs currently have to comply with the GMO regulation, sugar beet processors and downstream users of sugar beet products would very likely have to try to protect themselves in the same manner as they have done vis-à-vis GM- sugar beet, i.e. to ban such NGT sugar beet varieties from any sugar beet growing contract. The same would apply to NGT-derived varieties of other arable crops commonly grown in crop rotation with sugar beet (e.g. wheat, barley, potatoes, maize, sunflowers, oilseed rape).

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

- (●) Yes
- ( ) No

* Please provide details

It is too early to provide any detail about such challenges, given that, as far as we are aware, to date no sugar beet varieties obtained by NGTs are on the market and/or being developed/registered for market approval. The same applies, for the time being, to other arable crops commonly grown in rotation with sugar beet (e.g. wheat, barley, potatoes, maize, sunflowers, oilseed rape). However, it is our understanding that, since NGTs currently have to comply with the GMO regulation, and given the inevitable consequences on consumer perception, behaviour and choice, sugar beet processors and downstream users of sugar beet products would very likely have to try to protect themselves in the same manner they have done vis-à-vis GM-beet, i.e. to ban such NGT varieties from beet growing contracts.
The big challenge is of course that since there is no way to determine whether a mutation has been induced by an NGT or is a spontaneous mutation, it is difficult to see how it is possible to protect against:

- unintentional use of NGT-products
- intentional but not necessarily declared and/or traceable use of NGT-products

by third country competitors, leading to a non-level playing field as regards:

1-production (growers in other countries may be able to use varieties obtained by NGTs while growers in Europe may be prevented from doing so due to the current regulatory framework),

2-trade (third countries exporting NGTs and/or NGT-products (e.g. sugar obtained from the processing of sugar beet and/or sugar cane varieties obtained by NGTs) to Europe, without Europe being able to identify such products as obtained by NGTs,

3-marketing (such products from third countries being sold in Europe without being necessarily labelled – and certainly not being readily identifiable by the relevant EU and MS authorities, let alone by consumers – as arising by NGTs),

if these NGT-products cannot be distinguished from non-NGT-products and thus be clearly identified as NGT /NGT products.
On the other hand, the current regulatory situation in Europe may turn out to be so prohibitive for research and development efforts that NGT-derived sugar beet varieties even remotely ready for market approval in Europe may never materialise in the first place. The same would apply to NGT-derived varieties of other arable crops commonly grown in crop rotation with sugar beet (e.g. wheat, barley, potatoes, maize, sunflowers, oilseed rape).

* **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

* Please explain why not

For the moment there are no sugar beet varieties obtained by NGTs on the market. For the future, we consider that plants (in our specific case, sugar beet) obtained by NGTs such as mutagenesis should not be requested to comply with GMO legislation if they could have been obtained via conventional breeding (or spontaneous mutation) and are thus indistinguishable from sugar beet obtained by conventional breeding. If there is no change in the regulatory situation, then, given that NGTs currently have to comply with the GMO regulation, and given the inevitable consequences on consumer perception, behaviour and choice, sugar beet processors and downstream users of sugar beet products would very likely have to try to protect themselves in the same manner they have done vis-à-vis GM-beet, i.e. to ban such NGT varieties from beet growing contracts. The same would apply to NGT-derived varieties of other arable crops commonly grown in crop rotation with sugar beet (e.g. wheat, barley, potatoes, maize, sunflowers, oilseed rape).
Furthermore, the choice made by Austria, Wallonia in Belgium, Scotland, Wales & Northern Ireland in the UK, Bulgaria, Croatia, Cyprus, Denmark, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland and Slovenia to be excluded from requests for the approval of GMOs to be cultivated across the EU strongly limits from the outset the EU market for the cultivation of plant /crop varieties obtained by NGTs.

* 5 bis. What challenges have you encountered?

NGT-derived arable crop varieties are simply not available on the EU market and, given the current prohibitive regulatory context, probably never will become available to EU growers.

* **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?

Our sector is not facing such a situation yet as regards NGTs (there being no NGT-derived sugar beet varieties on the European market). The few GMO sugar beet varieties that do exist have never been authorised by beet growing contracts in Europe and are therefore effectively banned from being grown in Europe. At the same time, we are aware that GM sugar beet has been grown in the USA for over 10 years. If the regulatory context in the EU remains unchanged, then, given that NGTs currently have to comply with the GMO regulation, sugar beet processors and downstream users of sugar beet products would very likely have to try to protect themselves in the same manner they have done vis-à-vis GM-beet, i.e. to ban such NGT sugar beet varieties from sugar beet growing contracts. The same would apply to NGT-derived varieties of other arable crops commonly grown in crop rotation with sugar beet (e.g. wheat, barley, potatoes, maize (adoption of GM maize varieties currently exceeds 90% in major producers such as the USA, Brazil & Argentina, while it is limited to some 120 000 ha in the EU, less than 1% of the EU's maize area), sunflowers, oilseed rape).
Furthermore, the choice made by Austria, Wallonia in Belgium, Scotland, Wales & Northern Ireland in the UK, Bulgaria, Croatia, Cyprus, Denmark, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland and Slovenia to be excluded from requests for the approval of GMOs to be cultivated across the EU strongly limits from the outset the EU market for the cultivation of plant /crop varieties obtained by NGTs.

* **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

We consider that traceability studies used for tracing GM-products (such as for example GM sugar beet) cannot be used for tracing plants/products obtained via NGT mutagenesis insofar as these could have also been obtained via conventional breeding and would thus be indistinguishable from products (such as sugar beet) obtained via conventional breeding. The same would apply to NGT-derived varieties of other arable crops commonly grown in crop rotation with sugar beet (e.g. wheat, barley, potatoes, maize, sunflowers, oilseed rape).
Therefore, we consider it futile and a waste of resources to try to distinguish products obtained via NGT (notably mutagenesis), from those obtained via conventional breeding if the products obtained via NGT (notably mutagenesis) could have also been obtained via conventional breeding and are thus indistinguishable from those products. The Joint Research Centre (JRC) concluded that validation of an event-specific detection method and its implementation for market control is not feasible for NGT plant products carrying a DNA alteration that is not unique. That being said, European beet growers, like European farmers in general, are currently subject to traceability rules applied by food, feed and biofuel business operators (including for example organic beet and sustainable agriculture criteria). Record keeping carries a financial & human resource cost which will be passed down the chain to the primary producer. Costs must always be proportionate to the benefits and value they bring to the supply chain, consumers, society and/or the environment.

* **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

We replied "No" to question 8

* What best practices can you share?

We replied "No" to question 8

* Please explain why not

For the time being there are no sugar beet varieties obtained via NGT on the market. We consider that plants (in our specific case, sugar beet, but also varieties of other arable crops commonly grown in rotation with sugar beet) obtained by NGTs (notably mutagenesis) should not be requested to comply with the GMO legislation if they could have been obtained via conventional breeding (and/or spontaneous mutation) and are thus indistinguishable from sugar beet obtained via conventional breeding. Otherwise, it would mean having to label products obtained via NGTs (notably mutagenesis) which would be indistinguishable from products obtained via conventional breeding and which would not be labelled. The same would apply to NGT-derived varieties of other arable crops commonly grown in crop rotation with sugar beet (e.g. wheat, barley, potatoes, maize, sunflowers, oilseed rape).

* 8 bis. What challenges have you encountered?

Labelling would require traceability of NGT-products and of products derived from NGT products, including proper identification and quantification. The Joint Research Centre (JRC) concluded that validation of an event-specific detection method and its implementation for market control is not feasible for NGT plant products carrying a DNA alteration that is not unique.

* **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:

- ☑ Agri-food sector
- ☐ Industrial sector
- ☐ Medicinal sector

Agri-food sector

To the best of our knowledge, the GMO legislation applies to only 5 experimental releases concerning NGTs, notified at the Register for Deliberate release into the environment of plants GMOs for any other purposes than placing on the market (experimental releases) https://gmoinfo.jrc.ec.europa.eu/gmp_browse.aspx

- Notification B/ES/20/01: Field test of the development of tobacco cv K326 plants derived (by self-pollination) from lines L157-5, L192-6, L226-2 and L259-1, with mutations in the sequence of SPL transcription factors, generated by CRISPR / Cas9, 2020 campaign.
- Notification B/SE/19/5614: Potato lacking amylose starch
- Notification B/BE/19/V1: Scientific field evaluation of maize with an impaired DNA-repair mechanism
- Notification B/GB/19/52/01: Genetic regulation of Sulphur metabolism in Brassica oleracea
- Notification B/BE/18/V8: Scientific field evaluation of maize with an impaired DNA-repair mechanism and maize with modified growth characteristics

It is our understanding that applicants have not been able to provide a detection method for these trials under GMO requirements that can prove with enough certainty that plants that contain a particular mutation were developed by using NGTs.

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 explain why not

Our members are beet growers' associations & as such do not themselves carry out research. For the time being, research programmes related to sugar beet (such as the 8-year AKER project, in which the French Beet Research Institute ITB participates) have concentrated on conventional breeding - a long research route that necessitates significant investments. However, they do not by any means exclude the use of NGTs for future research/breeding programmes! Such NGTs could rapidly become part of research and breeding programmes in our sector (and ultimately of the beet growers' toolbox), were it not for the current regulatory context - which effectively prevents NGTs from being integrated into research & breeding programmes and from being adopted by plant breeders in their efforts to develop new beet varieties which can respond better to the current and future challenges, notably due to reduced availability of PPPs and due to climate change.

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

- ◉ Yes
- ○ No
- ○ Not applicable

* Please specify

We are aware that research is going on in our sector, involving for example:
- sugar beet breeding companies (such as for example the Genetics and Biotechnology Lab at NUI Galway working closely with plant breeding company KWS SAAT to develop genetic breeding strategies to produce hybrid sugar beet varieties with higher yield that can maintain high levels of sugar production),
- a Russian federal programme aiming to create 10 new varieties of gene-edited crops (with barley, sugar beet, wheat and potatoes listed as priorities) and animals by 2020 — and another 20 by 2027. Projects to develop gene-edited versions of these crops are already under way. Scientists at RAS institutes in Moscow are developing pathogen-resistant varieties of potatoes and sugar beet, while gene-editing research aiming to make barley and wheat both easier to process and more nutritious is in progress at the Vavilov Research Institute of Plant Industry in St Petersburg, and at the RAS Institute of Cytology and Genetics.
However, for reasons of confidentiality we are not in a position to provide detail. In our view, plant breeders, who recognise the potential of obtaining improved sugar beet varieties via NGTs, are looking into these NGTs but are - for the moment - not aiming to develop NGTs for the market due to the current status of NGTs as being the same as GMOs - which effectively closes the door for them at EU level.
We are also aware of NGT-related research in crops commonly grown in rotation with sugar beet, such as wheat, barley, maize, potatoes, sunflowers and oilseed rape. Examples include:
Wheat with resistance to powdery mildew
Wheat with increased grain weight and protein content
Barley with resistance against wheat dwarf virus
Maize with drought-stress tolerance
Maize with high amylopectin content
Potatoes with resistance to late blight (Phytophthora)
Potatoes with resistance to potato virus Y infection and tolerance to salt and osmotic stress
Sunflowers with drought-stress tolerance
Sunflowers with resistance against sclerotinia stem rot
Oilseed rape with resistance against sclerotinia stem rot
Oilseed rape with increased shatter resistance (avoids seed loss during mechanical harvesting).

*** 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

We consider that the Court of Justice of the EU ruling on mutagenesis has had a very negative impact on NGT-related research in the sugar beet sector. Since that ruling essentially considers - or is at least perceived by stakeholders to essentially consider - NGT mutagenesis as being GM and therefore having to confirm with GMO legislation, sugar beet breeders, while continuing to research into/with NGTs, will not - for the moment - aim to develop improved sugar beet varieties obtained via NGTs for the European market (i.e. for cultivation in Europe). The current regulatory context in the EU is simply too prohibitive. We consider that the ruling has had a similarly negative impact on NGT-related research on other crops commonly grown in crop rotations with sugar beet (e.g. wheat, barley, maize, potatoes, sunflowers and oilseed rape).
In this context, we are aware of concerns:
- in the scientific community that the decision is hampering its R&D work and putting up barriers and costs that do not have a commensurate effect for society and/or the environment, as expressed in a letter to Commission President Juncker in January 2019 and signed by 98 European research centers that have supported the position statement “Regulating genome editing as GMOs has negative consequences for agriculture, society and economy”. ;
- in the farming community in general and among sugar beet growers in particular (who often co-fund R&D related to sugar beet) that unless there is a change in the regulatory context, they will probably never even be given the opportunity to evaluate and adopt improved sugar beet varieties obtained via NGTs.

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

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

* Please provide concrete examples/data

NGT-related research can contribute to further improving the progress achieved made so far in the sustainability in sugar beet achieved by conventional breeding research (yield & quality, resistance to disease (s), improved input use efficiency), by being much faster and more targeted, allowing to find solutions in a reasonable time-frame to the present and future complex, specific, rapidly changing and multiple challenges (e.g. multiple tolerance/resistance to pests/diseases, improved resilience to abiotic stress factors such as drought & excessive rainfall), brought on notably by the reduction in the availability of PPPs and by climate change (more pests & diseases), by developing more situation-specific, multi-talented varieties. NGTs represent opportunities vis-à-vis conventional breeding, which is reaching its limits (slow, difficult to target several traits at same time, difficult to respond to multiple challenges (PPP availability, climate change), not just maintaining but improving productivity and thus sustainability). To put it bluntly: it can take 7 to 10 years for conventional plant breeding to develop minor improvements to existing traits.
To remain competitive and sustainable, sugar beet growers must:
- be able to continue to rely on public and private research activities (in the financing of which the sector, growers and processors, participates) to achieve the goals to adapt to climate change, fewer PPPs etc. and
- demand and have access to varieties which can help resolve these issues.

Developing improved sugar beet varieties that make optimal use of the genetic potential within the crop is key to meeting market & societal demand, social sustainability goals and to addressing the challenges arising from climate change and reduced availability of PPPs.
The same applies to other arable crop commonly grown in crop rotation with sugar beet (e.g. wheat, barley, maize, potatoes, sunflowers and oilseed rape).

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

- (●) Yes

- ○ No
- ○ Not applicable

* Please provide concrete examples/data

The principal challenge for NGT-related research in our sector is the current regulatory situation in the EU, which considers plant/crops obtained by NGTs as GMOs. This discourages plant breeders in general, including sugar beet breeders, from committing investment to market-oriented research to obtaining improved sugar beet varieties via NGTs which can be put on the market in Europe. We understand that the same also applies to arable crops commonly grown in crop rotation with sugar beet (e.g. wheat, barley, maize, potatoes, sunflowers and oilseed rape).

*** 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

With the increasing loss of plant protection products, research is inter alia turning to breeding to obtain improved sugar beet varieties which can cope better with several pests and diseases against which they can no longer be protected via PPPs, while at the same time continuing to improve their agronomic traits (yield, quality, input use efficiency). The same applies to other arable crops commonly grown in crop rotation with sugar beet (e.g. wheat, barley, maize, potatoes, sunflowers and oilseed rape). We therefore see NGTs as a tool that we need to add to our ever shrinking agronomical tool box, a tool which can speed up/help find solutions – NGTs are an essential building block to help growers carry on producing sustainably. If the current regulatory situation/context continues, there will simply be no (or at best nowhere near enough) research in our sector incorporating NGTs in trying to obtain improved sugar beet varieties to address the current and future complex, specific and multiple challenges, brought about by notably climate change and reduced availability of PPPs. It is therefore essential that research in European universities and in the European plant breeding sector (in our particular case, the sugar beet breeding companies) have access to the same breeding techniques (including NGTs) as other parts of the world.
Ultimately, no research activity and public funding will overcome the regulatory hurdles and costs associated with the current GMO regulation when it comes to the requirements of providing “unique identifiers” as soon as plants obtained by NGTs are supposed to be released for field trials.
We consider that the same also applies to arable crops commonly grown in crop rotation with sugar beet (e. g. wheat, barley, maize, potatoes, sunflowers and oilseed rape).

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

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C - Information on 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

NGT sugar beet varieties and/or sugar beet varieties derived from NGTs can contribute to further improving the progress made so far in the sustainability of sugar beet cultivation achieved by conventional breeding (yield & quality, resistance to disease(s), resilience to abiotic stressed arising from/related to climate change, improved input use efficiency), by being faster and more targeted, allowing to find solutions in a reasonable time-frame to the present and future complex, specific, rapidly changing and multiple challenges (e.g. multiple tolerance/resistance), brought on notably by the reduction in the availability of PPPs and by climate change (more pests & diseases), by developing more situation-specific, multi-talented varieties i.e. with good yield and quality traits as well as being efficient input (e.g. fertiliser) users and tolerant/resistant to several pests and diseases. NGTs represent opportunities vis-à-vis conventional breeding, which is reaching its limits (slow, difficult to difficult to target several traits at same time, difficult to respond to multiple challenges (PPP availability, climate change), not just maintaining but improving productivity).
Regarding sugar beet, NGTs may be used to obtain (and considerably faster than by conventional breeding) traits which are agronomically desirable, including from a sustainability point of view (reduced production inputs, alternatives to chemical plant protection products):

- Agronomic traits to further improve productivity/yield directly, such as higher sugar content and higher root yield, but also other indirect productivity and/or sustainability enhancing traits, such as faster growth & quicker establishing (thus controlling weeds quicker and requiring less herbicide treatment), quick(er) & deep (er) rooting varieties (enhanced early nutrient uptake & enhanced rapid canopy expansion), high/improved nitrogen use efficiency (NUE), easier to clean during harvesting, less susceptible to damage during harvesting, lower losses during storage after harvest and before processing, bolting resistance.
- Traits of resistance/tolerance to abiotic stress (e.g. drought)
- Traits of tolerance/resistance to biotic stress, such as virus yellows, Aphanomyces, Rhizomania (notably new strains of rhizomania, capable of overcoming current varietal resistance and thus posing a serious threat to current resistant varieties; if no further sources of novel resistance genes are identified, the likelihood of a future breakdown in rhizomania resistance is high), Rhizoctonia, Nematodes, leaf diseases such as Cercospora, Powdery Mildew, Ramularia & Rust, damping off diseases such as Fusarium, Alternaria and Pythium and pests such as aphids, weevils, beet flea beetles, moths, wireworms, springtails, symphylids, millipedes, pygmy beetles, leaf miners/mangold flies, etc.

Regarding other arable crops commonly grown in crop rotation with sugar beet, there are already some concrete examples of potential NGT applications in:
Wheat with:
resistance to powdery mildew,
increased grain weight & protein,
with longer seed dormancy period (may result in reduced pre-harvest sprouting of grains on spikes);
Barley with with highly efficient resistance against wheat dwarf virus;
Maize with:
high amylopectin content,
tolerance to drought stress;
Potatoes with:
high amylopectin content,
resistance to late blight,
increased resistance to potato virus Y infection & increased tolerance to salt & osmotic stress;
Oilseed rape with:
enhanced resistance against sclerotinia stem rot,
with increased shatter resistance (to avoid seed loss during mechanical harvest and to reduce the risk of weed oilseed rape in the succeeding crops).

Currently, there are no products/varieties derived from NGTs nearing market introduction in Europe, so at this stage NGTs are not bringing benefits/opportunities to Europe's beet/sugar sector. We see NGTs as a major part of the solution to the production challenges facing our sector in its efforts to:
- provide food, feed, energy and other products (notably biobased products) to the market;
- produce environmental goods & services (carbon sink)
- become more resource efficient (producing more with fewer inputs);
- being more resilient to and part of the solution vis-à-vis climate change.
Our concern is that with the current regulatory framework, NGTs may never get the chance to bring benefits /opportunities to our sector – which includes contributing to the Zero Hunger Sustainable Development Goals that the EU has committed to. If the EU does not allow its farmers to have an appropriate toolbox, the EU will import more, putting food security at risk elsewhere in the world.
We consider that the same also applies to arable crops commonly grown in crop rotation with sugar beet (e. g. wheat, barley, maize, potatoes, sunflowers and oilseed rape).

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

- (●) Yes
- ( ) No

* Please explain

These benefits/opportunities are specific to NGTs in that they can help address the complex, specific and multiple challenges which need to be addressed in a fast, responsive and targeted manner. Considering that sugar beet varieties obtained by NGTs (notably mutagenesis) could also be obtained by conventional breeding and would thus be indistinguishable from beet varieties obtained by conventional breeding, then these benefits/opportunities can be achieved sooner and in a more targeted way.
Thus, NGTs offer new possibilities in plant breeding: they make it possible to precisely edit plants, allowing the development of new functions to:
- optimise existing traits;
- identify and develop new traits within the current genetic variation;
- enable the editing of genes that present susceptibility to disease.
By permitting:
-greater use of genetic variability;
-better use of existing genetics, and
- more targeted genetic variations,
these NGTs can:
- help provide solutions to the numerous challenges our sector is facing;
- provide more predictable genetic results than conventional/traditional breeding techniques.
Last but not least, NGTs go hand in hand with other innovative technological developments (precision/digital /smart farming & bio-control).
We consider that the same also applies to arable crops commonly grown in crop rotation with sugar beet (e. g. wheat, barley, maize, potatoes, sunflower and oilseed rape).

* **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

Current & future (complex, multiple and rapidly evolving) challenges can be met by NGTs to provide benefits to society in general (food security, less land use by agriculture in the EU due to higher yields/better quality /improved input use efficiency/enhanced productivity, further improved sustainability). One major challenge to be met is the reduced availability of plant protection products (PPPs): numerous active substances (chloridazon, chlorpyrifos, chlorpyrifos-methyl, clothianidin, desmedipham, dimethoate, epoxiconazole, fenpropimorph, haloxyfop-P, imidacloprid, metalaxyl-M, propiconazole, quinoxyfen, quizalofop-P, thiamethoxam, thiacloprid, thiram) have been removed or are in the process of being removed (e.g. mancozeb, beta-cyfluthrin, thiophanate-methyl) from the beet growers' tool box because they have not had or are not having their approval renewed or having their use restricted (no use seed treatment, no use on outdoor crops). EU farmers in general and beet growers in particular are thus losing many tools to which they need to have the possibility to resort to protect their crops. This seriously increases risks for growers, in particular risks of significant decrease in yields and crop failures (e.g. beet weevil infestations led to significant losses - 19% of conventional and 71% of organic – of beet area in Austria in 2018) and puts competitiveness and sustainability of European agriculture (including beet growing) as well as food security and safety at risk. NGTs are part of the efficient toolbox that European farmers (including beet growers) need to ensure crop production, food security and safety for 450 million EU citizens and beyond, particularly in the context of the Farm to Fork Strategy, which calls on farmers (including beet growers) to significantly reduce the risk and uses of and dependence on chemical PPPs and fertilisers. Improved crop varieties with more resistance/tolerance to pests, diseases and pressure from weeds can play a part in this. We consider that the same also applies to arable crops commonly grown in crop rotation with sugar beet (e.g. wheat, barley, maize, potatoes, sunflowers and oilseed rape).

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

NGTs can bring such benefits to society by contributing to food security, food safety and climate smart agriculture. In our view, NGTs/NGT-products can only bring benefits to society in general if they are given a fair chance to do so. This can only be achieved via an appropriate regulatory/legislative framework and a science-based approach to such innovation as well as clear and pro-science and innovation communication by EU Institutions. The current regulatory context, in which NGTs are essentially considered as GMOs, as well as the communication and messages by public authorities will not give NGTs/NGT-products the chance to bring such benefits/opportunities to society.

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

- (●) Yes
- ( ) No

* Please explain

These benefits/opportunities are specific to NGTs in that they can help provide benefits to society in general (food security, less land use by agriculture in the EU due to higher yields, better quality, improved input use efficiency, enhanced productivity, further improved sustainability) by helping to address the complex, specific and multiple challenges, in particular the reduced availability of PPPs and climate change, which need to be addressed in a faster, more responsive and more targeted manner. Thus, NGTs can & should be part of the breeders' and NGT-products part of the growers' toolbox to address these specific challenges.

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

- ( ) Yes
- (•) No

* Please explain why not

We are not in a position to respond to this question.

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

- ( ) Yes
- (•) No

* Please explain why not

We are not in a position to respond to this question.

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

In the current regulatory context, our sector is unlikely to allow breeders and/or growers to have access to these tools and their products. This will make it more difficult for our sector to meet the current and future sustainability challenges. There are also level playing field implications regarding products and/or co-products, imports from third countries, such as sugar, beet pulp as well as for example biofuels or other bio-based materials obtained from such products and/or co-products. The same scenario is likely for other crops commonly grown in rotation with sugar beet (e.g. wheat, barley, potatoes, maize, sunflowers & oilseed rape). Furthermore, without international harmonisation of rules on NGTs, differing requirements will limit (reduce & slow down) the plant breeding sector's capacity to innovate, reduce the diversity of plant genetic resources, have a negative impact on research co-operations and hinder the movement of seed & germplasm.

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

- (•) Yes
- ( ) No

* Please explain

These challenges are specific to NGTs/NGT-products in the sense that varieties obtained via NGTs are currently considered as GMOs, which is not the case for varieties obtained via conventional breeding methods. Furthermore, all countries require pre-market assessment for GMOs (which can be distinguished from non-GMOs), which is not the case for NGTs. At the same time, some issues concern all breeding techniques. For example, Crops with herbicide tolerance appear to be unacceptable to certain stakeholders, regardless, of whether this herbicide tolerance was obtained via GM, NGT or even conventional breeding (e. g. administrative rejection of Conviso technology in France, notwithstanding the availability of Conviso Smart varieties to growers in Switzerland, Czech Republic, Spain, Hungary, Poland, Finland, Romania, Sweden, the UK) and regardless of the improvement they could bring to sustainability. Traits should not be rejected outright simply because of for example herbicide tolerance – this would be far too simplistic an approach by the EU institutions and certain stakeholders.

* **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

In our view, NGT/NGT-products could raise challenges/concerns no more or less than GM and/or traditional /conventional breeding (e.g. herbicide tolerant crops). NGTs and their products are a continuation of plant breeding innovation and thus part of the breeders' and ultimately of the growers'/farmers' toolbox. On the contrary, the non-availability of NGTs/NGT-products could raise concerns because it would:

- prevent farmers in the EU to use NGT plant varieties, which could put at risk/weaken efforts towards more sustainable farming;
- prevent the use of less PPPs because farmers cannot access more resilient NGT varieties that are resistant against pests and diseases or against competition from weeds (and thus require less PPPs);
- put plant health at risk and make farmers less competitive;
- lead to a situation where certain NGT products with clear consumer benefits (low gluten wheat) might not be available to EU consumers – except through imports.

It is the role of public authorities, together with the scientific community, to explain and communicate, based on science and risk assessment, and to prevent abuse of the precautionary principle, fake news and scare mongering campaign driven by ideology.

There is general non-acceptance of herbicide tolerant crops – regardless of how they have been obtained. These should be monitored to avoid herbicide tolerance being transferred to weeds – and/or to avoid herbicide tolerant crops from becoming weeds in other crops. However, they should not be rejected outright simply because they are herbicide tolerant; rather, the improvement to sustainability which can be brought about by herbicide tolerance (e.g. need for fewer herbicide applications) should be assessed against possible risks of transfer (e.g. of herbicide tolerance transfer to weeds).

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

- ○ Yes
- ◉ No

* Please explain why not

We are not in a position to respond to this question.

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

- Yes
- No

* Please explain why not

We are not in a position to respond to this question.

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E - Safety of NGTs/NGT-products

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

Given that products obtained by NGTs (e.g. improved sugar beet varieties), if they can also be obtained via conventional breeding and are thus indistinguishable from sugar beet varieties obtained via conventional breeding, we consider that NGTs/NGT-products are as safe as varieties obtained via conventional breeding. Therefore, the quality assurance systems and the trialling process for plant/crop varieties obtained by NGTs should be the same as for varieties obtained from conventional breeding.

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

- Yes
- No

* Please explain why not

We have no specific safety considerations on NGTs/NGT-products, given that if the plants obtained via NBTs could have been obtained via conventional breeding and/or spontaneous mutation in nature and are thus indistinguishable from plants obtained by conventional breeding.

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F - Ethical aspects of NGTs/NGT-products

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

In the sense that NGTs/NGT-products are indistinguishable from varieties obtained by traditional /conventional breeding, we see them as a continuation of the evolution of plant breeding and very likely an important milestone in the history of plant breeding, we consider that ethical aspects should not be used in abusive way to target a specific sector by those who are systematically against scientific progress in that sector and who resort to a systematically abusive interpretation of the precautionary principle to the detriment of scientific progress.
On the contrary, it would be unethical and abusive to wish to prevent scientific progress in plant breeding and its potential benefits to society.
The World Resource Report: Creating a sustainable future - A Menu of Solutions to Feed Nearly 10 Billion People by 2050, published by the World Resources Institute, clearly shows the importance of spurring innovation: “Fully closing the gaps requires many innovations. Fortunately, researchers have demonstrated good potential in every necessary area. Opportunities include crop traits or additives that reduce methane emissions from rice and cattle, improved fertilizer forms and crop properties that reduce nitrogen runoff, solar-based processes for making fertilizers, organic sprays that preserve fresh food for longer periods, and plant-based beef substitutes. A revolution in molecular biology opens up new opportunities for crop breeding. Progress at the necessary scale requires large increases in R&D funding, and flexible regulations that encourage private industry to develop and market new technologies.”
The report particularly notes that:
1-Breeding of improved crops is generally credited for half of all historical yield gains. Breeding can both increase the potential yield of crops under ideal conditions and help farmers come closer to those potential yields by better coping with environmental constraints. Countries that have invested more in recent years in crop breeding, such as Brazil and China, have seen vast improvements in their yields.
2-“Incremental” crop breeding has been the primary driver of yield gains through assessment and selection of the best performing existing crops, followed by purification, rebreeding, production, and distribution. In the United States, improved maize varieties are released every three years. Speeding new crop cycles would boost yield growth in many countries such as Kenya & India, where new grain varieties are released typically every 13 to 23 years.
3-Much debate has focused on GMOs, which involve insertion of genes from one plant into another. The debate has centered overwhelmingly on two types of traits that assist pest control through glyphosate resistance and expression of Bt (Bacillus thuringiensis), a biological pesticide. Some bona fide debate is appropriate about whether the ease of use and relatively lower toxicity provided by these traits in the short term, and their potential value to small farmers without access to pesticides, justifies the longer-term risks of building resistance in weeds, worms, and insects—potentially leading to more pesticide use in the future. There is no evidence that GMOs have directly harmed human health.
4-Gene editing has far greater potential (than GMOs). Sometimes new genes can provide the only viable mechanisms for crops to survive new diseases. New genes may also play a major role in combating environmental challenges by making crops more efficient at absorbing nitrogen or suppressing methane or nitrous oxide emissions.
5-The CRISPR-Cas9 revolution since 2013 dramatically increases opportunities to improve breeding through genetic manipulation. CRISPR enables researchers to alter genetic codes cheaply and quickly in precise locations, insert new genes, move existing genes around, and control expression of existing genes. CRISPR follows a related genomics revolution, which makes it cheap to map the entire genetic code of plants, test whether new plants have the desired DNA without fully growing them, and purify crop strains more rapidly.
6-According to the most recent assessments, global public agricultural research is roughly $30 billion per year for all purposes, and private crop-breeding research is around $4 billion, which the authors of the report consider modest. The vast opportunities created by new technologies warrant large and stable increases in crop-breeding budgets.
Finally, the European Academies Science Advisory Council (EASAC) makes it clear in its Report “The regulation of genome-edited plants in the European Union” that:

- there is pressing need to make use of the proportionality principle when introducing reform to

strengthen the use of scientific evidence and tackle future uncertainties;
- the potential costs of not using a new technology, or being slow in adoption, must be acknowledged.
“There is no time to lose in resolving the problems for food and nutrition security in Europe."

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

- (●) Yes
- ( ) No

* Please explain

In the sense that NGTs/NGT-products are indistinguishable from varieties obtained by traditional /conventional breeding, our ethical consideration on NGTs/NGT products are the same as on plant varieties obtained by conventional/traditional breeding. They represent further progress in and a continuation of the evolution of plant breeding and very likely an important milestone in the history of plant breeding. It would simply be highly unethical to hamper access for R&D to these innovative techniques via the current regulatory context and to effectively prevent European farmers from ever having access to the products from these NGTs.
EASAC makes it clear in its Report “The regulation of genome-edited plants in the European Union” that “New breeding techniques are emerging rapidly from advances in genomics research, for application in crop improvement. They enable targeted changes in the genome and they have significant potential for the sustainable intensification of agriculture, when used as part of the deployment of all available approaches to achieving food and nutrition security and building on existing good agronomic practice. Unlike chemical- or radiation-induced mutagenesis, often traditionally used for crop improvement tools, the new breeding techniques do not create multiple, unknown, unintended mutations throughout the genome. Furthermore, the products of the new breeding techniques are also unlike genetically modified organisms (GMOs) used in agriculture, in being more precisely targeted and having no foreign DNA in the end product. Advances in plant genome editing may also support other applications for the Bioeconomy in support of European competitiveness.”

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G - Consumers' right for information/freedom of choice

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

Labelling requires traceability, which is linked to the enforcement of any legislation that distinguishes products based on the plant breeding technique(s) used, whether conventional, GM, NGTs or other. Compulsory information on breeding methods at variety level must be meaningful, scientifically appropriate, not discriminate against innovative companies and products. ensure a level playing field between operators (EU-wide & internationally) and avoid consumer misinformation and fraud, especially in view of the international context and the lack of distinguishability regarding like-products.
If NGT-producs are regulated as GMOs in the European Union, the cultivation of such crops in Europe is likely to be unprofitable under the current labelling and coexistence policies.
Labelling of NGT-products is likely to lead to confusion, as it will result in plants obtained by NGTs (and possibly the products from these NGT-derived plants) to be labelled, while being indistinguishable from plants obtained by conventional plant breeding (and from the products obtained from these plants obtained by conventional plant breeding).

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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

It is regrettable that the maximum file size for supporting documentation was fixed at 1 MB, as this effectively prevents the uploading of larger files (for example with illustrations). In an age where very large files (5 to 10 MB) can be sent and received by email without any problem, it is difficult to understand why in this questionnaire file size for uploading documentation is nt allowed to exceed 1 MB.

The current regulatory situation (i.e. plants obtained via NGTs are GMOs) is not sustainable.
This regulatory framework will prevent these very promising NGTs from being
- integrated into research programmes aiming to bring improved crop varieties to the market;
- adopted by European farmers to become part of their agronomic toolbox help meet the current and future challenges, notably linked to climate change and reduced availability of PPPs.

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