

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

B a c k g r o u n d

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 .

I n s t r u c t i o n s

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

UNISTOCK - Transparency Registration n. 81131801106-72

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

Unistock Europe is the European association of professional portside storekeepers for agribulk commodities within the European Union.

Trade and related storage activities plays a vital role in the supply chain moving agricultural commodities from areas of surplus to areas of deficit efficiently and at affordable prices. This is a strategic contribution of global trade towards enhancing food security worldwide.

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

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

UNITOCK's answers are related to new plant varieties, crops and food and feed derived products. Other fields and technologies are not covered under the current replies.

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

No. UNISTOCK members are not actively engaged in developing NGTs, nor they are using NGTs, since there are no such varieties approved in the EU market.
Yes. Representing the commodities storage sector, UNISTOCK members will be exposed to NGT products entering intentionally or unintentionally the agricultural supply chain. As co-mingling and bulking is usual practice at farmgate and downstream, our major concern is in the commodity market.

* 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

Yes (virtual preparedness to abide by the applicable GMO legislation). - Currently, after the ECJ Ruling C528 /2016 of 25 July 2018, NGTs are under the GMOs regulatory framework , which establishes specific measures for pre-market approval and post-marketing monitoring (intended as General Surveillance or Case Specific Monitoring). Labelling and traceability, including measures for segregation of unintentional use of GMOs are at the same time present, along with the ""Low-Level Presence"" (LLP) technical solution, to maintain the intactness of the food supply chains.

No– (practical lack of technical preparedness due to absent tools and knowledge). - Nonetheless, the requirements of the GMO regulatory framework can only be met with the right information passed down the supply chain. For this, accurate, timely and accessible information on plant varieties produced using NGTs is essential for UNISTOCK members in order to take, if needed, measures regarding NGTs products that may enter their supply chain. This includes information on which varieties are being produced using NGTs; updates on seed registrations and commercialization, including data on the regulatory status of various NGT varieties in major markets.

Most of this information is not easily available today and as a consequence, protection measures are not feasible.

* 2 bis. Have you encountered any challenges?

- Yes
 No

* Please provide details

The rapidly evolving regulatory landscape worldwide is posing unprecedented challenges in terms of traceability and compliance, with the cereal sector potentially exposed to the presence of varieties considered under the GMOs regulatory framework in the EU.

* **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

UNISTOCK members are involved in the intra EU and international trade of raw materials. As such, some of our trade partners may have plans to develop or use NGTs in non-European countries.
We are aware of Third countries developing NGTs which could have a time-to -market of 2-3 years.
UNISTOCK members treat large volumes of agri commodities in bulk on a continuous basis. This means that it is impossible to separate those volumes at any point in time, and co-mingling with NGTs could occur unbeknownst to us. Involuntarily UNISTOCK members will be exposed to use these products once these NGTs-derived crops will be out there.
As far as the EU market is concerned, we are not currently aware of plans to develop NGTs.

* **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

As agri-commodities operators, we abide by all the regulations related to traceability and food safety, including HACCP measures (General Food Law and other vertical - horizontal legislation). As far as NGTs are concerned, traders must rely on the information communicated by other suppliers in the supply chain.

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

- Yes
 No

* Please provide details

As currently framed, the NGTs regulation impedes a clear traceability - the lack of detection methods being a major shortcoming.

*** 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

No.

While our members comply with traceability, labelling and post-market monitoring of GMOs, at present we are not aware of any products or crops derived from NGTs entering the global food and feed supply chain. Because of that, there are no management practices at present, despite possible trade disruptions.

UNISTOCK currently must consider NGTs as non-approved GMO events and from a legal perspective, assume the validity of the same measures applies as for regular non-approved GMOs (technical solutions, Low-Level Presence and monitoring of asynchronous events).

However, at present there are

- No events from NGTS communicated by B2B partners;
- No laboratory methodologies able to detect NGTs-derived crops, neither they are standardized and certified. Depending on the results, NGTs crops could not virtually distinguishable from conventional ones, and even with prior knowledge of the modified traits, there are no legally binding tools able to attribute with certainty the traits to the technology (modification could actually have occurred in nature). Such double levels of uncertainty pose traders with unprecedented and unpredictable challenges.

* 5 bis. What challenges have you encountered?

-

*** 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?

Neither UNISTOCK nor its national-level associations have been supported by national and European authorities to conform with the requests stemming from the legislation. This is perceived indeed as a major issue and causing uncertainties, as the current ECJ ruling should be immediately enforceable. Nevertheless, due to the very nature of an ECJ Ruling- as a reactive answer to real-world circumstances - this secondary law act, while legally binding, lacks all the provisions and specifications in place as by any ordinary EU Regulation. Because of that, guidance must be provided as soon as possible to ensure that operators in the food and feed supply chain can comply with the legislation and thus avoid trade disruptions.

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

- Yes
- No
- Not applicable

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

Along with business partners, UNISTOCK is constantly monitoring the regulatory pipeline of GMOs still not approved in the EU, in order for our traders to have the opportunity to check them along the supply chain. This could hardly be possible with NGTs due to the lack of a straightforward identification and regulatory scenario in the EU. Although we are indeed aware of traceability strategies, we are not certain that the currently available systems can be fully applied to NGTs. An effective traceability system requires a) transparency and information sharing along the chain regarding the NBT status to B2B partners (from providers of the crops in the likes of seed industry and then growers- this being the usual documental traceability;) b) presence of the correspondent analytical testing methodologies to assess the truthfulness of the document traceability and allow compliance assessment. Without any of the 2 provisions in place, the traceability system would be hampered. The JRC report on detection methods(European Network of GMO Laboratories (ENGL), Detection of food and feed plant products obtained by new mutagenesis techniques, 26 March 2019 (JRC116289)) in addition underlined that most of NGTs events cannot be strictly identified by PCR, fragilizing the compliance approach. In the absence of adequate detection methods, traceability would only be based on documents and certification schemes, compliance checks being more complicated with such systems, from operators as well as for control authorities. In addition, as many NGTs could result in mutations not distinguishable from those occurring in nature, lab tests could give false-positive outcomes which could further complicate the traceability. Should traceability strategies be developed, UNISTOCK and its members will be happy to contribute their knowledge of the functioning of the food and feed supply chain and the extent to which different approaches can be enforced for agri commodities, and at the same time provide all stakeholders with the relevant information.

(1)

*** 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

To our knowledge, there are no EU authorized NGT-products in the supply chain at the moment, and thus we are not faced with any requirements for labeling.
This being said, UNISTOCK members will only be in a position to take specific measures when solutions are available to ensure efficient identification and traceability of NGTs products.

* 8 bis. What challenges have you encountered?

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*** 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

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

- Yes
- No
- Not applicable

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

- Yes
- No
- Not applicable

* Please specify

UNISTOCK members are not engaged in NGT-related R&D in Europe.
The current framework strictly regulating NGTs products under the EU GMOs regulations does not encourage research activities. To the best of our knowledge, research is undertaken in non-European countries and at a science level in Academia in the EU.

*** 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

To our knowledge, many actors from the private sector have frozen their research programs.

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

- Yes
 No
 Not applicable

* Please provide concrete examples/data

Yes. NGTs could indeed bring important innovation and there is the potential to bring improvements and benefits to the agricultural sector and downstream supply chain. Gene editing technologies related to agriculture and the environment could bring -according to various international bodies (FAO , OECD)-, potential for conservation, bioremediation, the control of invasive species, and the protection of biodiversity, along with other benefits such as improvement of the nutrient profile of food&feed, reduction of the carbon foot print, mitigation of climate change, and food losses. NGTs research could bring many benefits to the breeding of new varieties, increasing the speed of new varieties to market and targeting of genes to provide traits that will benefit the end user and the environment. Storage and transport could benefit of cereal varieties more resilient during long transportation and less prone to mycotoxins attacks. Mycotoxins are actually one of the most impacting and harmful contaminants formed during the whole supply chain.

- FAO Global Partnership Initiative for Plant Breeding Capacity Building. Link at: <http://www.fao.org/in-action/plant-breeding/our-partners/en/>

- Friedrichs, S., Takasu, Y., Kearns, P. et al. Meeting report of the OECD conference on “Genome Editing: Applications in Agriculture—Implications for Health, Environment and Regulation”. *Transgenic Res* 28, 419–463 (2019). <https://doi.org/10.1007/s11248-019-00154-1>

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

- Yes
 No
 Not applicable

*** 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

UNISTOCK welcomes current research into testing methods needed to detect NGTs events. For this, we would greatly benefit from speedy development of R&D in this field.

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

The maximum file size is 1 MB

C - Information on potential opportunities and benefits of NGTs/NGT-products

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

- Yes
- No

* Please describe and provide concrete examples/data

UNISTOCK supports science and innovation in agriculture, to improve the quality and quantity of the food available for the world population. UNISTOCK believes that genetic engineering including gene-editing, is an important innovation that has a great potential to help us to achieve this mission.

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

- Yes
- No

* Please explain

It is apparent that the increased development speed and the reduced cost of last generation NGTs such as CRISPR is the first enabling technology of this kind.

*** 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

As mentioned before, UNISTOCK supports science and innovation in agriculture, to improve the quality and quantity of the food available for the world population.

UNISTOCK believes that genetic engineering including gene-editing, could be beneficial for the whole society (human and plant health, consumers...), in particular, with regard to the environmental and climate-related challenges that the world is facing.

Supporting the production of crops from NGTs in the EU and the import of NGT crops from outside, could provide health benefits for consumers (eg wheat with modified starch suitable for diabetics, gluten free wheat for coeliacs, high fibre wheat, improved oil profile oilseed crops, low acrylamide potatoes). Crops better able to withstand storage or negative effects of rainfall around harvest would result in less food waste. Crops with better drought tolerance would provide resilient options for farmers to grow with the current climate change challenges with less fear of crop failure. Crops with improved pest and disease resistance would perform better.

Conferring new disease resistance on crops through NGTs would reduce the reliance on some pesticides. As NGTs allow much faster progress, they would also be a useful tool for overcoming emerging pest and disease problems, and therefore enhance productivity.

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

-

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

- Yes
 No

- * Please explain

It is apparent that the increased development speed and the reduced cost of last generation NGTs such as CRISPR is the first enabling technology of this kind.

- * **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

Not applicable

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

- Yes
 No

- * Please explain why not

Not applicable

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

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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

There is an ongoing discussion as to how these new techniques should be regulated and as to whether some or all of them should be subject to existing conventional GMOs regulations. Over the next few years, the proliferation of NGTs varieties - if no coherent regulatory requirements or marketplace transparency are in place - will create significant new challenges for commodity and specialty supply-chains. One critical element in the introduction of NGTs' products into the global food system is ensuring there are consistent approaches to regulatory oversight of the technology to guarantee these agricultural products can move across borders easily. Furthermore, European Member States- could display different and diverging requirements on NGTs due to the difficulty of implementing the ECJ Ruling. This fragmentation could result in not harmonized official controls in place. This would pose risks for the uninterrupted trade flow, with emerging costs and challenges in charge of the trading sector.

Should NGTs products be considered and/or regulated as GMOs, an additional challenge is about the impossibility of the operators to detect, trace and label them properly.

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

- Yes
- No

* Please explain why not

Not applicable

*** 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 describe and provide concrete examples/data

UNISTOCK believes there is the need to ensuring NGTSs are safe and useful. To be successful in bringing these benefits, UNISTOCK supports a comprehensive stakeholders' approach in demonstrating the viability of such technologies as well as a fit-for-purpose legislation. At the same time, societal concerns, while fully legitimate, should not impair scientific risk-assessment but rather reinforce it. For this, we fully endorse and trust the existing engagement fora, leveraging on the experience acquired by EFSA and the Commission in recent years.

Explanation to the public should be scientifically accurate and describe the benefits to consumers and the environment.

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

-

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

- Yes
 No

- * Please explain why not

Not applicable

- * **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

Not applicable

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

- Yes
 No

- * Please explain why not

Not applicable

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

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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**

UNISTOCK supports and abides by food&feed safety provisions along the entire supply chain globally, including the need for a proper risk assessment.

We believe an assurance of safety for foods resulting from NGTs is critical to build trust with consumers, governments, and our customers. Since NGTs can create a spectrum of changes from single nucleotides to the creation of new metabolic pathways, risk assessment frameworks for NGTs must be flexible and the degree of oversight commensurate with the risk. That's why UNISTOCK supports the development of mandatory, flexible, tiered approaches to scientific risk assessment, applied on a case-by-case basis and according to the risk represented by specific products—rather than a one size fits all risk assessment system that is broadly applied to the gene-editing process as a whole. It means that UNISTOCK supports the development of a continuum of scientific risk assessment requirements according to the potential risk represented by the genetic events at stake, rather than the strict application of the ECJ ruling with all NGTs products falling under the existing EU GM regulatory framework.

For this UNISTOCK believes a coherent global regulatory structure is needed in order to ensure the safe and expeditious implementation of these technologies, and to enable the trade and integration of these technologies into the global food system. The recent EFSA's Opinion on the applicability of SDN-3 safety assessment for SDN-1, SDN-2 and oligonucleotide-directed mutagenesis assessment is quite promising and enlightening in this respect. EFSA (2020) Applicability of the EFSA opinion on site-directed nucleases type for the 3-safety assessment of plants developed using site-directed nucleases type 1 and 2 and oligonucleotide-directed mutagenesis. EFSA Panel on Genetically Modified Organisms (GMO).

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

- Yes
 No

* Please explain why not

UNISTOCK relies on scientific bodies entitled to the highest level of knowledge for a competent and trustworthy risk-assessment. Since storekeepers are global players, worldwide harmonization/ compatibility in risk assessment and risk management again is key in order to have a seamless food&feed supply chains in place. Safety considerations will depend much more on the end product than on the process used to obtain new varieties. All things being equal, NGTs offer more accurate tools for breeders and allow better control of off-target events.

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

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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**

Not applicable

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

- Yes
 No

* Please explain why not

Not applicable

Please upload any supporting documentation for this section here

The maximum file size is 1 MB

G - Consumers' right for information/freedom of choice

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

As a food&feed supplier, UNISTOCK believes that information related to the commercialization of NGTs must be accurate, timely, and accessible to all stakeholders for agricultural supply chains and markets to function effectively. This includes information available to farmers on which seed varieties have been produced using NGT and information on the regulatory status of various NGT varieties in major markets. Transparency of such information to agricultural stakeholders will ensure that customers and consumers can choose what they want to buy, enable specialty markets to coexist, and ensure that information is available to allow for choice and ensuring regulatory compliance for cross-border systems.

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

H - Final question

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

- Yes
 No

Please provide your comments here

UNISTOCK thanks the Commission for the opportunity to consult with in view the Study on NGTs. However, we would highlight how many questions (i.e., 1,2,7,8,28) were actually composite questions, with several ones entangled under the same text and/or with several semantic and logic layers to cope with. This complicated a straightforward "yes" or "no" answer. For this, we are sure the Commission will take into full account the very detail of the answers as such more than the preliminary direction given by the "yes" or "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

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