Contribution ID: 0c91bb7f-9c1c-409a-97e0-b693586fdab5
Date: 13/05/2020 21:23:47

# 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

FEFANA ASBL-EU Association of Specialty Feed ingredients & their mixture
FEFANA
EC Transparency Register ID:
20132976103-18

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

Fermentation products used as specialty food and feed ingredients (i.e. additives, flavorings and processing aids). Examples: vitamins, amino-acids, oligosaccharides, flavorings and enzymes.
Live microorganisms used as feed and food additives (probiotics, silage agents).
Our members may also be active in the fields of e.g. live microorganisms resp. fermentation products used in food, food supplements, biofuel, agriculture (biocontrol, biostimulant), household care, cosmetics, plastic, base chemicals, industrial processes, water treatment etc.

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

Answers to this questionnaire have been prepared in collaboration with several associations and companies active in the Industrial Biotechnology sector.

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

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

* **1. Are your members developing, using, or planning to use NGTs/NGT-products?**
  - (●) Yes
  - ( ) No
  - ( ) Not applicable

* Please provide details

Industrial Biotechnology is innovating constantly and dynamically. In doing so we use all technologies of interest and relevance to our research and development activities. Many of these technologies were developed after 2001 – therefore we use NGTs. We do not see year 2001 as a particular milestone from a scientific, technological or safety point of view.
Gene technology has been over the past 20+ years evolving towards higher precision and ease of use, and R&D work has been shifting to the use of state-of-the-art techniques. As many post-2001 techniques are used routinely by our members, providing specific examples from the fermentation industry is not relevant.
One reason why we would not use a specific technology would be lack of IP access or in a particular region such as the EU, what we consider as an inadequately tailored/unsupportive regulatory framework. The regulatory framework on GMOs directly impacts if we see more or less products from industrial biotech on the market in the future.
Examples of (potential) applications of genome editing for the benefit of consumers are provided in answers 3, 13 and 17.

* **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

Our members have quality systems that check the compliance of all received products with applicable legislation. Should we purchase products obtained with NGTs, this quality system would apply in the same way as for all other purchases.
Every company has a quality system in place and, as part of that, needs to request information from its suppliers and to provide information to its customers, about the compliance of a product with all applicable legislation. GMO statements and GMO questionnaires are an integral part of these quality systems, for regulated products. However, both statements and GMO questionnaires may not (yet) contain specific wording on the use of genome editing.

* 2 bis. Have you encountered any challenges?

- ◉ Yes
- ○ No

* Please provide details

Supply chains in the food industry are often long and complex. To get all required information on the (potential) use of genome editing transmitted all along the supply chain is a significant administrative and technical challenge, due to non-harmonized regulatory standards on genome editing globally.

* **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

Please see answers to Q1. Genome editing techniques are used to improve microbial strains for the production of food and feed additives and processing aids. Such improvements may include: (a) the targeted deletion of genes that are of potential safety concern (such as antibiotic resistance genes or genes involved in mycotoxin biosynthesis); (b) the targeted duplication/multiplication of intrinsic genes of an organism, to increase production of, e.g., amino acids, vitamins, or other compounds of interest; or (c) the targeted introduction of a (heterologous) gene from another organism, to allow sustainable production of human or animal products (such as human milk oligosaccharides or bovine chymosin).

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

- ○ Yes
- ○ No
- ◉ Not applicable

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

Our members comply with relevant legislation, and this compliance includes microorganisms (and products thereof) improved by pre-2001 and post-2001 gene technology tools. Specific compliance measures: each company has a quality management system and associated processes in place, requiring information on the GM status of raw materials and products to be shared between suppliers and customers. Industry is committed to comply with all GM legislation, including the EU's current interpretation that products of genome editing fall under the scope of the EU Food and Feed GM regulations. However, currently, requesting and providing the pertinent information on genome editing all along the often complex supply chains may not (yet) be fully implemented and operational.
The resources required for implementation (in terms of workforce and costs) are significant, but differ from company to company. Costs incurred include: (a) implementation costs to amend the quality questionnaires; (b) additional time required to adequately assess the supplier questionnaires and the (potential) impacts on the "GM statements" (and other quality documents) that need to be provided to customers downstream in the value chain; (c) higher personnel costs due to the higher technical expertise required to adequately assess the supplier questionnaires. The net result is continuously increasing overhead costs, with very limited value for the consumers or for product safety.

* What best practices can you share?

Reference can be made to the quality systems which companies already have in place, and which also cover the compliance with GMO legislation (see above).

* 5 bis. What challenges have you encountered?

Additional to the above answer, the technology-based approach of the Directive makes it challenging to even determine whether an organism would fall within the scope or not. An approach based on the characteristics of organisms instead of the technologies used to develop it would make authorization and compliance straightforward and robust.
Please see the answer to question 2 and the text further up in this question (on overhead costs).

* **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?

We did not need support by authorities to comply with the current, outdated GM legislation (as applied to NGTs). We would however very much appreciate their commitment and support towards a future legislation that will be fit-for-purpose. We expect such future legislation to be science-based, risk-proportionate, and product-centric (instead of the current process-centric approach).

* **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

Microorganisms that have been modified in a way that does not distinguish them from nature-sourced counterparts or classical mutagenesis can only be subject to documentary traceability, as analytical traceability will be impossible.
Microorganisms that have been modified in ways that are analogous to trans-genesis could also be subject to documentary traceability. In addition to this, there would be the possibility to perform an analytical traceability, based on the microorganism's unique genetic characteristics that were described by the applicant when applying for authorization for deliberate release. The latter option would however require significant resources and technology at control laboratories.

* **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

NA

* What best practices can you share?

NA

* 8 bis. What challenges have you encountered?

NA

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

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

* Please describe for the:

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

Agri-food sector

We understand this question as applying to all organisms falling in the scope of the GMO legislation, as we do not see why the 2001 date would make a difference. The experience we have is that the legislation does not in practice lead to any approval for release, due to political (not scientific) hurdles. The legislation is therefore in our experience not functional anymore, and this is not linked to “NGTs”.

Industrial sector

We understand this question as applying to all organisms falling in the scope of the GMO legislation, as we do not see why the 2001 date would make a difference. The experience we have is that the legislation does not in practice lead to any approval for release, due to political (not scientific) hurdles. The legislation is therefore in our experience not functional anymore, and this is not linked to “NGTs”.

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

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## B - Information on research on NGTs/NGT-products

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

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

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

(see also response to Q3) Our members are companies operating in the field of industrial biotechnology. This is a constantly innovating sector, in which we use the latest available set of tools to perform our R&D. Since NGTs are defined as post-2001 technologies, it is clear that we have been using many of these in our research and development.
For IP and competitive reasons our members cannot disclose the subject, type of research and resources allocated. However, it is right to assume that this concerns all fields of application of industrial biotechnology and each and any product. NGTs are and will be applied in the production of new microorganisms.
Research location: many of our members are global companies, having R&D facilities around the globe

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

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

* Please specify

We are aware of specific examples, but rather than providing those specific examples, it seems more appropriate to express our firm belief that genome editing techniques are used rather as a norm rather than an exception by those doing targeted improvements of production strains in the fermentation industry. Again, if one can choose between the use of old-fashioned GMO techniques (requiring GM labelling), vs. the use of state-of-the-art, precise genome editing (also requiring GM labelling), what would be the rationale for staying with the old-fashioned approach?

* **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

The CJEU ruling emphasized the fact that the technology-based approach of Directive 2001/18 makes it obsolete considering the innovation rate in modern biotechnology. Subsequent debates around the ruling made it clear that it would take a lot of efforts to modernize the legislation and facilitate global trade. This led to debates in the global-orientated industrial biotechnology sector on whether it was still worth keeping R&D facilities and jobs in the EU and placing innovative products on the EU market.
In more details, there was an immediate negative impact by preventing that innovative concepts could be pursued that would have benefitted both the conventional and non-GM markets. For some products intended for non-GM applications, industry needed to resort to classical mutagenesis rather than using more appropriate genome editing approaches. So, as a bottom line, the verdict of the EU Court of Justice prevented the use of innovative approaches of genome editing in some markets. One example is the potential use of genome editing in generating bacteriophage-resistant dairy cultures (Börner et al., FEMS Microbiol. Lett. 366:fny291, 2019; Stuer-Lauridsen & Janzen, European Patent No. EP 1 838 839 B1). As dairy cultures are traditionally a non-GM business, the “GM classification” of such phage-resistant strains plays an important role in determining market access and market success.

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

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

* Please provide concrete examples/data

(see also response to Q10) What this question calls “NGT-related research” is simply “industrial biotechnology research using available technologies and tools”, as the division by a specific date has no scientific relevance. There have been many significant scientific advances in the past 19 years; one example is the CRISPR set of tools, which allows genetic changes to be made with improved accuracy, control and efficiency, and with much less non-targeted effects than with “pre-2001” technologies (e.g. classical mutagenesis).
As already outlined in the answer to Q3, potential benefits/opportunities may include the targeted deletion of mycotoxin gene clusters (or other sequences of potential safety concern); the targeted deletion of sequences contributing to strain instability, thereby securing even better consistency in product quality; or the targeted deletion of antibiotic resistance genes (some microorganisms intrinsically contain such resistance genes!). In addition, competing pathways resulting in unwanted side products in the final commercial preparation may be deleted in a targeted manner.

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

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

* Please provide concrete examples/data

(see also responses to Q12, Q13, Q16) We believe that the current EU regulatory framework and impact on consumer perception discourages our members from developing and placing innovative microorganisms on the European market. The most significant challenge is the potential regulatory burden to commercialize products obtained through up-to-date gene technology, in different regions where the legislations are not harmonized.

*** 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

For use of genome editing in R&D to develop commercial products (in the Food and Feed industry; i.e. primarily working with safe microorganisms), two important aspects are worth mentioning: (a) the intrinsic higher precision and accuracy of state-of-the-art genome editing approaches to achieve a desired improvement of a strain as compared to the more traditional approaches of genetic engineering; and (b) the availability and ease of whole-genome DNA sequencing to confirm that the strain improvements have happened as planned and did not lead to unintentional side effects. These two aspects, taken together, lead to the conclusion that there are no additional risks on top of those already considered and assessed for more traditional approaches of genetic engineering, and that the current risk assessment framework can also be applied to assess products obtained with genome editing.

*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

There are many opportunities and benefits from modern biotechnology, incl. NGTs. In general, up-to-date technologies materialize these benefits through higher accuracy, and often through less impactful changes needed to obtain the desired effect in the modified organism.
For instance, microorganisms used in Food and Feed as cultures/probiotics/silage agents: the genetic basis for e.g. antibiotic resistance and or toxigenic/virulence factors can be accurately and easily eliminated. The benefits include assured food safety as well an improved use of feed by animals, supporting less use of raw materials and less production of waste. In more details, in microorganisms, by using this technology, one can significantly improve the production of desired proteins or metabolites without introducing foreign DNA. Additionally, antibiotic resistant genes can be removed without affecting the functionality of the entire organism.
In general, NGTs allow the development and selection of new organisms at a speed unmatched with the so-called conventional methods, making it possible to place quickly and for an affordable cost on the market products of important benefits for the end-users.
Microorganisms used in Agriculture: several agronomical properties such as increased nutrient uptake and resistance to heat or draught and protection against plant pests can be introduced into a single microorganism, which would in many cases be very challenging with “pre-2001” technology. The benefits are an improved use of nutrients and a more consistent yield of crops under challenging pest pressures and climate conditions, without additional or with reduced use of mineral fertilizers or chemical plant protection products.

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

- (●) Yes
- ( ) No

* Please explain

The opportunity of advanced understanding of the microbial genomes, the ability to modify these with high accuracy, the laboratory selection tools, and the characterization methods (e.g. sequencing) have been tremendously improved over the past 10-20 years. This also led to a much better in-depth understanding of the genomic characteristics that have to be taken into account when performing risk assessments. For example, in developing plant cultivars as sources of bioactive molecules for extraction and use in natural preservatives and human/animal health products, CRISPR-Cas9 in particular allows gene deletions which can have a profound improvement in the morphology of the plants as detailed above; and secondly allows hyperaccumulation of a particular molecule for extraction making products more efficient and less costly to produce. These benefits are specific to NGTs.

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

(see also response to Q16) Common features of many industrial biotech solutions are increased sustainability and bio-based, natural raw materials, the ability to increase production efficiency by decreasing raw material use and lowering waste production, replace increasingly scarcer resources, substitute (putative hazardous) chemicals. Modern tools such as NGTs are offering the process and method advancements as described and therefore increase the overall efficiency in product development.
Through the precise and targeted deletion of (a) mycotoxin gene clusters (or other sequences of potential safety concern) and (b) pathways resulting in the formation of unwanted side products, the intrinsic safety of production strains used in industrial fermentations, as well as the consistency in final product quality can be further improved. In addition, the use of precise and targeted techniques to improve production strains, combined with whole-genome sequence analysis to confirm the correctness of the targeted mutations will allow to continuously reduce the need for animal experimentation to confirm the safety of fermentation products, thereby contributing to animal welfare. An example of clear-cut environmental benefits is, for instance, the fermentative production of riboflavin (vitamin B2) using genetically engineered production strains. While the current industrial production strains for vitamin B2 were generated using traditional genetic engineering approaches, it is conceivable that further improved production strains can be obtained by genome editing. Vitamin B2 is an indispensable, mandatory component of infant food, and biotechnological production is the most environment-friendly approach to produce it.
Sustainability is becoming more and more important around the world. What better was to accomplish this than using plants or microorganisms as manufacturers of complex molecules for human use in food preservation and more specifically for human and animal health. NGTs and specifically CRISPR-Cas9 allow a more precise and faster way to develop novel and unique plants to accomplish these objectives – which would otherwise only be limited to natural variation optimized through conventional plants breeding.
With microorganisms, variants could be developed to enhance functionality and positive traits of strains already recognised as safe.

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

There needs to be a political acceptance of the fact that industrial biotechnology provides benefits that are crucial to society in general such as for the environment, human, animal and plant health, consumers, animal welfare, as well as social and economic benefits.
That commitment needs to be implemented explicitly in policies such as the Green Deal and Farm to Fork. It must result in a legislation that secures consumers' and environmental safety, while allowing innovative products of industrial biotechnology to reach the market in a timely and proportionate way.

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

- (●) Yes
- ( ) No

* Please explain

(see also response to Q10 and Q13) Innovation in industrial biotechnology relies on the use of up-to-date technologies and tools. Such tools have been dubbed "NGTs" solely based on a specific date – so yes, NGTs provide specific, essential benefits.

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

Certain technologies developed in the last 10 years are less complex or costly to implement than older gene technology tools. This makes them in principle more accessible to SMEs. However, the same regulatory obstacles as for larger companies apply to SMEs (current legislative framework and /or EU policy and associated perceptions on the use of these current techniques).

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

- ( ) Yes
- (●) No

* Please explain why not

(see also response to Q23)
The question of genome editing has little to do with the question of patenting. For patenting, a set of boundary conditions need to be fulfilled: (a) there must be an inventive step; (b) the invention must provide a benefit; (c) and the patent disclosure needs to allow a person skilled in the art to reproduce the invention. Whether genome editing is used or not has no impact on the functioning of the patent system.

*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 explain why not

As explained in other answers above, NGTs are an essential part of industrial biotech's toolbox. The most significant challenge and concern is the potential regulatory burden, dependent on the future regulatory framework for biotechnological products.

* **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

Innovation in industrial biotechnology must be able to take place under a legislation that addresses possible safety and societal concerns posed by the products/organisms. Provided that this is done, the technology itself is not an issue.
There is no reason for NGTs (compared to pre-2001 technologies) to raise specific concerns. The challenges or concerns would be connected to the genetic changes made to an organism, and these are not technology-specific.
On the other hand, we believe that arbitrarily giving a name ("NGTs") to a set of technologies that merely have in common the time period when they were developed, risks creating unfounded concerns. Products should be assessed on their safety as and when placed on the market, not on the technique used to create them, to create a clear and trustworthy system based on science.
However, the use of advanced technologies will likely raise concerns and possibly fears in parts of society. Therefore, next to a science-based, risk-proportionate, and product-centric future regulatory framework, also open and transparent information and education of the public is required to secure buy-in and support for innovative, future-proof approaches to biotechnology that best support the ambitious EU Green Deal and Farm-to-Fork strategy.

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

- ◉ Yes
- ○ No

* Please explain and provide concrete examples and data

The regulatory burden and near impossibility to obtain authorizations for release of NGT microorganisms into the environment are an even bigger issue for SMEs compared to big companies. If the regulatory burden is reasonable, SMEs would have an advantage in entering the market as the NGTs offer speed to R&D.

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

The patent landscape for certain technologies (e.g. CRISPR) is very complex to navigate, which deters certain companies from trying to get access to them for their R&D work. In general, for NGTs and this quickly developing field currently it takes years to select the right IP strategy and get the license agreements in place. These years are significantly increasing the time-to-market.

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

The maximum file size is 1 MB

## E - Safety of NGTs/NGT-products

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

The degree of understanding of the microbial genomes, the ability to modify them with accuracy, the laboratory selection tools, and the characterization methods (e.g. using bio-informatics tools such as sequencing) have been tremendously improved over the past 10-20 years. This also led to a much better in-depth understanding of the genomic characteristics that have to be taken into account when performing risk assessments. The safety of a product depends on and should be assessed based on what has been modified, not as a function of when the technique used was invented (i.e. before or after 2001).
If anything, the intrinsic higher precision and accuracy of state-of-the-art genome editing approaches to achieve a desired improvement, as well as the availability of whole-genome DNA sequencing to characterize the modified organisms, make risk assessment easier and more straightforward.

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

- ( ) Yes
- (●) No

* Please explain why not

(see also response to Q24) The safety of a microorganism depends on the safety of its parental strain, and on the safety of the genetic changes that have been performed on it. It has nothing to do with the technologies used for making these changes or the time when a technique was invented.

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

The maximum file size is 1 MB

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

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

Our views on this are not any different with products sourced via other processes/technologies than NGTs. The ethical aspects of innovation in biotechnology should not be viewed in the light of the technologies used – but rather by looking at the product/organism and its intended uses.
The nature of potential ethical concerns is in no way different than those discussed in the context of traditional genetic engineering (classical “GMOs”). For some, genome editing may be seen as interfering with mother nature, and with their religious beliefs. On the other hand, it needs to be emphasized that human beings are interfering with natural evolution since more than 10,000 years, by selecting traits that are of specific and particular benefit to human beings. Since desired improvements can be achieved with higher precision and often with more subtle changes to the genetic make-up of an organism, it might potentially be argued that genome editing, particularly if restricted to an organism’s own genome sequence (i.e., without introduction of heterologous genes) might be ethically slightly more acceptable for some parts of society than traditional genetic engineering approaches.
It should be stressed, though, that NOT leveraging the benefits offered by biotechnology (both traditional genetic engineering and state-of-the-art genome editing approaches) is probably more objectionable from an ethical perspective than using them. Golden Rice, as the most evident example, would have saved many lives already, if science-based, rational thinking rather than ideology had dictated regulatory and political decision making. To provide sufficient, healthy, affordable food to 10 billion people globally WILL require innovative solutions, combining “the best of all worlds”, including biotechnology. It is an ethical imperative to create the adequate regulatory and political framework to best serve society globally – and we are convinced that biotechnology, including genome editing, MUST be part of the toolbox to realize such sustainable solutions.

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

- (●) Yes
- ( ) No

* Please explain

A number of challenges are presently facing our planet and societies: global warming and climate change, food security, scarcity of land and resources, (plastic) pollution etc. Considering all of these we would find it unethical that the European Union does not do its utmost to promote technologies and products that offer solutions and could help safely address some of these challenges. Industrial biotechnology (and therefore NGTs) is among such technologies, and it would be ethical that the EU commits to using modern technologies by promoting adequate policies and legislation.
The European Union claims to leadership on scientific and innovative developments but appears to be lagging behind other peer institutions in other regions in the world, with which it currently holds bilateral scientific/other agreements that also uphold ethics. For example, the US do not see the need for regulatory approval under the GM legislation, fully supporting innovation in the biotechnology sector and best solutions.

*Please upload any supporting documentation for this section here*

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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**

A decision to label a consumer product should be based on criteria that are significant and are not misleading the consumer. Labelling requirements should be restricted to food quality and food safety. Basing a labeling decision on the technologies used to obtain the product is therefore a matter of transparency, but misleading as it does not inform on the safety and quality of the product. Labeling of industrial biotechnology products, should it be considered, must be based on the products' characteristics, not on whether they have been developed with pre-2001 or post-2001 technologies.
This particularly goes for organisms developed using NGTs (e.g. SDN-1), that cannot be distinguished from similar organisms developed using pre-2001 technology or obtained directly from nature. It would simply be misleading to consumers to label the former as GMOs and not to label the latter – since they are for all purposes identical.
In summary, NGT labeling might suggest that NGTs are dangerous per se and may de facto cause rejection of modern biotechnology, leading to reduced innovation power for sustainable food and industrial solutions.
In addition, NGT labelling would add to confusion, often be misleading, and difficult to enforce and therefore, are not considered as an effective way of informing consumers.

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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

The present questionnaire seems to imply that it is uncertain whether products of up-to-date gene technology / industrial biotechnology provide benefits to society. Such premises seem inappropriate and outdated as it is state of art and used potentially for each and any new innovative product from biotech. Industrial biotechnology is here to stay, as it is essential if the EU wants to fight resource scarcity and climate change and plays its role in meeting the UN SDGs. The present GMO legislation, as well as the singling out of post- vs. pre-2001 technologies, is preventing this essential tool from being used effectively and broadly.
Industrial biotechnology is in need of an updated legislation, as Directive 2001/18 (as well as Directive 2009 /41) is not fit for purpose anymore. As an industrial biotechnology organization, we have the following policy asks:

- We call for a future-proof, science- and risk-based, operational legislation that is predictable and proportionate. This legislation shall be based on the characteristics of the organisms rather than on the technologies used to develop them.
- In certain cases, similar organisms can be obtained through application of different technologies, and cannot be distinguished one from the other. By regulating these organisms in an identical way, the legislation will be transparent, fair and enforceable.
- This future-proof, science and risk-based approach will instill confidence in the regulatory oversight system assuring safety for consumers and the environment.
- This approach will foster innovation and competitiveness in Europe, and facilitate alignment with other legislations globally.

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