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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 / E C) .

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) 2 0 1 8 / 1 7 2 5

- [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 fillingout 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

Primary Food Processors (PFP) represents the European Primary Food Processing industry PFP and is registered in the Transparency Register under nr 71338036982-24.

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

Primary Food Processors (PFP) is composed of six trade associations, representing manufacturers of sugar, starch, flour, vegetable proteins, cocoa, and vegetable oil and protein meal products respectively. The principal activity of PFP members is to process agricultural raw materials into a range of commodities or ingredients that are purchased by secondary processors for food, feed and non-food uses. The primary food processing industry uses around 220 million tonnes of agricultural raw commodities (cereals, sugar beet, rapeseeds, soybeans, sunflower seeds, crude vegetable oil, starch potatoes, cocoa etc.) a year, employing over 120,000 people in Europe. PFP members form a vital link in the food chain, delivering efficiently produced, high quality safe food for our customers and the consumer.

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

European Committee of Sugar Manufacturers (CEFS)

European Cocoa Association (ECA)

European Flour Milling Association (European Flour Millers)

European Vegetable Protein Association (EUVEPRO)

European Vegetable Oil and Proteinmeal Industry (FEDIOL)

European Starch Industry Association (Starch Europe)

PFP has examined all the questions of this questionnaire and decided to only reply to some of them, considering that specific inputs will also be given by individual PFP member associations. PFP replies to the following questions: 1, 16, 20, 28. Therefore, answers to most questions are chosen by default due to the mandatory fields.

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)

- Yes
- No
- Not applicable

Please explain why not

Within the scope of their activities, PFP members currently do not develop plants derived from NGTs. Similarly, for the time being, PFP sectors ask their suppliers to provide non-NGT derived materials or products, mainly because of the non-authorisation in the context of Directive 2001/18/EC as well as detectability difficulties of NGTs throughout the supply chain. Nevertheless, should NGT products for different agricultural commodities become available, PFP members would consider to source and/or process them in accordance with EU legislation. A crucial factor to enable this, would be a tailored regulatory framework for these techniques and for commercialization of derived products. See however answer to question 28 relating to consumers' acceptability.

6	iT-products?
)	Yes
	No
	Not applicable
	Please provide details
,	Answer chosen by default, it does not represent a PFP answer
	2 bis. Have you encountered any challenges?
)	Yes
	No
	Please provide details
,	Answer chosen by default, it does not represent a PFP answer
	A volu outono of initiativos in volum ocatan to develor tree on of plane to tree NOT-/NOT product
	e you aware of initiatives in your sector to develop, use, or of plans to use NGTs/NGT-product Yes
	No
000	Not applicable
	Please provide details
_	Please provide details Answer chosen by default, it does not represent a PFP answer
	Answer chosen by default, it does not represent a PFP answer
)	Answer chosen by default, it does not represent a PFP answer you know of any initiatives in your sector to guard against unintentional use of NGT-products
)	Answer chosen by default, it does not represent a PFP answer you know of any initiatives in your sector to guard against unintentional use of NGT-product Yes
_	Answer chosen by default, it does not represent a PFP answer you know of any initiatives in your sector to guard against unintentional use of NGT-products
)	Answer chosen by default, it does not represent a PFP answer you know of any initiatives in your sector to guard against unintentional use of NGT-products Yes No
	Answer chosen by default, it does not represent a PFP answer you know of any initiatives in your sector to guard against unintentional use of NGT-product Yes No Not applicable
	Answer chosen by default, it does not represent a PFP answer you know of any initiatives in your sector to guard against unintentional use of NGT-products Yes No Not applicable Please provide details
	Answer chosen by default, it does not represent a PFP answer you know of any initiatives in your sector to guard against unintentional use of NGT-products Yes No Not applicable Please provide details Answer chosen by default, it does not represent a PFP answer
	Answer chosen by default, it does not represent a PFP answer you know of any initiatives in your sector to guard against unintentional use of NGT-product Yes No Not applicable Please provide details Answer chosen by default, it does not represent a PFP answer 4 bis. Are you aware of any challenges encountered?
	Answer chosen by default, it does not represent a PFP answer you know of any initiatives in your sector to guard against unintentional use of NGT-product Yes No Not applicable Please provide details Answer chosen by default, it does not represent a PFP answer 4 bis. Are you aware of any challenges encountered? Yes

* 2. Have your members taken or planned to take measures to protect themselves from unintentional use

Please also see question 8 specifically on labelling

obtained by NGTs?

	YesNoNot applicable
*	Please describe the measures and their effectiveness including details on the required financial, human resources and technical expertise
	Answer chosen by default, it does not represent a PFP answer
*	What best practices can you share?
	Answer chosen by default, it does not represent a PFP answer
*	5 bis. What challenges have you encountered?
	Answer chosen by default, it does not represent a PFP answer
au	thorities to conform to the legislation? Ves No Not applicable
*	Please describe what type of support and what best practices you can share
	Answer chosen by default, it does not represent a PFP answer
	Does your sector have experience or knowledge on traceability strategies, which could be used for cing NGT-products? Yes No Not applicable Please describe the traceability strategy, including details on the required financial, human resources and technical expertise
	Answer chosen by default, it does not represent a PFP answer
	Are your members taking specific measures for NGT-products to ensure the compliance with the pelling 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

	Answer chosen by default, it does not represent a PFP answer
*	What best practices can you share?
	Answer chosen by default, it does not represent a PFP answer
*	8 bis. What challenges have you encountered?
	Answer chosen by default, it does not represent a PFP answer
leg	Do you have other experience or knowledge that you can share on the application of the GMO islation, including experimental releases (such as field trials or clinical trials), concerning NGTs/NGT- oducts? Yes No No
*	Please describe for the: Agri-food sector Industrial sector Medicinal sector
	Agri-food sector
	Answer chosen by default, it does not represent a PFP answer
w <i>h</i>	ease upload any supporting documentation for this section here. For each document, please indicate ich question it is complementing he maximum file size is 1 MB - Information on research on NGTs/NGT-products
* 10.	Are your members carrying out NGT-related research in your sector? Yes No Not applicable
*	Please specify including subject, type of research, resources allocated, research location
	Answer chosen by default, it does not represent a PFP answer
* 11	Are you aware of other NGT-related research in your sector?

Yes

	Not applicable
*	Please specify
	Answer chosen by default, it does not represent a PFP answer
Jus	Has there been any immediate impact on NGT-related research in your sector following the Court of stice of the EU ruling on mutagenesis? ourt of Justice ruling: Case C-528/16 http://curia.europa.eu/juris/documents.jsf?num=C-528/16 Yes No No Not applicable
*	Please describe
	Answer chosen by default, it does not represent a PFP answer
* 13.	Could NGT-related research bring benefits/opportunities to your sector/field of interest? Yes No Not applicable
*	Please provide concrete examples/data
	Answer chosen by default, it does not represent a PFP answer
* 14.	Is NGT-related research facing challenges in your sector/field of interest? Yes No Not applicable
*	Please provide concrete examples/data
	Answer chosen by default, it does not represent a PFP answer
* 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
	Answer chosen by default, it does not represent a PFP answer

O No

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

The maximum file size is 1 MB

YesNo

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?

Please describe and provide concrete examples/data

	The ambitions set out in the European Green Deal as well as the focus of the forthcoming Farm to Fork strategy on sustainable and more resilient food systems, demonstrates the need to reduce the environmental impact of the agricultural supply chain. As food business operators we can and want to play a important role in this transition. PFP believes that innovation and new technologies are needed in this
	context.
	NGTs provide a promising potential for the PFP member companies as they may:
	a) Provide breeders with innovative solutions to enhance plants disease resistance, thus reducing the
	need for pesticides;
	b) Enhance plants tolerance to drought, and effectively adapt to climate change;
	c) Assist in reducing plants allergenicity (the potential to cause an allergic reaction);
	d) Improve food quality and properties;
	e) Contribute to enhanced food safety with varieties less prone to mycotoxins or other problems that pose a health risk.
*	Please explain PFP considers NGTs to be complementary tools to support the transition towards more sustainable production of raw materials and ingredients while maintaining a high standard of food safety and quality. The key opportunity for PFP members lies in the faster and more cost-efficient way this can be achieved,
	compared to conventional breeding techniques. Could NGTs/NGT-products bring benefits/opportunities to society in general such as for the vironment, human, animal and plant health, consumers, animal welfare, as well as social and
eco	onomic benefits?
	Yes
	O No
*	Please describe and provide concrete examples/data
	Answer chosen by default, this does not represent a PFP answer

	Answer chosen by default, this does not represent a PFP answer
*	Are these benefits/opportunities specific to NGTs/NGT-products? Yes No
*	Please explain
	Answer chosen by default, this does not represent a PFP answer
	Do you see particular opportunities for SMEs/small scale operators to access markets with their Ts/NGT-products?
	Yes No
*	Please describe and provide concrete examples/data
	Answer chosen by default, this does not represent a PFP answer
* 19. *	Do you see benefits/opportunities from patenting or accessing patented NGTs/NGT-products? Yes No Please describe and provide concrete examples/data
	Answer chosen by default, this does not represent a PFP answer
wh Th	ease upload any supporting documentation for this section here. For each document, please indicate ich question it is complementing ne maximum file size is 1 MB - Information on potential challenges and concerns on NGTs/NGT-products
	Could NGTs/NGT-products raise challenges/concerns for your sector/field of interest? Yes No
*	Please describe and provide concrete examples/data

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

NGTs and NGT-derived products have the potential to bring much added value to PFP sectors in food processing, yet there are a number of obstacles that need to be taken into account. There is currently a high degree of legal uncertainty surrounding NGTs, which does not encourage R&D and commercial efforts. The competitiveness of the agri-food sector also needs to be considered in view of the EU's position on the global market. Currently, NGTs are regulated according to the GMO Directive, whereas third countries already have or are developing legislation that enables the use of NGTs. Hence, the EU risks a competitive disadvantage in global agricultural commodity trade as well as innovation.

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

Please explain and provide concrete examples and data

YesNo

Yes. If NGTs are treated as GMOs in the EU, this will cause divergence with the legislation in many countries outside of the EU. A particular issue then would be that most NGTs are indistinguishable from plants obtained via traditional means, there is no means to detect them analytically.
Could NGTs/NGT-products raise challenges/concerns for society in general such as for th ironment, human, animal and plant health, consumers, animal welfare, as well as social an nomic challenges?
Yes
D No
Please describe and provide concrete examples/data
Answer chosen by default, it does not represent a PFP answer
Under which conditions do you consider this would be the case?
Answer chosen by default, it does not represent a PFP answer
Are these challenges/concerns specific to NGTs/products obtained by NGTs?
YesNo
Please explain

* 23	. Do you see challenges/concerns from patenting or accessing patented NGTs/NGT-products?
	Yes
	O No
*	Please describe and provide concrete examples/data
	Answer chosen by default, it does not represent a PFP answer
w <i>h</i>	ease upload any supporting documentation for this section here. For each document, please indicate nich question it is complementing The maximum file size is 1 MB
_	- Safety of NGTs/NGT-products
* 24	. What is your view on the safety of NGTs/NGT-products? Please substantiate your reply
	PFP does not answer to this question.
* 25	. Do you have specific safety considerations on NGTs/NGT-products? Yes No
*	Please explain
	Answer chosen by default, it does not represent a PFP answer
wh	ease upload any supporting documentation for this section here. For each document, please indicate nich question it is complementing The maximum file size is 1 MB
F	- Ethical aspects of NGTs/NGT-products
* 26	. What is your view on ethical aspects related to NGTs/NGT-products? Please substantiate your reply
	PFP does not answer to this question.

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

Yes

Answer chosen by default, it does not represent a PFP answer

	Please explain
	Answer chosen by default, it does not represent a PFP answer
	ase upload any supporting documentation for this section here se maximum file size is 1 MB
ì	- Consumers' right for information/freedom of choice
3.	What is your view on the labelling of NGT-products? Please substantiate your reply
3.	PFP considers that transparency and traceability are key elements with regard to NGT products. The
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H - Final question

The maximum file size is 1 MB

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

Yes

No

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

The maximum file size is 1 MB

Contact

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